Page 1 of 2

Table 1.3 Demographic Summary

Trait Cohort 1

--------------------------------------------------------------------------------

Gender Female 3 ( 30%)

Male 7 ( 70%)

Race Black or African American 3 ( 30%)

White 7 ( 70%)

White, Black or African American 0 ( 0%)

Age\* (yrs) N 10

Mean 28.5

SD 7.81

Minimum 20

Median 26.5

Maximum 46

Weight (kg) N 10

Mean 75.82

SD 13.319

Minimum 58.7

Median 74.75

Maximum 104.1

Height (cm) N 10

Mean 172.5

SD 8.97

Minimum 158

Median 173.0

Maximum 189

Note: Cohort 1 = 50 mg TD-1439 or placebo

\* Age is based on date of first dose.

BMI (body mass index) and weight are based on the CRF data collected at admission (Day -3).

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_demsummary.sas 15SEP2016 19:01

Page 2 of 2

Table 1.3 Demographic Summary

Trait Cohort 1

--------------------------------------------------------------------------------

BMI (kg/m²) N 10

Mean 25.372

SD 3.5659

Minimum 21.20

Median 24.320

Maximum 31.75

Note: Cohort 1 = 50 mg TD-1439 or placebo

\* Age is based on date of first dose.

BMI (body mass index) and weight are based on the CRF data collected at admission (Day -3).

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_demsummary.sas 15SEP2016 19:01

Page 1 of 1

Table 1.4.1 Adverse Events (I of II)

Time From

Last Dose Onset Resolved Duration

Subject ---------- --------------- --------------- ----------

Number Cohort TE?^ Adverse Event (DD:HH:MM) Date Time Date Time (DD:HH:MM)

-------------------------------------------------------------------------------------------------------

1001 1 None

1002 1 Yes DIAPHORESIS 00:04:15 29AUG2016 11:33 29AUG2016 11:38 00:00:05

Yes LIGHTHEADEDNESS 00:04:15 29AUG2016 11:33 29AUG2016 11:38 00:00:05

Yes BLURRED VISION 00:04:16 29AUG2016 11:34 29AUG2016 11:35 00:00:01

1003 1 Yes CHILLS 00:04:15 01SEP2016 12:15 01SEP2016 12:25 00:00:10

Yes DIAPHORESIS 00:04:15 01SEP2016 12:15 01SEP2016 12:25 00:00:10

Yes PALLOR 00:04:15 01SEP2016 12:15 01SEP2016 12:25 00:00:10

Yes POSTURAL DIZZINESS 00:04:15 01SEP2016 12:15 01SEP2016 12:25 00:00:10

Yes DIZZINESS 00:04:25 01SEP2016 12:25 01SEP2016 14:20 00:01:55

1004 1 Yes DIAPHORESIS 00:04:14 01SEP2016 12:17 01SEP2016 12:30 00:00:13

Yes PALLOR 00:04:14 01SEP2016 12:17 01SEP2016 12:30 00:00:13

Yes POSTURAL DIZZINESS 00:04:14 01SEP2016 12:17 01SEP2016 12:30 00:00:13

1005 1 None

1006 1 Yes URINARY TRACT INFECTION 04:12:27 05SEP2016 20:36

1007 1 None

1008 1 None

1009 1 None

1010 1 No GENERALIZED BACKACHE 31AUG2016 8:00 04SEP2016 6:20 03:22:20

Note: Cohort 1 = 50 mg TD-1439 or placebo

^ = Abbreviation for treatment-emergent.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae1.sas 15SEP2016 18:57

Page 1 of 2

Table 1.4.2 Adverse Events (II of II)

Action Action

Relation- Taken Taken

Onset ship to With With

Subject --------------- Study Study Study

Number Cohort Adverse Event Date Time Frequency Severity Serious Outcome Drug Treatment Drug

-------------------------------------------------------------------------------------------------------------------------------------

1001 1 None

1002 1 DIAPHORESIS 29AUG2016 11:33 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

LIGHTHEADEDNESS 29AUG2016 11:33 Intermittent Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

BLURRED VISION 29AUG2016 11:34 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

1003 1 CHILLS 01SEP2016 12:15 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

DIAPHORESIS 01SEP2016 12:15 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

PALLOR 01SEP2016 12:15 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

POSTURAL DIZZINESS 01SEP2016 12:15 Continuous Mild Not Recovered/ Possibly/ Other Dose

serious Resolved Probably not

Related changed

DIZZINESS 01SEP2016 12:25 Intermittent Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

1004 1 DIAPHORESIS 01SEP2016 12:17 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

Note: Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae2.sas 15SEP2016 18:57

Page 2 of 2

Table 1.4.2 Adverse Events (II of II)

Action Action

Relation- Taken Taken

Onset ship to With With

Subject --------------- Study Study Study

Number Cohort Adverse Event Date Time Frequency Severity Serious Outcome Drug Treatment Drug

-------------------------------------------------------------------------------------------------------------------------------------

1004 1 PALLOR 01SEP2016 12:17 Continuous Mild Not Recovered/ Possibly/ None Dose

serious Resolved Probably not

Related changed

POSTURAL DIZZINESS 01SEP2016 12:17 Continuous Mild Not Recovered/ Possibly/ Other Dose

serious Resolved Probably not

Related changed

1005 1 None

1006 1 URINARY TRACT INFECTION 05SEP2016 20:36 Continuous Mild Possibly/

Probably

Related

1007 1 None

1008 1 None

1009 1 None

1010 1 GENERALIZED BACKACHE 31AUG2016 8:00 Continuous Mild Not Recovered/ Not None Dose

serious Resolved Related not

changed

Note: Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae2.sas 15SEP2016 18:57

Page 1 of 1

Table 1.4.3 Adverse Event Non Drug Therapy

Onset Therapy

Subject --------------- ------------------------------------

Number Cohort Adverse Event Date Time Date Time Description

---------------------------------------------------------------------------------------------------

1003 1 POSTURAL DIZZINESS 01SEP2016 12:15 01SEP2016 12:15 SUPINE POSITION

1004 1 POSTURAL DIZZINESS 01SEP2016 12:17 01SEP2016 12:17 SUPINE POSITION

Note: Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae3.sas 15SEP2016 18:57

Page 1 of 5

Table 1.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Calcium (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 1 8 0 0 0 0

1 Chloride (mEq/L) Day 2 0 0 0 0 9 1 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 8 1 0 0 0

1 Bicarbonate (mmol/L) Day 2 0 0 0 1 9 0 0 0 0

Day 3 0 0 0 1 9 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 1 8 0 0 0 0

1 Magnesium (mg/dL) Day 2 2 1 0 0 6 0 0 1 0

Day 3 3 0 0 1 5 0 0 1 0

Day 4 2 1 0 0 6 0 0 1 0

Day 10 2 1 0 0 6 0 0 0 0

1 Potassium (mEq/L) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 8 1 0 0 0

1 Sodium (mEq/L) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 8 1 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 2 of 5

Table 1.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Albumin (g/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Blood Urea Nitrogen (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Creatinine (mg/dL) Day 2 0 0 0 0 9 0 0 0 1

Day 3 0 0 0 0 9 0 0 0 1

Day 4 0 0 0 0 9 0 0 0 1

Day 10 0 0 0 0 8 0 0 0 1

1 Glucose (mg/dL) Day 2 0 0 0 0 9 0 0 0 1

Day 3 0 0 0 0 9 0 0 0 1

Day 4 0 0 0 0 9 0 0 1 0

Day 10 0 0 0 0 8 0 0 1 0

1 Alkaline Phosphatase (U/L) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Alanine Aminotransferase (U/L) Day 2 1 0 0 1 8 0 0 0 0

Day 3 1 0 0 1 8 0 0 0 0

Day 4 1 0 0 1 8 0 0 0 0

Day 10 1 0 0 2 6 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 3 of 5

Table 1.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Aspartate Aminotransferase (U/L) Day 2 2 0 0 2 6 0 0 0 0

Day 3 2 0 0 2 6 0 0 0 0

Day 4 1 1 0 1 7 0 0 0 0

Day 10 2 0 0 1 6 0 0 0 0

1 Direct Bilirubin (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Indirect Bilirubin (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Total Bilirubin (mg/dL) Day 2 0 0 0 1 9 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 GGT (U/L) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Cholesterol (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 4 of 5

Table 1.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 HDL Cholesterol (mg/dL) Day 2 0 1 0 0 9 0 0 0 0

Day 3 0 1 0 0 9 0 0 0 0

Day 4 1 0 0 1 8 0 0 0 0

Day 10 1 0 0 0 8 0 0 0 0

1 LDL Cholesterol (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Creatine Kinase (U/L) Day 2 1 0 0 1 8 0 0 0 0

Day 3 1 0 0 0 9 0 0 0 0

Day 4 1 0 0 0 9 0 0 0 0

Day 10 1 0 0 0 6 2 0 0 0

1 Lactate Dehydrogenase (U/L) Day 2 3 0 0 3 4 0 0 0 0

Day 3 2 1 0 2 5 0 0 0 0

Day 4 2 1 0 4 3 0 0 0 0

Day 10 1 1 0 1 6 0 0 0 0

1 Triglycerides (mg/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 2 7 0 0 0 0

1 Lipase (U/L) Day 2 0 0 0 0 9 0 0 1 0

Day 3 0 0 0 0 9 0 0 1 0

Day 4 0 0 0 0 9 0 0 1 0

Day 10 0 0 0 0 8 0 0 1 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 5 of 5

Table 1.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Amylase (U/L) Day 2 0 0 0 0 8 0 0 1 1

Day 3 0 0 0 0 8 0 0 1 1

Day 4 0 0 0 0 8 0 0 1 1

Day 10 0 0 0 0 7 0 0 2 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 1 of 3

Table 1.5.2 Clinical Laboratory Shift From Baseline - Hematology

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Hemoglobin (g/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 3 6 0 0 0 0

1 Hematocrit (%) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 1 9 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 3 6 0 0 0 0

1 Platelet Count (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 8 1 0 0 0

1 Red Blood Cell Count (Mil/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 1 9 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 3 6 0 0 0 0

1 MCH (pg) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 MCHC (g/dL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 2 of 3

Table 1.5.2 Clinical Laboratory Shift From Baseline - Hematology

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 MCV (fL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 White Blood Cell Count (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Basophils (%) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Absolute Basophils (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Eosinophils (%) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 9 1 0 0 0

Day 10 0 0 0 0 7 2 0 0 0

1 Absolute Eosinophils (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 8 1 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 3 of 3

Table 1.5.2 Clinical Laboratory Shift From Baseline - Hematology

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Lymphocytes (%) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Absolute Lymphocytes (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Monocytes (%) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 1 8 1 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Absolute Monocytes (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 1 9 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Neutrophils (%) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Absolute Neutrophils (Thou/uL) Day 2 0 0 0 0 10 0 0 0 0

Day 3 0 0 0 0 10 0 0 0 0

Day 4 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 1 of 2

Table 1.5.3 Clinical Laboratory Shift From Baseline - Urinalysis

Baseline\* N Baseline\* O

----------------- -----------------

Postdose Postdose

----------------- -----------------

Cohort Laboratory Test (units) Time Point N O N O

--------------------------------------------------------------------------------------------

1 Blood Day 2 8 2 0 0

Day 3 10 0 0 0

Day 4 9 1 0 0

Day 10 7 2 0 0

1 pH, Urine Day 2 10 0 0 0

Day 3 10 0 0 0

Day 4 10 0 0 0

Day 10 9 0 0 0

1 Specific Gravity Day 2 10 0 0 0

Day 3 9 1 0 0

Day 4 10 0 0 0

Day 10 7 2 0 0

1 Glucose Day 2 10 0 0 0

Day 3 10 0 0 0

Day 4 10 0 0 0

Day 10 8 1 0 0

1 Ketones Day 2 10 0 0 0

Day 3 10 0 0 0

Day 4 10 0 0 0

Day 10 9 0 0 0

1 Leukocyte Esterase Day 2 10 0 0 0

Day 3 8 2 0 0

Day 4 10 0 0 0

Day 10 9 0 0 0

Note: N = Within Reference Range, O = Outside Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 2 of 2

Table 1.5.3 Clinical Laboratory Shift From Baseline - Urinalysis

Baseline\* N Baseline\* O

----------------- -----------------

Postdose Postdose

----------------- -----------------

Cohort Laboratory Test (units) Time Point N O N O

--------------------------------------------------------------------------------------------

1 Nitrite Day 2 9 0 0 1

Day 3 9 0 0 1

Day 4 9 0 0 1

Day 10 8 0 1 0

1 Protein Day 2 10 0 0 0

Day 3 10 0 0 0

Day 4 10 0 0 0

Day 10 9 0 0 0

1 Bilirubin Day 2 10 0 0 0

Day 3 10 0 0 0

Day 4 10 0 0 0

Day 10 9 0 0 0

1 Urobilinogen Day 2 10 0 0 0

Day 3 10 0 0 0

Day 4 10 0 0 0

Day 10 9 0 0 0

Note: N = Within Reference Range, O = Outside Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 1 of 1

Table 1.5.4 Clinical Laboratory Shift From Baseline - Coagulation

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

1 Prothrombin Time/INR Day 2 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Prothrombin Time (seconds) Day 2 0 0 0 0 10 0 0 0 0

Day 10 0 0 0 0 9 0 0 0 0

1 Partial Thromboplastin Time Day 2 0 0 0 0 10 0 0 0 0

(seconds)

Day 10 0 0 0 0 9 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshiftcoag.sas 15SEP2016 18:57

Page 1 of 3

Table 1.5.5.1.1 Unscheduled and Out-of-Range Results - Serum Chemistry (I of III)

Calcium Chloride Bicarbonate Magnesium Potassium Sodium

Subject Study 8.6-10.4 97-105 24-33.2 1.9-2.4 3.7-5.2 135-143

Number Period Cohort Day Hour Date (mg/dL) (mEq/L) (mmol/L) (mg/dL) (mEq/L) (mEq/L)

--------------------------------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 1.6 LN

1 1 -3 -73.5 26AUG2016 1.7 LN

1 -0.2 29AUG2016 1.8 LN

2 24.0 30AUG2016 1.7 LN

3 48.0 31AUG2016 1.7 LN

4 72.0 01SEP2016 1.7 LN

10 216.0 07SEP2016 1.7 LN

1002 Screen 1 16AUG2016 2.1 141

1 1 -3 -73.5 26AUG2016 2.0 144 HN

1 -0.2 29AUG2016 1.9 140

2 24.0 30AUG2016 1.9 140

3 48.0 31AUG2016 1.8 LN 141

4 72.0 01SEP2016 1.9 140

10 216.0 07SEP2016 2.0 141

1004 Screen 1 18AUG2016 141

1 1 -3 -73.5 29AUG2016 143

1 -0.2 01SEP2016 141

2 24.0 02SEP2016 139

3 48.0 03SEP2016 139

4 72.0 04SEP2016 141

10 216.0 10SEP2016 144 HN

1005 Screen 1 26AUG2016 105

1 1 -3 -73.5 29AUG2016 106 HN

1 -0.2 01SEP2016 100

2 24.0 02SEP2016 103

3 48.0 03SEP2016 102

4 72.0 04SEP2016 103

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 2 of 3

Table 1.5.5.1.1 Unscheduled and Out-of-Range Results - Serum Chemistry (I of III)

Calcium Chloride Bicarbonate Magnesium Potassium Sodium

Subject Study 8.6-10.4 97-105 24-33.2 1.9-2.4 3.7-5.2 135-143

Number Period Cohort Day Hour Date (mg/dL) (mEq/L) (mmol/L) (mg/dL) (mEq/L) (mEq/L)

--------------------------------------------------------------------------------------------------------------------------

1005 1 1 10 216.0 10SEP2016 104

1006 Screen 1 18AUG2016 104 24.6 1.9

1 1 -3 -73.5 29AUG2016 102 26.5 1.9

1 -0.2 01SEP2016 103 26.6 1.8 LN

2 24.0 02SEP2016 106 HN 24.9 1.8 LN

3 48.0 03SEP2016 103 25.2 1.8 LN

4 72.0 04SEP2016 103 26.2 1.8 LN

10 216.0 10SEP2016 106 HN 23.9 LN 2.0

1007 Screen 1 28AUG2016 1.9

1 1 -3 -73.5 29AUG2016 1.8 LN

1 -0.2 01SEP2016 1.8 LN

2 24.0 02SEP2016 1.9

3 48.0 03SEP2016 1.8 LN

4 72.0 04SEP2016 1.9

10 216.0 10SEP2016 1.8 LN

1008 Screen 1 16AUG2016 23.7 LN 2.0

1 1 -3 -73.5 08SEP2016 23.7 LN 2.0

1 -0.2 11SEP2016 24.5 2.6 HN

2 24.0 12SEP2016 23.6 LN 2.0

3 48.0 13SEP2016 22.3 LN 2.0

4 72.0 14SEP2016 24.8 2.0

1009 Screen 1 24AUG2016 5.1

1 1 -3 -73.5 29AUG2016 4.9

1 -0.2 01SEP2016 4.9

2 24.0 02SEP2016 4.9

3 48.0 03SEP2016 4.6

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 3 of 3

Table 1.5.5.1.1 Unscheduled and Out-of-Range Results - Serum Chemistry (I of III)

Calcium Chloride Bicarbonate Magnesium Potassium Sodium

Subject Study 8.6-10.4 97-105 24-33.2 1.9-2.4 3.7-5.2 135-143

Number Period Cohort Day Hour Date (mg/dL) (mEq/L) (mmol/L) (mg/dL) (mEq/L) (mEq/L)

--------------------------------------------------------------------------------------------------------------------------

1009 1 1 4 72.0 04SEP2016 4.7

10 216.0 10SEP2016 5.3 HN

1010 Screen 1 28AUG2016 9.6

1 1 -3 -73.5 29AUG2016 9.4

1 -0.2 01SEP2016 9.5

2 24.0 02SEP2016 9.3

3 48.0 03SEP2016 9.2

4 72.0 04SEP2016 9.6

10 216.0 10SEP2016 8.5 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

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Page 1 of 3

Table 1.5.5.1.2 Unscheduled and Out-of-Range Results - Serum Chemistry (II of III)

Blood

Urea Alanine Aspartate

Nitrogen Creatinine Amino- Amino- Total

F: 6-17 F: .5-.9 Glucose transferase transferase Bilirubin

Subject Study M: 7-20 M: .69-1.2 73-105 10-67 14-48 .2-1.6

Number Period Cohort Day Hour Date (mg/dL) (mg/dL) (mg/dL) (U/L) (U/L) (mg/dL)

----------------------------------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 1.34 HN

1 1 -3 -73.5 26AUG2016 1.42 HYR

Recheck 1 -3 -73.5 27AUG2016 1.46 HY-

1 1 1 -0.2 29AUG2016 1.49 HY^

2 24.0 30AUG2016 1.56 HY^

Recheck 1 2 24.0 31AUG2016 1.46 HY^

1 1 3 48.0 31AUG2016 1.46 HY^

4 72.0 01SEP2016 1.40 HN

10 216.0 07SEP2016 1.46 HY-

1003 Screen 1 18AUG2016 14

1 1 -3 -73.5 29AUG2016 24 HN

1 -0.2 01SEP2016 17

2 24.0 02SEP2016 18

3 48.0 03SEP2016 13

4 72.0 04SEP2016 13

10 216.0 10SEP2016 16

1004 Screen 1 18AUG2016 105

1 1 -3 -73.5 29AUG2016 103

1 -0.2 01SEP2016 107 HN

2 24.0 02SEP2016 113 HN

3 48.0 03SEP2016 106 HN

4 72.0 04SEP2016 99

10 216.0 10SEP2016 100

1005 Screen 1 26AUG2016 10 15

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 2 of 3

Table 1.5.5.1.2 Unscheduled and Out-of-Range Results - Serum Chemistry (II of III)

Blood

Urea Alanine Aspartate

Nitrogen Creatinine Amino- Amino- Total

F: 6-17 F: .5-.9 Glucose transferase transferase Bilirubin

Subject Study M: 7-20 M: .69-1.2 73-105 10-67 14-48 .2-1.6

Number Period Cohort Day Hour Date (mg/dL) (mg/dL) (mg/dL) (U/L) (U/L) (mg/dL)

----------------------------------------------------------------------------------------------------------------------------

1005 1 1 -3 -73.5 29AUG2016 10 15

1 -0.2 01SEP2016 10 15

2 24.0 02SEP2016 9 LN 13 LN

3 48.0 03SEP2016 9 LN 13 LN

4 72.0 04SEP2016 9 LN 13 LN

10 216.0 10SEP2016 9 LN 17

1006 Screen 1 18AUG2016 23 22

1 1 -3 -73.5 29AUG2016 10 13 LN

1 -0.2 01SEP2016 11 14

2 24.0 02SEP2016 11 13 LN

3 48.0 03SEP2016 10 13 LN

4 72.0 04SEP2016 11 14

10 216.0 10SEP2016 9 LN 12 LN

1007 Screen 1 28AUG2016 13 LN

1 1 -3 -73.5 29AUG2016 12 LN

1 -0.2 01SEP2016 12 LN

2 24.0 02SEP2016 12 LN

3 48.0 03SEP2016 13 LN

4 72.0 04SEP2016 15

10 216.0 10SEP2016 12 LN

1008 Screen 1 16AUG2016 .5

1 1 -3 -73.5 08SEP2016 .3

1 -0.2 11SEP2016 .2

2 24.0 12SEP2016 0.0 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 3 of 3

Table 1.5.5.1.2 Unscheduled and Out-of-Range Results - Serum Chemistry (II of III)

Blood

Urea Alanine Aspartate

Nitrogen Creatinine Amino- Amino- Total

F: 6-17 F: .5-.9 Glucose transferase transferase Bilirubin

Subject Study M: 7-20 M: .69-1.2 73-105 10-67 14-48 .2-1.6

Number Period Cohort Day Hour Date (mg/dL) (mg/dL) (mg/dL) (U/L) (U/L) (mg/dL)

----------------------------------------------------------------------------------------------------------------------------

1008 1 1 3 48.0 13SEP2016 .3

4 72.0 14SEP2016 .4

1009 Screen 1 24AUG2016 1.13

Recheck 1 28AUG2016 .91

1 1 -3 -73.5 29AUG2016 .87

1 -0.2 01SEP2016 .95

2 24.0 02SEP2016 .92

3 48.0 03SEP2016 .89

4 72.0 04SEP2016 .89

10 216.0 10SEP2016 .94

1010 Screen 1 28AUG2016 8 LN 12 LN

1 1 -3 -73.5 29AUG2016 8 LN 12 LN

1 -0.2 01SEP2016 7 LN 11 LN

2 24.0 02SEP2016 7 LN 10 LN

3 48.0 03SEP2016 7 LN 10 LN

4 72.0 04SEP2016 7 LN 11 LN

10 216.0 10SEP2016 6 LN 10 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

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Page 1 of 3

Table 1.5.5.1.3 Unscheduled and Out-of-Range Results - Serum Chemistry (III of III)

Creatine

HDL Kinase Lactate

Cholesterol F: 28-207 Dehydrogenase Triglyceride Lipase Amylase

Subject Study 34-96 M: 43-350 131-249 38-269 14-70 29-119

Number Period Cohort Day Hour Date (mg/dL) (U/L) (U/L) (mg/dL) (U/L) (U/L)

-------------------------------------------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 203 151

1 1 -3 -73.5 26AUG2016 543 HYR 159

Recheck 1 -3 -73.5 27AUG2016 407 HN

1 1 1 -0.2 29AUG2016 236 147

2 24.0 30AUG2016 170 125 LN

3 48.0 31AUG2016 174 135

4 72.0 01SEP2016 160 125 LN

10 216.0 07SEP2016 164 139

1002 Screen 1 16AUG2016 140 168 50

1 1 -3 -73.5 26AUG2016 219 164 57

1 -0.2 29AUG2016 93 142 50

2 24.0 30AUG2016 81 115 LN 48

3 48.0 31AUG2016 80 116 LN 68

4 72.0 01SEP2016 88 120 LN 100

10 216.0 07SEP2016 371 HN 155 32 LN

1003 Screen 1 18AUG2016 50

1 1 -3 -73.5 29AUG2016 120 HYR

Recheck 1 -3 -73.5 30AUG2016 47

1 1 1 -0.2 01SEP2016 62

2 24.0 02SEP2016 48

3 48.0 03SEP2016 53

4 72.0 04SEP2016 41

10 216.0 10SEP2016 40

1004 Screen 1 18AUG2016 79 HY- 117

1 1 -3 -73.5 29AUG2016 82 HYR 133 HNR

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 2 of 3

Table 1.5.5.1.3 Unscheduled and Out-of-Range Results - Serum Chemistry (III of III)

Creatine

HDL Kinase Lactate

Cholesterol F: 28-207 Dehydrogenase Triglyceride Lipase Amylase

Subject Study 34-96 M: 43-350 131-249 38-269 14-70 29-119

Number Period Cohort Day Hour Date (mg/dL) (U/L) (U/L) (mg/dL) (U/L) (U/L)

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1004 Recheck 1 -3 -73.5 30AUG2016 73 HN 129 HN

1 1 1 -0.2 01SEP2016 73 HN 123 HN

2 24.0 02SEP2016 65 102

3 48.0 03SEP2016 56 105

4 72.0 04SEP2016 57 116

10 216.0 10SEP2016 56 108

1005 Screen 1 26AUG2016 113 158 47

1 1 -3 -73.5 29AUG2016 124 162 220 HYR

Recheck 1 -3 -73.5 30AUG2016 41

1 1 1 -0.2 01SEP2016 104 167 39

2 24.0 02SEP2016 63 140 35

3 48.0 03SEP2016 63 142 41

4 72.0 04SEP2016 54 126 LN 39

10 216.0 10SEP2016 233 HN 145 41

1006 Screen 1 18AUG2016 96 147 63

1 1 -3 -73.5 29AUG2016 39 157 69

1 -0.2 01SEP2016 24 LN 131 82

2 24.0 02SEP2016 23 LN 124 LN 77

3 48.0 03SEP2016 23 LN 129 LN 100

4 72.0 04SEP2016 21 LN 122 LN 117

10 216.0 10SEP2016 24 LN 121 LN 37 LN

1007 Screen 1 28AUG2016 136

1 1 -3 -73.5 29AUG2016 138

1 -0.2 01SEP2016 125 LN

2 24.0 02SEP2016 129 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

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Page 3 of 3

Table 1.5.5.1.3 Unscheduled and Out-of-Range Results - Serum Chemistry (III of III)

Creatine

HDL Kinase Lactate

Cholesterol F: 28-207 Dehydrogenase Triglyceride Lipase Amylase

Subject Study 34-96 M: 43-350 131-249 38-269 14-70 29-119

Number Period Cohort Day Hour Date (mg/dL) (U/L) (U/L) (mg/dL) (U/L) (U/L)

-------------------------------------------------------------------------------------------------------------------------------------

1007 1 1 3 48.0 03SEP2016 137

4 72.0 04SEP2016 139

10 216.0 10SEP2016 131

1008 Screen 1 16AUG2016 45 151

1 1 -3 -73.5 08SEP2016 38 128 LN

1 -0.2 11SEP2016 36 118 LN

2 24.0 12SEP2016 37 124 LN

3 48.0 13SEP2016 36 117 LN

4 72.0 14SEP2016 32 LN 124 LN

1009 Screen 1 24AUG2016 109 HN 593 HYR 106

Recheck 1 28AUG2016 212

1 1 -3 -73.5 29AUG2016 92 169 111

1 -0.2 01SEP2016 87 133 163 HY^

2 24.0 02SEP2016 89 116 139 HN

3 48.0 03SEP2016 85 123 137 HN

4 72.0 04SEP2016 82 127 140 HY^

10 216.0 10SEP2016 86 294 112

1010 Screen 1 28AUG2016 40 58 108 LN

1 1 -3 -73.5 29AUG2016 38 58 112 LN

1 -0.2 01SEP2016 33 LN 46 95 LN

2 24.0 02SEP2016 34 41 LN 91 LN

3 48.0 03SEP2016 34 43 93 LN

4 72.0 04SEP2016 33 LN 46 100 LN

10 216.0 10SEP2016 33 LN 52 102 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

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Page 1 of 2

Table 1.5.5.2.1 Unscheduled and Out-of-Range Results - Hematology (I of II)

Red Blood

Hemoglobin Hematocrit Platelet Cell Count

F: 12-15.9 F: 35.3-47 Count F: 3.95-5.21

Subject Study M: 13.6-17.4 M: 40.6-52.3 155-361 M: 4.43-5.81

Number Period Cohort Day Hour Date (g/dL) (%) (Thou/uL) (Mil/uL)

----------------------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 4.85

1 1 -3 -73.5 26AUG2016 4.67

1 -0.2 29AUG2016 4.84

2 24.0 30AUG2016 4.78

3 48.0 31AUG2016 4.66

4 72.0 01SEP2016 4.57

10 216.0 07SEP2016 4.41 LN

1004 Screen 1 18AUG2016 14.1 41.7

1 1 -3 -73.5 29AUG2016 13.9 42.2

1 -0.2 01SEP2016 14.0 41.1

2 24.0 02SEP2016 14.4 42.4

3 48.0 03SEP2016 13.7 39.8 LN

4 72.0 04SEP2016 14.1 41.8

10 216.0 10SEP2016 13.5 LN 40.2 LN

1006 Screen 1 18AUG2016 13.3

1 1 -3 -73.5 29AUG2016 13.9

1 -0.2 01SEP2016 13.2

2 24.0 02SEP2016 13.5

3 48.0 03SEP2016 13.0

4 72.0 04SEP2016 12.5

10 216.0 10SEP2016 11.8 LY-

1007 Screen 1 28AUG2016 41.6 4.62

1 1 -3 -73.5 29AUG2016 42.7 4.71

1 -0.2 01SEP2016 42.7 4.75

2 24.0 02SEP2016 43.8 4.93

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

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Page 2 of 2

Table 1.5.5.2.1 Unscheduled and Out-of-Range Results - Hematology (I of II)

Red Blood

Hemoglobin Hematocrit Platelet Cell Count

F: 12-15.9 F: 35.3-47 Count F: 3.95-5.21

Subject Study M: 13.6-17.4 M: 40.6-52.3 155-361 M: 4.43-5.81

Number Period Cohort Day Hour Date (g/dL) (%) (Thou/uL) (Mil/uL)

----------------------------------------------------------------------------------------------------------------

1007 1 1 3 48.0 03SEP2016 42.1 4.73

4 72.0 04SEP2016 42.4 4.73

10 216.0 10SEP2016 38.4 LN 4.27 LN

1009 Screen 1 24AUG2016 349

1 1 -3 -73.5 29AUG2016 340

1 -0.2 01SEP2016 336

2 24.0 02SEP2016 349

3 48.0 03SEP2016 329

4 72.0 04SEP2016 353

10 216.0 10SEP2016 373 HN

1010 Screen 1 28AUG2016 15.1 42.8 4.53

1 1 -3 -73.5 29AUG2016 14.7 42.1 4.47

1 -0.2 01SEP2016 15.0 42.2 4.49

2 24.0 02SEP2016 15.1 42.4 4.55

3 48.0 03SEP2016 14.4 40.6 4.37 LN

4 72.0 04SEP2016 14.9 42.2 4.55

10 216.0 10SEP2016 12.4 LY- 35.7 LN 3.78 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

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Page 1 of 2

Table 1.5.5.2.2 Unscheduled and Out-of-Range Results - Hematology (II of II)

Absolute Absolute

Eosinophils Eosinophils Monocytes Monocytes

Subject Study .5-7.4 0-.5 4.9-12.8 .3-.9

Number Period Cohort Day Hour Date (%) (Thou/uL) (%) (Thou/uL)

---------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 10.0

1 1 -3 -73.5 26AUG2016 12.4

1 -0.2 29AUG2016 10.9

2 24.0 30AUG2016 12.4

3 48.0 31AUG2016 12.9 HN

4 72.0 01SEP2016 12.4

10 216.0 07SEP2016 12.3

1003 Screen 1 18AUG2016 3.1 .2

1 1 -3 -73.5 29AUG2016 8.2 HN .5

1 -0.2 01SEP2016 6.1 .3

2 24.0 02SEP2016 5.5 .3

3 48.0 03SEP2016 6.0 .3

4 72.0 04SEP2016 6.0 .4

10 216.0 10SEP2016 9.1 HN .6 HN

1005 Screen 1 26AUG2016 .7 HN

1 1 -3 -73.5 29AUG2016 .6 HN

1 -0.2 01SEP2016 .3

2 24.0 02SEP2016 .3

3 48.0 03SEP2016 .3

4 72.0 04SEP2016 .3

10 216.0 10SEP2016 .2

1009 Screen 1 24AUG2016 7.0 .4

1 1 -3 -73.5 29AUG2016 12.9 HY- .8 HN

1 -0.2 01SEP2016 6.9 .4

2 24.0 02SEP2016 6.6 .5

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 2 of 2

Table 1.5.5.2.2 Unscheduled and Out-of-Range Results - Hematology (II of II)

Absolute Absolute

Eosinophils Eosinophils Monocytes Monocytes

Subject Study .5-7.4 0-.5 4.9-12.8 .3-.9

Number Period Cohort Day Hour Date (%) (Thou/uL) (%) (Thou/uL)

---------------------------------------------------------------------------------------------------

1009 1 1 3 48.0 03SEP2016 7.2 .4

4 72.0 04SEP2016 9.4 HN .5

10 216.0 10SEP2016 8.4 HN .5

1010 Screen 1 28AUG2016 5.5 .3

1 1 -3 -73.5 29AUG2016 5.9 .3

1 -0.2 01SEP2016 5.6 .3

2 24.0 02SEP2016 5.7 .3

3 48.0 03SEP2016 4.8 LN .2 LN

4 72.0 04SEP2016 5.6 .3

10 216.0 10SEP2016 6.9 .3

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

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Page 1 of 3

Table 1.5.5.3.1 Unscheduled and Out-of-Range Results - Urinalysis (I of III)

Blood Specific

Subject Study F: NEG, TRACE pH, Urine Gravity Glucose

Number Period Cohort Day Hour Date M: NEGATIVE 5.0-8.0 1.005-1.030 NEGATIVE

----------------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 1.003 LN

1 1 -3 -73.5 26AUG2016 1.003 LN

1 -2.5 29AUG2016 1.020

2 22.5 30AUG2016 1.019

3 46.5 31AUG2016 1.025

4 70.5 01SEP2016 1.021

10 215.5 07SEP2016 1.012

1004 Screen 1 18AUG2016 NEGATIVE NEGATIVE

1 1 -3 -73.5 29AUG2016 NEGATIVE NEGATIVE

1 -2.5 01SEP2016 NEGATIVE NEGATIVE

2 22.5 02SEP2016 1+ \*Y- NEGATIVE

3 46.5 03SEP2016 NEGATIVE NEGATIVE

4 70.5 04SEP2016 NEGATIVE NEGATIVE

10 215.5 10SEP2016 TRACE \*Y- TRACE \*N

1005 Screen 1 26AUG2016 NEGATIVE

1 1 -3 -73.5 29AUG2016 NEGATIVE

1 -2.5 01SEP2016 NEGATIVE

2 22.5 02SEP2016 2+ \*Y-

3 46.5 03SEP2016 NEGATIVE

4 70.5 04SEP2016 4+ \*Y-

10 215.5 10SEP2016 1+ \*Y-

1006 Screen 1 18AUG2016 NEGATIVE 7.0 1.004 LN NEGATIVE

1 1 -3 -73.5 29AUG2016 NEGATIVE 7.0 1.005 NEGATIVE

Recheck 1 -3 -73.5 30AUG2016 NEGATIVE 6.0 1.012 NEGATIVE

1 1 1 -2.5 01SEP2016 NEGATIVE 6.0 1.012 NEGATIVE

Note: \* = No Match to Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 2 of 3

Table 1.5.5.3.1 Unscheduled and Out-of-Range Results - Urinalysis (I of III)

Blood Specific

Subject Study F: NEG, TRACE pH, Urine Gravity Glucose

Number Period Cohort Day Hour Date M: NEGATIVE 5.0-8.0 1.005-1.030 NEGATIVE

----------------------------------------------------------------------------------------------------------

1006 1 1 2 22.5 02SEP2016 NEGATIVE 6.5 1.014 NEGATIVE

3 46.5 03SEP2016 NEGATIVE 6.0 1.004 LN NEGATIVE

Recheck 1 3 46.5 03SEP2016 NEGATIVE 6.5 1.004 LN NEGATIVE

1 1 4 70.5 04SEP2016 NEGATIVE 6.0 1.007 NEGATIVE

10 215.5 10SEP2016 NEGATIVE 6.5 1.005 NEGATIVE

1008 Screen 1 16AUG2016 NEGATIVE 5.0 1.006 NEGATIVE

1 1 -3 -73.5 08SEP2016 NEGATIVE 5.0 1.020 NEGATIVE

1 -2.5 11SEP2016 NEGATIVE 6.0 1.015 NEGATIVE

2 22.5 12SEP2016 TRACE 6.0 1.015 NEGATIVE

3 46.5 13SEP2016 NEGATIVE 5.0 1.012 NEGATIVE

Recheck 1 2 22.5 13SEP2016 NEGATIVE 5.0 1.012 NEGATIVE

1 1 4 70.5 14SEP2016 NEGATIVE 5.0 1.010 NEGATIVE

1009 Screen 1 24AUG2016 1.013

1 1 -3 -73.5 29AUG2016 1.018

1 -2.5 01SEP2016 1.014

2 22.5 02SEP2016 1.017

3 46.5 03SEP2016 1.019

4 70.5 04SEP2016 1.019

10 215.5 10SEP2016 1.003 LN

1010 Screen 1 28AUG2016 1.003 LN

1 1 -3 -73.5 29AUG2016 1.007

1 -2.5 01SEP2016 1.019

2 22.5 02SEP2016 1.021

3 46.5 03SEP2016 1.008

4 70.5 04SEP2016 1.021

Note: \* = No Match to Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 3 of 3

Table 1.5.5.3.1 Unscheduled and Out-of-Range Results - Urinalysis (I of III)

Blood Specific

Subject Study F: NEG, TRACE pH, Urine Gravity Glucose

Number Period Cohort Day Hour Date M: NEGATIVE 5.0-8.0 1.005-1.030 NEGATIVE

----------------------------------------------------------------------------------------------------------

1010 1 1 10 215.5 10SEP2016 1.003 LN

Note: \* = No Match to Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 1 of 1

Table 1.5.5.3.2 Unscheduled and Out-of-Range Results - Urinalysis (II of III)

Leukocyte

Subject Study Ketones Esterase Nitrite Protein

Number Period Cohort Day Hour Date NEG, TRACE NEG, TRACE NEGATIVE NEG, TRACE

-----------------------------------------------------------------------------------------------------------

1006 Screen 1 18AUG2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1 1 -3 -73.5 29AUG2016 NEGATIVE NEGATIVE POSITIVE \*Y- NEGATIVE

Recheck 1 -3 -73.5 30AUG2016 NEGATIVE NEGATIVE POSITIVE \*Y- NEGATIVE

1 1 1 -2.5 01SEP2016 NEGATIVE NEGATIVE POSITIVE \*Y^ NEGATIVE

2 22.5 02SEP2016 NEGATIVE NEGATIVE POSITIVE \*Y^ NEGATIVE

3 46.5 03SEP2016 NEGATIVE 1+ \*YR POSITIVE \*YR NEGATIVE

Recheck 1 3 46.5 03SEP2016 NEGATIVE NEGATIVE POSITIVE \*Y^ NEGATIVE

1 1 4 70.5 04SEP2016 NEGATIVE NEGATIVE POSITIVE \*Y^ NEGATIVE

10 215.5 10SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1007 Screen 1 28AUG2016 NEGATIVE

1 1 -3 -73.5 29AUG2016 NEGATIVE

1 -2.5 01SEP2016 NEGATIVE

2 22.5 02SEP2016 NEGATIVE

3 46.5 03SEP2016 1+ \*Y^

4 70.5 04SEP2016 NEGATIVE

10 215.5 10SEP2016 NEGATIVE

1008 Screen 1 16AUG2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1 1 -3 -73.5 08SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1 -2.5 11SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

2 22.5 12SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

3 46.5 13SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

Recheck 1 2 22.5 13SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1 1 4 70.5 14SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

Note: \* = No Match to Reference Range

Computer: Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 1 of 1

Table 1.5.5.3.3 Unscheduled and Out-of-Range Results - Urinalysis (III of III)

Casts RBC WBC

Subject Study Bilirubin Urobilinogen Bacteria 0-1 0-3 0-7

Number Period Cohort Day Hour Date NEGATIVE NEGATIVE NEGATIVE (/lpf) (/hpf) (/hpf)

-------------------------------------------------------------------------------------------------------------------

1005 1 1 2 22.5 02SEP2016 NEGATIVE 0

4 70.5 04SEP2016 1+ \*N 7-9 HY^

10 215.5 10SEP2016 NEGATIVE 0-1

1006 Screen 1 18AUG2016 NEGATIVE NEGATIVE

1 1 -3 -73.5 29AUG2016 NEGATIVE NEGATIVE 2+ \*N 0 0 1-3

Recheck 1 -3 -73.5 30AUG2016 NEGATIVE NEGATIVE 3+ \*Y- 0 0-1 3-5

1 1 1 -2.5 01SEP2016 NEGATIVE NEGATIVE 4+ \*Y^ 0 0-2 3-6

2 22.5 02SEP2016 NEGATIVE NEGATIVE 4+ \*Y^ 0 1-2 5-7

3 46.5 03SEP2016 NEGATIVE NEGATIVE 4+ \*Y^ 0 0 10-15 HY^

Recheck 1 3 46.5 03SEP2016 NEGATIVE NEGATIVE 3+ \*Y^ 0 0 2-5

1 1 4 70.5 04SEP2016 NEGATIVE NEGATIVE 4+ \*Y^ 0 0 8-10 HY^

10 215.5 10SEP2016 NEGATIVE NEGATIVE

1007 1 1 3 46.5 03SEP2016 1+ \*N

1008 Screen 1 16AUG2016 NEGATIVE NEGATIVE

1 1 -3 -73.5 08SEP2016 NEGATIVE NEGATIVE

1 -2.5 11SEP2016 NEGATIVE NEGATIVE

2 22.5 12SEP2016 NEGATIVE NEGATIVE

3 46.5 13SEP2016 NEGATIVE NEGATIVE

Recheck 1 2 22.5 13SEP2016 NEGATIVE NEGATIVE

1 1 4 70.5 14SEP2016 NEGATIVE NEGATIVE

Note: \* = No Match to Reference Range, H = Above Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, ^ = Will be Retested at a Later Event

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor1.sas 15SEP2016 18:58

Page 1 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1001 Screen 1 16AUG2016 12:50:13 86.5 28.67

SUP10 RIGHT 123 / 73 62 14 36.6

12:51:28 SUP1 RIGHT 121 / 81 58

12:54:57 STD3 RIGHT 132 / 89 66

1 1 -3 -73.50 26AUG2016 6:15:29 87.8 29.08

-72.75 26AUG2016 6:55:10 SUP10 RIGHT 120 / 60 65 10 36.6

6:56:30 SUP1 RIGHT 114 / 63 58

6:59:55 STD3 RIGHT 135 / 72 75

-2 -48.17 27AUG2016 7:12:31 SUP5 RIGHT 134 / 54 58 16 36.6

7:14:17 SUP1 RIGHT 141(\*)/ 63 60

-1 -25.33 28AUG2016 5:55:27 SUP5 RIGHT 125 / 64 62 12 36.8

5:57:30 SUP1 RIGHT 116 / 59 55

1 -1.33 29AUG2016 5:55:28 SUP10 RIGHT 121 / 63 59 20 36.2

5:57:02 SUP1 RIGHT 115 / 63 58

6:00:08 STD3 RIGHT 144(\*)/ 74 110(#)

0.33 29AUG2016 7:37:01 SUP5 RIGHT 129 / 69 62

7:38:48 SUP1 RIGHT 138 / 57 69

0.58 29AUG2016 7:50:09 SUP5 RIGHT 114 / 64 60

7:51:17 SUP1 RIGHT 105 / 74 63

1.08 29AUG2016 8:20:01 SUP5 RIGHT 113 / 69 69

8:21:25 SUP1 RIGHT 110 / 64 66

2.08 29AUG2016 9:20:05 SUP5 RIGHT 131 / 64 62

9:21:10 SUP1 RIGHT 113 / 53 64

3.08 29AUG2016 10:20:20 SUP5 RIGHT 118 / 62 60

10:21:46 SUP1 RIGHT 118 / 63 59

4.17 29AUG2016 11:25:24 SUP10 RIGHT 117 / 64 58 18 37.2

11:27:08 SUP1 RIGHT 121 / 65 67

11:30:26 STD3 RIGHT 123 / 82 102(#)

6.08 29AUG2016 13:21:27 SUP5 RIGHT 103 / 63 69

13:22:41 SUP1 RIGHT 102 / 50 68

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 2 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1001 1 1 1 8.08 29AUG2016 15:20:11 SUP5 RIGHT 118 / 69 61

15:21:23 SUP1 RIGHT 116 / 69 67

12.17 29AUG2016 19:25:12 SUP10 RIGHT 114 / 65 62 14 37.1

19:26:30 SUP1 RIGHT 113 / 64 62

19:29:35 STD3 RIGHT 131 / 82 98

2 24.17 30AUG2016 7:25:41 SUP10 RIGHT 120 / 66 63 14 37

7:26:49 SUP1 RIGHT 114 / 65 59

7:30:06 STD3 RIGHT 138 / 84 96

36.08 30AUG2016 19:23:33 SUP5 RIGHT 127 / 66 74 14 37.1

19:24:56 SUP1 RIGHT 131 / 68 62

3 48.08 31AUG2016 7:20:15 SUP5 RIGHT 123 / 60 61 16 37.1

7:21:28 SUP1 RIGHT 121 / 67 55

4 72.08 01SEP2016 7:20:46 SUP5 RIGHT 116 / 57 58 18 37.1

7:22:10 SUP1 RIGHT 117 / 50 60

10 216.08 07SEP2016 7:20:31 SUP5 RIGHT 119 / 68 56 10 36.8

7:22:25 SUP1 RIGHT 117 / 65 66

216.25 07SEP2016 7:28:42 85.6 28.37

1002 Screen 1 16AUG2016 11:32:05 66.1 22.42

SUP10 RIGHT 114 / 64 53 16 36.7

11:33:15 SUP1 RIGHT 114 / 69 56

11:36:29 STD3 RIGHT 118 / 79 69

1 1 -3 -73.50 26AUG2016 5:55:03 67.0 22.71

-72.75 26AUG2016 6:23:11 SUP10 RIGHT 123 / 67 62 14 36.4

6:24:35 SUP1 RIGHT 124 / 63 63

6:27:39 STD3 RIGHT 123 / 75 83

-2 -48.17 27AUG2016 7:09:33 SUP5 RIGHT 113 / 61 61 16 36.8

7:10:40 SUP1 RIGHT 116 / 59 58

-1 -25.33 28AUG2016 5:58:13 SUP5 RIGHT 125 / 68 58 14 36.7

5:59:44 SUP1 RIGHT 120 / 68 57

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 3 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1002 1 1 1 -1.33 29AUG2016 5:57:59 SUP10 RIGHT 119 / 64 60 14 36.6

5:59:21 SUP1 RIGHT 118 / 63 61

6:03:00 STD3 RIGHT 133 / 73 81

0.33 29AUG2016 7:40:16 SUP5 RIGHT 123 / 64 62

7:41:39 SUP1 RIGHT 123 / 63 64

0.58 29AUG2016 7:53:02 SUP5 RIGHT 123 / 63 62

7:54:04 SUP1 RIGHT 123 / 58 59

1.08 29AUG2016 8:22:43 SUP5 RIGHT 120 / 67 66

8:24:00 SUP1 RIGHT 126 / 74 64

2.08 29AUG2016 9:23:00 SUP5 RIGHT 127 / 70 62

9:24:06 SUP1 RIGHT 117 / 61 62

3.08 29AUG2016 10:23:16 SUP5 RIGHT 121 / 68 61

10:24:29 SUP1 RIGHT 124 / 61 60

4.17 29AUG2016 11:28:20 SUP10 RIGHT 123 / 59 56 10 36.7

11:29:38 SUP1 RIGHT 125 / 66 58

11:32:59 STD3 RIGHT 107 / 79 81

6.08 29AUG2016 13:23:05 SUP5 RIGHT 120 / 65 61

13:24:25 SUP1 RIGHT 118 / 55 64

8.08 29AUG2016 15:23:13 SUP5 RIGHT 117 / 66 64

15:24:22 SUP1 RIGHT 115 / 66 63

12.17 29AUG2016 19:27:51 SUP10 RIGHT 125 / 63 63 18 37.2

19:29:09 SUP1 RIGHT 123 / 56 62

19:32:29 STD3 RIGHT 124 / 77 96

2 24.17 30AUG2016 7:28:16 SUP10 RIGHT 123 / 66 62 18 36.8

7:29:45 SUP1 RIGHT 125 / 68 62

7:32:54 STD3 RIGHT 121 / 75 99

36.08 30AUG2016 19:23:34 SUP5 RIGHT 133 / 71 67 20 37.1

19:25:04 SUP1 RIGHT 139 / 61 67

3 48.08 31AUG2016 7:23:03 SUP5 RIGHT 124 / 66 64 14 36.7

7:24:50 SUP1 RIGHT 124 / 61 65

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 4 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1002 1 1 4 72.08 01SEP2016 7:23:41 SUP5 RIGHT 130 / 70 64 9 37.6

7:25:32 SUP1 RIGHT 133 / 71 67

10 216.08 07SEP2016 7:23:10 SUP5 RIGHT 114 / 63 65 14 36.7

7:24:41 SUP1 RIGHT 115 / 64 64

216.25 07SEP2016 7:29:12 66.2 22.46

1003 Screen 1 18AUG2016 10:19:19 75.9 25.01

SUP10 RIGHT 114 / 62 52 12 37

10:20:40 SUP1 RIGHT 113 / 58 54

10:24:15 STD3 RIGHT 113 / 73 55

1 1 -3 -73.50 29AUG2016 6:48:46 74.4 24.52

-72.75 29AUG2016 7:14:36 SUP10 RIGHT 109 / 64 49 14 36.7

7:16:20 SUP1 RIGHT 109 / 61 51

7:19:40 STD3 RIGHT 121 / 75 56

-2 -48.17 30AUG2016 7:51:24 SUP5 RIGHT 100 / 62 46 14 37

7:52:30 SUP1 RIGHT 98 / 56 47

-1 -25.33 31AUG2016 6:40:28 SUP5 RIGHT 106 / 65 47 18 36.6

6:41:50 SUP1 RIGHT 101 / 67 47

1 -1.33 01SEP2016 6:40:51 SUP10 RIGHT 104 / 67 47 16 36.6

6:42:56 SUP1 RIGHT 103 / 62 46

6:46:13 STD3 RIGHT 119 / 77 68

0.33 01SEP2016 8:20:05 SUP5 RIGHT 112 / 63 46

8:21:09 SUP1 RIGHT 105 / 58 49

0.58 01SEP2016 8:36:37 SUP5 RIGHT 114 / 69 52

8:38:11 SUP1 RIGHT 108 / 62 51

1.08 01SEP2016 9:05:03 SUP5 RIGHT 111 / 72 47

9:06:11 SUP1 RIGHT 113 / 61 48

2.08 01SEP2016 10:05:11 SUP5 RIGHT 111 / 67 48

10:06:21 SUP1 RIGHT 110 / 63 48

3.08 01SEP2016 11:05:09 SUP5 RIGHT 108 / 63 46

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 5 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1003 1 1 1 3.08 01SEP2016 11:06:17 SUP1 RIGHT 112 / 67 47

4.17 01SEP2016 12:10:12 SUP10 RIGHT 110 / 63 49 22 37.3

12:11:28 SUP1 RIGHT 114 / 64 51

12:15:02 STD3 RIGHT 76(\*) / 55 70

6.08 01SEP2016 14:05:21 SUP5 RIGHT 112 / 57 58

14:06:38 SUP1 RIGHT 112 / 57 57

8.08 01SEP2016 16:05:10 SUP5 RIGHT 124 / 67 58

16:06:49 SUP1 RIGHT 122 / 59 60

12.17 01SEP2016 20:10:00 SUP10 RIGHT 124 / 70 51 14 36.9

20:12:16 SUP1 RIGHT 116 / 60 52

20:15:45 STD3 RIGHT 130 / 85 75

2 24.17 02SEP2016 8:09:52 SUP10 RIGHT 124 / 73 50 22 36.7

8:11:32 SUP1 RIGHT 122 / 70 49

8:14:43 STD3 RIGHT 126 / 74 73

36.08 02SEP2016 20:06:43 SUP5 RIGHT 125 / 67 60 16 37.2

20:08:24 SUP1 RIGHT 135 / 69 93

3 48.08 03SEP2016 8:06:42 SUP5 RIGHT 134 / 62 53 14 36.7

8:08:05 SUP1 RIGHT 109 / 62 54

4 72.08 04SEP2016 8:05:17 SUP5 RIGHT 111 / 59 56 14 37.1

8:06:39 SUP1 RIGHT 116 / 63 56

10 216.08 10SEP2016 8:05:32 SUP5 RIGHT 116 / 64 54 20 36.8

8:07:35 SUP1 RIGHT 119 / 63 57

216.25 10SEP2016 8:15:01 74.3

1004 Screen 1 18AUG2016 12:29:19 68.8 24.26

SUP10 RIGHT 119 / 71 86 16 36.9

12:30:27 SUP1 RIGHT 120 / 73 86

12:33:43 STD3 RIGHT 119 / 84 102(#)

1 1 -3 -73.50 29AUG2016 7:22:59 68.4 24.12

-72.75 29AUG2016 7:45:50 SUP10 RIGHT 122 / 77 82 18 36.6

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 6 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1004 1 1 -3 -72.75 29AUG2016 7:47:32 SUP1 RIGHT 126 / 76 83

7:51:03 STD3 RIGHT 128 / 88 97

-2 -48.17 30AUG2016 7:53:15 SUP5 RIGHT 116 / 74 76 14 36.8

7:54:44 SUP1 RIGHT 113 / 75 75

-1 -25.33 31AUG2016 6:43:10 SUP5 RIGHT 119 / 78 70 10 37.1

6:44:38 SUP1 RIGHT 119 / 80 68

1 -1.33 01SEP2016 6:43:24 SUP10 RIGHT 117 / 71 69 14 36.8

6:44:45 SUP1 RIGHT 111 / 71 68

6:47:46 STD3 RIGHT 113 / 73 96

0.33 01SEP2016 8:23:03 SUP5 RIGHT 111 / 76 67

8:24:06 SUP1 RIGHT 109 / 77 75

0.58 01SEP2016 8:38:11 SUP5 RIGHT 120 / 72 70

8:39:23 SUP1 RIGHT 121 / 70 74

1.08 01SEP2016 9:08:02 SUP5 RIGHT 108 / 69 74

9:09:18 SUP1 RIGHT 113 / 70 76

2.08 01SEP2016 10:08:11 SUP5 RIGHT 118 / 73 82

10:09:15 SUP1 RIGHT 119 / 75 84

3.08 01SEP2016 11:08:00 SUP5 RIGHT 110 / 68 80

11:09:01 SUP1 RIGHT 109 / 69 82

4.17 01SEP2016 12:13:00 SUP10 RIGHT 112 / 68 85 16 37.3

12:14:00 SUP1 RIGHT 111 / 74 87

12:17:24 STD3 RIGHT 95 / 39(^) 121(#)

6.08 01SEP2016 14:08:02 SUP5 RIGHT 114 / 69 100

R 14:11:03 SUP5 RIGHT 96

14:12:08 SUP1 RIGHT 113 / 71 99

8.08 01SEP2016 16:08:02 SUP5 RIGHT 128 / 68 94

16:09:07 SUP1 RIGHT 121 / 73 86

12.17 01SEP2016 20:13:16 SUP10 RIGHT 120 / 73 85 16 37.7

20:14:50 SUP1 RIGHT 127 / 75 89

20:18:08 STD3 RIGHT 121 / 77 126(#)

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 7 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1004 1 1 2 24.17 02SEP2016 8:13:08 SUP10 RIGHT 119 / 71 77 16 36.7

8:14:19 SUP1 RIGHT 114 / 68 77

8:17:31 STD3 RIGHT 123 / 71 116(#)

36.08 02SEP2016 20:08:28 SUP5 RIGHT 125 / 69 87 16 37

20:10:32 SUP1 RIGHT 118 / 74 84

3 48.08 03SEP2016 8:10:29 SUP5 RIGHT 108 / 73 76 12 36.6

8:12:13 SUP1 RIGHT 121 / 76 78

4 72.08 04SEP2016 8:08:04 SUP5 RIGHT 125 / 73 82 14 37.1

8:09:06 SUP1 RIGHT 123 / 73 83

10 216.08 10SEP2016 8:10:09 SUP5 RIGHT 122 / 71 70 12 35.7

8:11:14 SUP1 RIGHT 128 / 75 76

216.25 10SEP2016 8:24:29 68.3

1005 Screen 1 26AUG2016 12:05:41 59.5 22.86

SUP10 RIGHT 108 / 59 54 12 37.1

12:06:45 SUP1 RIGHT 113 / 54 60

12:09:55 STD3 RIGHT 106 / 60 75

1 1 -3 -73.50 29AUG2016 7:00:17 58.7 22.58

-72.75 29AUG2016 8:11:46 SUP10 RIGHT 113 / 53 69 14 36.8

8:13:51 SUP1 RIGHT 113 / 63 72

8:17:45 STD3 RIGHT 116 / 66 74

-2 -48.17 30AUG2016 7:56:25 SUP5 RIGHT 112 / 56 66 12 37.1

7:57:33 SUP1 RIGHT 118 / 65 67

-1 -25.33 31AUG2016 6:45:59 SUP5 RIGHT 110 / 68 71 12 37.1

6:47:09 SUP1 RIGHT 117 / 66 69

1 -1.33 01SEP2016 6:45:48 SUP10 RIGHT 122 / 69 61 14 37.1

6:47:13 SUP1 RIGHT 122 / 60 69

6:50:31 STD3 RIGHT 123 / 57 91

0.33 01SEP2016 8:26:33 SUP5 RIGHT 126 / 64 60

8:27:36 SUP1 RIGHT 134 / 58 61

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 8 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1005 1 1 1 0.58 01SEP2016 8:41:13 SUP5 RIGHT 117 / 65 60

8:42:15 SUP1 RIGHT 123 / 64 70

1.08 01SEP2016 9:11:18 SUP5 RIGHT 120 / 66 60

9:12:53 SUP1 RIGHT 118 / 65 62

2.08 01SEP2016 10:11:51 SUP5 RIGHT 126 / 69 61

10:13:53 SUP1 RIGHT 127 / 66 60

3.08 01SEP2016 11:11:16 SUP5 RIGHT 128 / 68 61

11:12:20 SUP1 RIGHT 118 / 62 65

4.17 01SEP2016 12:16:14 SUP10 RIGHT 123 / 64 60 10 37.1

12:17:31 SUP1 RIGHT 120 / 76 59

12:21:10 STD3 RIGHT 126 / 74 86

6.08 01SEP2016 14:11:12 SUP5 RIGHT 129 / 73 70

14:12:19 SUP1 RIGHT 134 / 66 78

8.08 01SEP2016 16:11:06 SUP5 RIGHT 134 / 71 70

16:12:08 SUP1 RIGHT 118 / 68 68

12.17 01SEP2016 20:16:26 SUP10 RIGHT 113 / 60 66 16 37.6

20:17:52 SUP1 RIGHT 112 / 52 73

20:20:53 STD3 RIGHT 110 / 85 98

2 24.17 02SEP2016 8:16:14 SUP10 RIGHT 107 / 52 61 12 37

8:17:30 SUP1 RIGHT 115 / 63 63

8:21:13 STD3 RIGHT 120 / 68 107(#)

36.08 02SEP2016 20:11:04 SUP5 RIGHT 118 / 64 78 18 37.4

20:12:13 SUP1 RIGHT 120 / 66 78

3 48.08 03SEP2016 8:12:06 SUP5 RIGHT 118 / 60 63 12 36.8

8:13:20 SUP1 RIGHT 121 / 58 67

4 72.08 04SEP2016 8:11:15 SUP5 RIGHT 113 / 57 70 16 36.9

8:12:25 SUP1 RIGHT 115 / 60 59

10 216.08 10SEP2016 8:12:20 SUP5 RIGHT 112 / 65 69 14 36.9

8:13:23 SUP1 RIGHT 116 / 61 73

216.25 10SEP2016 8:19:09 55.4

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 9 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1006 Screen 1 18AUG2016 11:45:37 76.1 24.57

SUP10 RIGHT 121 / 83 68 12 37.3

11:46:42 SUP1 RIGHT 121 / 76 68

11:49:54 STD3 RIGHT 122 / 90 85

1 1 -3 -73.50 29AUG2016 7:01:09 76.4 24.65

-72.75 29AUG2016 7:45:01 SUP10 RIGHT 116 / 81 57 10 37.1

7:46:40 SUP1 RIGHT 113 / 75 60

7:49:48 STD3 RIGHT 134 / 96(^) 84

-2 -48.17 30AUG2016 7:58:07 SUP5 RIGHT 112 / 75 56 14 37

7:59:53 SUP1 RIGHT 116 / 69 57

-1 -25.33 31AUG2016 6:49:06 SUP5 RIGHT 107 / 69 57 20 37

6:50:11 SUP1 RIGHT 103 / 68 57

1 -1.33 01SEP2016 6:49:48 SUP10 RIGHT 108 / 75 54 10 37

6:51:11 SUP1 RIGHT 108 / 70 58

6:54:11 STD3 RIGHT 116 / 87 78

0.33 01SEP2016 8:29:01 SUP5 RIGHT 112 / 74 56

8:30:11 SUP1 RIGHT 111 / 66 55

0.58 01SEP2016 8:44:01 SUP5 RIGHT 105 / 76 59

8:45:09 SUP1 RIGHT 112 / 67 60

1.08 01SEP2016 9:14:08 SUP5 RIGHT 105 / 72 58

9:15:13 SUP1 RIGHT 104 / 70 56

2.08 01SEP2016 10:14:09 SUP5 RIGHT 108 / 72 57

10:15:13 SUP1 RIGHT 114 / 73 62

3.08 01SEP2016 11:14:14 SUP5 RIGHT 111 / 68 57

11:15:17 SUP1 RIGHT 106 / 66 57

4.17 01SEP2016 12:22:27 SUP10 RIGHT 115 / 74 55 12 37.7

12:23:42 SUP1 RIGHT 112 / 71 59

12:26:58 STD3 RIGHT 141(\*)/ 93(^) 101(#)

6.08 01SEP2016 14:14:44 SUP5 RIGHT 101 / 58 73

14:15:56 SUP1 RIGHT 103 / 61 71

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 10 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1006 1 1 1 8.08 01SEP2016 16:14:03 SUP5 RIGHT 111 / 67 65

16:15:05 SUP1 RIGHT 103 / 62 63

12.17 01SEP2016 20:20:27 SUP10 RIGHT 105 / 69 63 16 37

20:21:56 SUP1 RIGHT 104 / 64 61

20:25:25 STD3 RIGHT 120 / 86 93

2 24.17 02SEP2016 8:19:15 SUP10 RIGHT 111 / 69 63 14 36.4

8:20:39 SUP1 RIGHT 103 / 67 63

8:24:29 STD3 RIGHT 123 / 78 102(#)

36.08 02SEP2016 20:13:44 SUP5 RIGHT 107 / 66 68 14 37

20:15:14 SUP1 RIGHT 108 / 70 72

3 48.08 03SEP2016 8:14:49 SUP5 RIGHT 110 / 66 59 22 36.6

8:15:57 SUP1 RIGHT 111 / 67 61

4 72.08 04SEP2016 8:14:02 SUP5 RIGHT 107 / 66 62 14 36.7

8:15:14 SUP1 RIGHT 106 / 75 65

10 216.08 10SEP2016 8:14:05 SUP5 RIGHT 110 / 76 58 14 37.3

8:15:28 SUP1 RIGHT 112 / 68 61

216.25 10SEP2016 8:27:49 78.7

1007 Screen 1 28AUG2016 8:32:31 104.6 31.89

SUP10 RIGHT 107 / 67 53 18 36.9

8:33:40 SUP1 RIGHT 103 / 59 51

8:36:49 STD3 RIGHT 112 / 74 78

1 1 -3 -73.50 29AUG2016 6:50:35 104.1 31.75

-72.75 29AUG2016 7:33:26 SUP10 RIGHT 108 / 63 53 18 36.8

7:35:03 SUP1 RIGHT 104 / 57 52

7:38:06 STD3 RIGHT 118 / 79 76

-2 -48.17 30AUG2016 8:02:00 SUP5 RIGHT 106 / 59 55 14 36.8

8:03:09 SUP1 RIGHT 100 / 61 51

-1 -25.33 31AUG2016 6:52:37 SUP5 RIGHT 110 / 65 48 20 36.4

6:54:04 SUP1 RIGHT 100 / 59 49

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 11 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1007 1 1 1 -1.33 01SEP2016 6:51:53 SUP10 RIGHT 108 / 57 51 24 36.7

6:53:22 SUP1 RIGHT 105 / 63 51

6:56:51 STD3 RIGHT 121 / 79 85

0.33 01SEP2016 8:32:22 SUP5 RIGHT 116 / 64 55

8:33:41 SUP1 RIGHT 114 / 60 55

0.58 01SEP2016 8:47:15 SUP5 RIGHT 117 / 64 52

8:48:41 SUP1 RIGHT 117 / 71 53

1.08 01SEP2016 9:17:08 SUP5 RIGHT 110 / 65 59

9:18:33 SUP1 RIGHT 104 / 60 50

2.08 01SEP2016 10:17:09 SUP5 RIGHT 139 / 77 57

10:18:12 SUP1 RIGHT 130 / 72 54

3.08 01SEP2016 11:17:07 SUP5 RIGHT 124 / 59 52

11:18:15 SUP1 RIGHT 121 / 63 56

4.17 01SEP2016 12:22:55 SUP10 RIGHT 116 / 64 51 16 37.2

12:24:08 SUP1 RIGHT 119 / 67 59

12:27:25 STD3 RIGHT 139 / 82 93

6.08 01SEP2016 14:17:15 SUP5 RIGHT 122 / 63 64

14:18:19 SUP1 RIGHT 119 / 59 61

8.08 01SEP2016 16:17:13 SUP5 RIGHT 123 / 63 58

16:18:35 SUP1 RIGHT 125 / 62 56

12.17 01SEP2016 20:22:37 SUP10 RIGHT 118 / 64 60 18 37.7

20:23:59 SUP1 RIGHT 125 / 66 60

20:27:24 STD3 RIGHT 124 / 77 91

2 24.17 02SEP2016 8:22:14 SUP10 RIGHT 117 / 59 54 20 36.9

8:23:47 SUP1 RIGHT 112 / 70 58

8:27:16 STD3 RIGHT 108 / 68 92

36.08 02SEP2016 20:17:26 SUP5 RIGHT 118 / 61 61 18 36.7

20:19:14 SUP1 RIGHT 117 / 70 62

3 48.08 03SEP2016 8:17:21 SUP5 RIGHT 118 / 68 56 20 36.6

8:19:10 SUP1 RIGHT 115 / 66 56

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 12 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1007 1 1 4 72.08 04SEP2016 8:17:07 SUP5 RIGHT 130 / 70 60 20 37

8:18:29 SUP1 RIGHT 131 / 65 68

10 216.08 10SEP2016 8:19:48 SUP5 RIGHT 122 / 56 59 18 36.9

8:21:11 SUP1 RIGHT 116 / 58 57

216.25 10SEP2016 8:27:00 104.0

1008 Screen 1 16AUG2016 12:02:35 75.0 29.85

SUP10 RIGHT 111 / 68 60 16 37.2

12:03:43 SUP1 RIGHT 117 / 64 66

12:06:53 STD3 RIGHT 125 / 77 78

1 1 -3 -73.45 08SEP2016 5:56:26 75.1 29.88

-72.70 08SEP2016 6:54:39 SUP10 RIGHT 125 / 78 68 16 36.9

6:55:56 SUP1 RIGHT 121 / 72 67

6:59:10 STD3 RIGHT 125 / 79 84

-2 -48.17 09SEP2016 7:02:07 SUP5 RIGHT 118 / 70 58 14 37.1

7:03:22 SUP1 RIGHT 117 / 65 61

-1 -25.33 10SEP2016 5:52:02 SUP5 RIGHT 126 / 64 59 14 36.7

5:53:15 SUP1 RIGHT 123 / 74 62

1 -1.33 11SEP2016 5:52:13 SUP10 RIGHT 116 / 69 64 12 36.4

5:53:49 SUP1 RIGHT 120 / 66 62

5:57:27 STD3 RIGHT 107 / 76 87

0.33 11SEP2016 7:32:23 SUP5 RIGHT 112 / 66 58

7:33:34 SUP1 RIGHT 114 / 66 64

0.58 11SEP2016 7:47:18 SUP5 RIGHT 122 / 71 64

7:48:38 SUP1 RIGHT 117 / 66 71

1.08 11SEP2016 8:17:09 SUP5 RIGHT 110 / 69 68

8:18:14 SUP1 RIGHT 118 / 70 67

2.08 11SEP2016 9:16:46 SUP5 RIGHT 121 / 74 61

9:18:06 SUP1 RIGHT 118 / 76 61

3.08 11SEP2016 10:16:45 SUP5 RIGHT 131 / 72 70

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 13 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1008 1 1 1 3.08 11SEP2016 10:18:20 SUP1 RIGHT 115 / 72 64

4.17 11SEP2016 11:22:06 SUP10 RIGHT 120 / 71 68 12 36.6

11:23:44 SUP1 RIGHT 117 / 73 70

11:26:49 STD3 RIGHT 130 / 76 117(#)

6.08 11SEP2016 13:17:06 SUP5 RIGHT 111 / 63 78

13:18:14 SUP1 RIGHT 111 / 61 80

8.08 11SEP2016 15:17:06 SUP5 RIGHT 99 / 63 80

15:18:15 SUP1 RIGHT 109 / 62 78

12.17 11SEP2016 19:22:05 SUP10 RIGHT 112 / 67 81 16 36.6

19:23:12 SUP1 RIGHT 115 / 66 90

19:26:20 STD3 RIGHT 131 / 84 113(#)

2 24.17 12SEP2016 7:24:17 SUP10 RIGHT 114 / 71 69 12 36.6

7:25:42 SUP1 RIGHT 112 / 64 66

7:28:44 STD3 RIGHT 121 / 85 89

36.08 12SEP2016 19:18:03 SUP5 RIGHT 97 / 62 86 14 37.1

19:20:14 SUP1 RIGHT 98 / 53 72

3 48.08 13SEP2016 7:17:18 SUP5 RIGHT 112 / 72 62 12 36.7

7:18:25 SUP1 RIGHT 113 / 63 68

4 72.08 14SEP2016 7:16:50 SUP5 RIGHT 126 / 72 71 20 36.6

7:18:21 SUP1 RIGHT 118 / 70 65

1009 Screen 1 24AUG2016 9:45:23 62.4 21.05

SUP10 RIGHT 114 / 68 62 16 36.3

9:46:52 SUP1 RIGHT 116 / 69 63

9:50:05 STD3 RIGHT 123 / 73 78

1 1 -3 -73.50 29AUG2016 6:53:12 62.9 21.20

-72.75 29AUG2016 7:14:30 SUP10 RIGHT 110 / 71 57 16 36

7:16:06 SUP1 RIGHT 108 / 71 58

7:20:22 STD3 RIGHT 118 / 83 68

-2 -48.17 30AUG2016 8:08:09 SUP5 RIGHT 114 / 69 60 14 37

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 14 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1009 1 1 -2 -48.17 30AUG2016 8:09:16 SUP1 RIGHT 117 / 65 60

-1 -25.33 31AUG2016 6:58:05 SUP5 RIGHT 115 / 77 59 20 36.8

6:59:15 SUP1 RIGHT 116 / 68 58

1 -1.33 01SEP2016 6:58:15 SUP10 RIGHT 120 / 66 59 16 36.4

6:59:46 SUP1 RIGHT 111 / 63 60

7:02:53 STD3 RIGHT 117 / 72 83

0.33 01SEP2016 8:38:12 SUP5 RIGHT 129 / 66 60

8:40:17 SUP1 RIGHT 123 / 75 58

0.58 01SEP2016 8:53:07 SUP5 RIGHT 119 / 68 59

8:54:12 SUP1 RIGHT 119 / 70 59

1.08 01SEP2016 9:24:36 SUP5 RIGHT 126 / 67 59

9:25:57 SUP1 RIGHT 123 / 71 63

2.08 01SEP2016 10:21:17 SUP5 RIGHT 118 / 70 60

10:22:19 SUP1 RIGHT 124 / 66 60

3.08 01SEP2016 11:32:04 SUP5 RIGHT 114 / 72 57

11:33:09 SUP1 RIGHT 119 / 75 58

4.17 01SEP2016 12:30:24 SUP10 RIGHT 112 / 72 62 12 36.4

12:31:54 SUP1 RIGHT 113 / 73 62

12:35:06 STD3 RIGHT 121 / 72 98

6.08 01SEP2016 14:23:04 SUP5 RIGHT 115 / 66 82

14:24:05 SUP1 RIGHT 118 / 66 85

8.08 01SEP2016 16:23:02 SUP5 RIGHT 116 / 69 72

16:24:06 SUP1 RIGHT 122 / 68 77

12.17 01SEP2016 20:28:31 SUP10 RIGHT 110 / 69 67 14 37.1

20:29:42 SUP1 RIGHT 118 / 69 67

20:32:47 STD3 RIGHT 128 / 81 103(#)

2 24.17 02SEP2016 8:28:18 SUP10 RIGHT 109 / 64 63 18 36.6

8:29:52 SUP1 RIGHT 115 / 65 64

8:33:17 STD3 RIGHT 116 / 86 91

36.08 02SEP2016 20:22:59 SUP5 RIGHT 111 / 67 71 18 37

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 15 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1009 1 1 2 36.08 02SEP2016 20:24:04 SUP1 RIGHT 110 / 66 72

3 48.08 03SEP2016 8:22:28 SUP5 RIGHT 107 / 58 66 12 36.9

8:23:42 SUP1 RIGHT 109 / 76 69

4 72.08 04SEP2016 8:25:10 SUP5 RIGHT 112 / 59 64 16 36.4

8:26:19 SUP1 RIGHT 113 / 68 64

10 216.08 10SEP2016 8:22:02 SUP5 RIGHT 113 / 68 54 18 36

8:23:08 SUP1 RIGHT 112 / 70 54

216.25 10SEP2016 8:28:47 62.8

1010 Screen 1 28AUG2016 9:14:37 82.8 23.06

SUP10 RIGHT 120 / 67 75 14 36.2

9:15:46 SUP1 RIGHT 127 / 71 74

9:18:52 STD3 RIGHT 141(\*)/ 84 92

1 1 -3 -73.50 29AUG2016 6:47:49 83.4 23.23

-72.75 29AUG2016 7:24:49 SUP10 RIGHT 108 / 56 68 12 36.4

7:26:32 SUP1 RIGHT 112 / 70 67

7:30:15 STD3 RIGHT 136 / 75 76

-2 -48.17 30AUG2016 8:11:11 SUP5 RIGHT 110 / 64 64 14 36.8

8:12:32 SUP1 RIGHT 119 / 66 61

-1 -25.33 31AUG2016 7:01:16 SUP5 RIGHT 114 / 63 60 12 36.4

7:02:23 SUP1 RIGHT 118 / 64 59

1 -1.33 01SEP2016 7:01:14 SUP10 RIGHT 122 / 69 67 10 37

7:02:44 SUP1 RIGHT 121 / 62 67

7:05:50 STD3 RIGHT 127 / 70 85

0.33 01SEP2016 8:41:04 SUP5 RIGHT 115 / 62 64

8:42:13 SUP1 RIGHT 118 / 68 65

0.58 01SEP2016 8:56:41 SUP5 RIGHT 113 / 64 65

8:57:52 SUP1 RIGHT 107 / 63 65

1.08 01SEP2016 9:26:05 SUP5 RIGHT 119 / 71 64

9:27:24 SUP1 RIGHT 123 / 68 64

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 16 of 16

Table 1.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

1010 1 1 1 2.08 01SEP2016 10:26:15 SUP5 RIGHT 112 / 65 62

10:27:25 SUP1 RIGHT 114 / 70 64

3.08 01SEP2016 11:26:07 SUP5 RIGHT 125 / 66 65

11:27:25 SUP1 RIGHT 114 / 55 69

4.17 01SEP2016 12:32:18 SUP10 RIGHT 117 / 71 70 10 37.1

12:33:36 SUP1 RIGHT 125 / 72 66

12:37:05 STD3 RIGHT 108 / 79 106(#)

6.08 01SEP2016 14:26:11 SUP5 RIGHT 111 / 68 78

14:27:17 SUP1 RIGHT 112 / 66 85

8.08 01SEP2016 16:26:05 SUP5 RIGHT 119 / 66 74

16:27:08 SUP1 RIGHT 105 / 64 70

12.17 01SEP2016 20:30:21 SUP10 RIGHT 117 / 63 69 14 36.9

20:32:07 SUP1 RIGHT 118 / 68 66

20:35:58 STD3 RIGHT 125 / 78 93

2 24.17 02SEP2016 8:30:59 SUP10 RIGHT 122 / 64 60 12 36.6

8:32:30 SUP1 RIGHT 114 / 63 60

8:37:08 STD3 RIGHT 120 / 68 94

36.08 02SEP2016 20:26:07 SUP5 RIGHT 113 / 60 66 14 36.6

20:27:24 SUP1 RIGHT 115 / 62 64

3 48.08 03SEP2016 8:26:02 SUP5 RIGHT 111 / 62 68 18 36.6

8:27:04 SUP1 RIGHT 112 / 63 66

4 72.08 04SEP2016 8:26:12 SUP5 RIGHT 121 / 71 70 16 37.1

8:27:28 SUP1 RIGHT 118 / 65 72

10 216.08 10SEP2016 8:26:19 SUP5 RIGHT 114 / 61 65 20 36.6

8:27:33 SUP1 RIGHT 124 / 74 67

216.25 10SEP2016 8:36:51 83.9

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 1 = 50 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 1 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1001 1 1 1 Baseline 29AUG2016 SUP RIGHT 118.0/ 63.0 58.5 20 36.2

STD RIGHT 144.0/ 74.0 110.0

0.33 29AUG2016 SUP RIGHT 15.5/ 0.0 7.0

0.58 29AUG2016 SUP RIGHT -8.5/ 6.0 3.0

1.08 29AUG2016 SUP RIGHT -6.5/ 3.5 9.0

2.08 29AUG2016 SUP RIGHT 4.0/ -4.5 4.5

3.08 29AUG2016 SUP RIGHT 0.0/ -0.5 1.0

4.17 29AUG2016 SUP RIGHT 1.0/ 1.5 4.0 -2 1.0

STD RIGHT -21.0/ 8.0 -8.0

6.08 29AUG2016 SUP RIGHT -15.5/ -6.5 10.0

8.08 29AUG2016 SUP RIGHT -1.0/ 6.0 5.5

12.17 29AUG2016 SUP RIGHT -4.5/ 1.5 3.5 -6 0.9

STD RIGHT -13.0/ 8.0 -12.0

2 24.17 30AUG2016 SUP RIGHT -1.0/ 2.5 2.5 -6 0.8

STD RIGHT -6.0/ 10.0 -14.0

36.08 30AUG2016 SUP RIGHT 11.0/ 4.0 9.5 -6 0.9

3 48.08 31AUG2016 SUP RIGHT 4.0/ 0.5 -0.5 -4 0.9

4 72.08 01SEP2016 SUP RIGHT -1.5/ -9.5 0.5 -2 0.9

10 216.1 07SEP2016 SUP RIGHT 0.0/ 3.5 2.5 -10 0.6

216.3 07SEP2016 /

1002 1 1 1 Baseline 29AUG2016 SUP RIGHT 118.5/ 63.5 60.5 14 36.6

STD RIGHT 133.0/ 73.0 81.0

0.33 29AUG2016 SUP RIGHT 4.5/ 0.0 2.5

0.58 29AUG2016 SUP RIGHT 4.5/ -3.0 0.0

1.08 29AUG2016 SUP RIGHT 4.5/ 7.0 4.5

2.08 29AUG2016 SUP RIGHT 3.5/ 2.0 1.5

3.08 29AUG2016 SUP RIGHT 4.0/ 1.0 0.0

4.17 29AUG2016 SUP RIGHT 5.5/ -1.0 -3.5 -4 0.1

STD RIGHT -26.0/ 6.0 0.0

6.08 29AUG2016 SUP RIGHT 0.5/ -3.5 2.0

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 2 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1002 1 1 1 8.08 29AUG2016 SUP RIGHT -2.5/ 2.5 3.0

12.17 29AUG2016 SUP RIGHT 5.5/ -4.0 2.0 4 0.6

STD RIGHT -9.0/ 4.0 15.0

2 24.17 30AUG2016 SUP RIGHT 5.5/ 3.5 1.5 4 0.2

STD RIGHT -12.0/ 2.0 18.0

36.08 30AUG2016 SUP RIGHT 17.5/ 2.5 6.5 6 0.5

3 48.08 31AUG2016 SUP RIGHT 5.5/ 0.0 4.0 0 0.1

4 72.08 01SEP2016 SUP RIGHT 13.0/ 7.0 5.0 -5 1.0

10 216.1 07SEP2016 SUP RIGHT -4.0/ 0.0 4.0 0 0.1

216.3 07SEP2016 /

1003 1 1 1 Baseline 01SEP2016 SUP RIGHT 103.5/ 64.5 46.5 16 36.6

STD RIGHT 119.0/ 77.0 68.0

0.33 01SEP2016 SUP RIGHT 5.0/ -4.0 1.0

0.58 01SEP2016 SUP RIGHT 7.5/ 1.0 5.0

1.08 01SEP2016 SUP RIGHT 8.5/ 2.0 1.0

2.08 01SEP2016 SUP RIGHT 7.0/ 0.5 1.5

3.08 01SEP2016 SUP RIGHT 6.5/ 0.5 0.0

4.17 01SEP2016 SUP RIGHT 8.5/ -1.0 3.5 6 0.7

STD RIGHT -43.0/-22.0 2.0

6.08 01SEP2016 SUP RIGHT 8.5/ -7.5 11.0

8.08 01SEP2016 SUP RIGHT 19.5/ -1.5 12.5

12.17 01SEP2016 SUP RIGHT 16.5/ 0.5 5.0 -2 0.3

STD RIGHT 11.0/ 8.0 7.0

2 24.17 02SEP2016 SUP RIGHT 19.5/ 7.0 3.0 6 0.1

STD RIGHT 7.0/ -3.0 5.0

36.08 02SEP2016 SUP RIGHT 26.5/ 3.5 30.0 0 0.6

3 48.08 03SEP2016 SUP RIGHT 18.0/ -2.5 7.0 -2 0.1

4 72.08 04SEP2016 SUP RIGHT 10.0/ -3.5 9.5 -2 0.5

10 216.1 10SEP2016 SUP RIGHT 14.0/ -1.0 9.0 4 0.2

216.3 10SEP2016 /

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 3 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1004 1 1 1 Baseline 01SEP2016 SUP RIGHT 114.0/ 71.0 68.5 14 36.8

STD RIGHT 113.0/ 73.0 96.0

0.33 01SEP2016 SUP RIGHT -4.0/ 5.5 2.5

0.58 01SEP2016 SUP RIGHT 6.5/ 0.0 3.5

1.08 01SEP2016 SUP RIGHT -3.5/ -1.5 6.5

2.08 01SEP2016 SUP RIGHT 4.5/ 3.0 14.5

3.08 01SEP2016 SUP RIGHT -4.5/ -2.5 12.5

4.17 01SEP2016 SUP RIGHT -2.5/ 0.0 17.5 2 0.5

STD RIGHT -18.0/-34.0 25.0

6.08 01SEP2016 SUP RIGHT -0.5/ -1.0 31.0

8.08 01SEP2016 SUP RIGHT 10.5/ -0.5 21.5

12.17 01SEP2016 SUP RIGHT 9.5/ 3.0 18.5 2 0.9

STD RIGHT 8.0/ 4.0 30.0

2 24.17 02SEP2016 SUP RIGHT 2.5/ -1.5 8.5 2 -0.1

STD RIGHT 10.0/ -2.0 20.0

36.08 02SEP2016 SUP RIGHT 7.5/ 0.5 17.0 2 0.2

3 48.08 03SEP2016 SUP RIGHT 0.5/ 3.5 8.5 -2 -0.2

4 72.08 04SEP2016 SUP RIGHT 10.0/ 2.0 14.0 0 0.3

10 216.1 10SEP2016 SUP RIGHT 11.0/ 2.0 4.5 -2 -1.1

216.3 10SEP2016 /

1005 1 1 1 Baseline 01SEP2016 SUP RIGHT 122.0/ 64.5 65.0 14 37.1

STD RIGHT 123.0/ 57.0 91.0

0.33 01SEP2016 SUP RIGHT 8.0/ -3.5 -4.5

0.58 01SEP2016 SUP RIGHT -2.0/ 0.0 0.0

1.08 01SEP2016 SUP RIGHT -3.0/ 1.0 -4.0

2.08 01SEP2016 SUP RIGHT 4.5/ 3.0 -4.5

3.08 01SEP2016 SUP RIGHT 1.0/ 0.5 -2.0

4.17 01SEP2016 SUP RIGHT -0.5/ 5.5 -5.5 -4 0.0

STD RIGHT 3.0/ 17.0 -5.0

6.08 01SEP2016 SUP RIGHT 9.5/ 5.0 9.0

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 4 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1005 1 1 1 8.08 01SEP2016 SUP RIGHT 4.0/ 5.0 4.0

12.17 01SEP2016 SUP RIGHT -9.5/ -8.5 4.5 2 0.5

STD RIGHT -13.0/ 28.0 7.0

2 24.17 02SEP2016 SUP RIGHT -11.0/ -7.0 -3.0 -2 -0.1

STD RIGHT -3.0/ 11.0 16.0

36.08 02SEP2016 SUP RIGHT -3.0/ 0.5 13.0 4 0.3

3 48.08 03SEP2016 SUP RIGHT -2.5/ -5.5 0.0 -2 -0.3

4 72.08 04SEP2016 SUP RIGHT -8.0/ -6.0 -0.5 2 -0.2

10 216.1 10SEP2016 SUP RIGHT -8.0/ -1.5 6.0 0 -0.2

216.3 10SEP2016 /

1006 1 1 1 Baseline 01SEP2016 SUP RIGHT 108.0/ 72.5 56.0 10 37.0

STD RIGHT 116.0/ 87.0 78.0

0.33 01SEP2016 SUP RIGHT 3.5/ -2.5 -0.5

0.58 01SEP2016 SUP RIGHT 0.5/ -1.0 3.5

1.08 01SEP2016 SUP RIGHT -3.5/ -1.5 1.0

2.08 01SEP2016 SUP RIGHT 3.0/ 0.0 3.5

3.08 01SEP2016 SUP RIGHT 0.5/ -5.5 1.0

4.17 01SEP2016 SUP RIGHT 5.5/ 0.0 1.0 2 0.7

STD RIGHT 25.0/ 6.0 23.0

6.08 01SEP2016 SUP RIGHT -6.0/-13.0 16.0

8.08 01SEP2016 SUP RIGHT -1.0/ -8.0 8.0

12.17 01SEP2016 SUP RIGHT -3.5/ -6.0 6.0 6 0.0

STD RIGHT 4.0/ -1.0 15.0

2 24.17 02SEP2016 SUP RIGHT -1.0/ -4.5 7.0 4 -0.6

STD RIGHT 7.0/ -9.0 24.0

36.08 02SEP2016 SUP RIGHT -0.5/ -4.5 14.0 4 0.0

3 48.08 03SEP2016 SUP RIGHT 2.5/ -6.0 4.0 12 -0.4

4 72.08 04SEP2016 SUP RIGHT -1.5/ -2.0 7.5 4 -0.3

10 216.1 10SEP2016 SUP RIGHT 3.0/ -0.5 3.5 4 0.3

216.3 10SEP2016 /

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 5 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1007 1 1 1 Baseline 01SEP2016 SUP RIGHT 106.5/ 60.0 51.0 24 36.7

STD RIGHT 121.0/ 79.0 85.0

0.33 01SEP2016 SUP RIGHT 8.5/ 2.0 4.0

0.58 01SEP2016 SUP RIGHT 10.5/ 7.5 1.5

1.08 01SEP2016 SUP RIGHT 0.5/ 2.5 3.5

2.08 01SEP2016 SUP RIGHT 28.0/ 14.5 4.5

3.08 01SEP2016 SUP RIGHT 16.0/ 1.0 3.0

4.17 01SEP2016 SUP RIGHT 11.0/ 5.5 4.0 -8 0.5

STD RIGHT 18.0/ 3.0 8.0

6.08 01SEP2016 SUP RIGHT 14.0/ 1.0 11.5

8.08 01SEP2016 SUP RIGHT 17.5/ 2.5 6.0

12.17 01SEP2016 SUP RIGHT 15.0/ 5.0 9.0 -6 1.0

STD RIGHT 3.0/ -2.0 6.0

2 24.17 02SEP2016 SUP RIGHT 8.0/ 4.5 5.0 -4 0.2

STD RIGHT -13.0/-11.0 7.0

36.08 02SEP2016 SUP RIGHT 11.0/ 5.5 10.5 -6 0.0

3 48.08 03SEP2016 SUP RIGHT 10.0/ 7.0 5.0 -4 -0.1

4 72.08 04SEP2016 SUP RIGHT 24.0/ 7.5 13.0 -4 0.3

10 216.1 10SEP2016 SUP RIGHT 12.5/ -3.0 7.0 -6 0.2

216.3 10SEP2016 /

1008 1 1 1 Baseline 11SEP2016 SUP RIGHT 118.0/ 67.5 63.0 12 36.4

STD RIGHT 107.0/ 76.0 87.0

0.33 11SEP2016 SUP RIGHT -5.0/ -1.5 -2.0

0.58 11SEP2016 SUP RIGHT 1.5/ 1.0 4.5

1.08 11SEP2016 SUP RIGHT -4.0/ 2.0 4.5

2.08 11SEP2016 SUP RIGHT 1.5/ 7.5 -2.0

3.08 11SEP2016 SUP RIGHT 5.0/ 4.5 4.0

4.17 11SEP2016 SUP RIGHT 0.5/ 4.5 6.0 0 0.2

STD RIGHT 23.0/ 0.0 30.0

6.08 11SEP2016 SUP RIGHT -7.0/ -5.5 16.0

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 6 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1008 1 1 1 8.08 11SEP2016 SUP RIGHT -14.0/ -5.0 16.0

12.17 11SEP2016 SUP RIGHT -4.5/ -1.0 22.5 4 0.2

STD RIGHT 24.0/ 8.0 26.0

2 24.17 12SEP2016 SUP RIGHT -5.0/ 0.0 4.5 0 0.2

STD RIGHT 14.0/ 9.0 2.0

36.08 12SEP2016 SUP RIGHT -20.5/-10.0 16.0 2 0.7

3 48.08 13SEP2016 SUP RIGHT -5.5/ 0.0 2.0 0 0.3

4 72.08 14SEP2016 SUP RIGHT 4.0/ 3.5 5.0 8 0.2

1009 1 1 1 Baseline 01SEP2016 SUP RIGHT 115.5/ 64.5 59.5 16 36.4

STD RIGHT 117.0/ 72.0 83.0

0.33 01SEP2016 SUP RIGHT 10.5/ 6.0 -0.5

0.58 01SEP2016 SUP RIGHT 3.5/ 4.5 -0.5

1.08 01SEP2016 SUP RIGHT 9.0/ 4.5 1.5

2.08 01SEP2016 SUP RIGHT 5.5/ 3.5 0.5

3.08 01SEP2016 SUP RIGHT 1.0/ 9.0 -2.0

4.17 01SEP2016 SUP RIGHT -3.0/ 8.0 2.5 -4 0.0

STD RIGHT 4.0/ 0.0 15.0

6.08 01SEP2016 SUP RIGHT 1.0/ 1.5 24.0

8.08 01SEP2016 SUP RIGHT 3.5/ 4.0 15.0

12.17 01SEP2016 SUP RIGHT -1.5/ 4.5 7.5 -2 0.7

STD RIGHT 11.0/ 9.0 20.0

2 24.17 02SEP2016 SUP RIGHT -3.5/ 0.0 4.0 2 0.2

STD RIGHT -1.0/ 14.0 8.0

36.08 02SEP2016 SUP RIGHT -5.0/ 2.0 12.0 2 0.6

3 48.08 03SEP2016 SUP RIGHT -7.5/ 2.5 8.0 -4 0.5

4 72.08 04SEP2016 SUP RIGHT -3.0/ -1.0 4.5 0 0.0

10 216.1 10SEP2016 SUP RIGHT -3.0/ 4.5 -5.5 2 -0.4

216.3 10SEP2016 /

1010 1 1 1 Baseline 01SEP2016 SUP RIGHT 121.5/ 65.5 67.0 10 37.0

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 7 of 7

Table 1.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

1010 1 1 1 Baseline 01SEP2016 STD RIGHT 127.0/ 70.0 85.0

0.33 01SEP2016 SUP RIGHT -5.0/ -0.5 -2.5

0.58 01SEP2016 SUP RIGHT -11.5/ -2.0 -2.0

1.08 01SEP2016 SUP RIGHT -0.5/ 4.0 -3.0

2.08 01SEP2016 SUP RIGHT -8.5/ 2.0 -4.0

3.08 01SEP2016 SUP RIGHT -2.0/ -5.0 0.0

4.17 01SEP2016 SUP RIGHT -0.5/ 6.0 1.0 0 0.1

STD RIGHT -19.0/ 9.0 21.0

6.08 01SEP2016 SUP RIGHT -10.0/ 1.5 14.5

8.08 01SEP2016 SUP RIGHT -9.5/ -0.5 5.0

12.17 01SEP2016 SUP RIGHT -4.0/ 0.0 0.5 4 -0.1

STD RIGHT -2.0/ 8.0 8.0

2 24.17 02SEP2016 SUP RIGHT -3.5/ -2.0 -7.0 2 -0.4

STD RIGHT -7.0/ -2.0 9.0

36.08 02SEP2016 SUP RIGHT -7.5/ -4.5 -2.0 4 -0.4

3 48.08 03SEP2016 SUP RIGHT -10.0/ -3.0 0.0 8 -0.4

4 72.08 04SEP2016 SUP RIGHT -2.0/ 2.5 4.0 6 0.1

10 216.1 10SEP2016 SUP RIGHT -2.5/ 2.0 -1.0 10 -0.4

216.3 10SEP2016 /

Note: SUP = Supine, STD = Standing

Cohort 1 = 50 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 1 of 3

Table 1.6.3 Vital Signs - Supine Averages and Respective Orthostatic Changes

Average of Supine Standing Orthostatic Change@

Subject Study ------------------------ ------------------------ ---------------------------

Number Period Cohort Day Hour Systolic/Diastolic Pulse Systolic/Diastolic Pulse Systolic/Diastolic Pulse

--------------------------------------------------------------------------------------------------------------------

1001 Screen 1 122.0/77.0 60.0 132/ 89 66 -10.0 /-12.0 6.0

1 1 -3 -72.75 117.0/61.5 61.5 135/ 72 75 -18.0 /-10.5 13.5

1 -1.33 118.0/63.0 58.5 144/ 74 110 -26.0 /-11.0 51.5(#)

4.17 119.0/64.5 62.5 123/ 82 102 -4.0 /-17.5 39.5(#)

12.17 113.5/64.5 62.0 131/ 82 98 -17.5 /-17.5 36.0(#)

2 24.17 117.0/65.5 61.0 138/ 84 96 -21.0 /-18.5 35.0(#)

1002 Screen 1 114.0/66.5 54.5 118/ 79 69 -4.0 /-12.5 14.5

1 1 -3 -72.75 123.5/65.0 62.5 123/ 75 83 0.5 /-10.0 20.5

1 -1.33 118.5/63.5 60.5 133/ 73 81 -14.5 / -9.5 20.5

4.17 124.0/62.5 57.0 107/ 79 81 17.0 /-16.5 24.0

12.17 124.0/59.5 62.5 124/ 77 96 0.0 /-17.5 33.5(#)

2 24.17 124.0/67.0 62.0 121/ 75 99 3.0 / -8.0 37.0(#)

1003 Screen 1 113.5/60.0 53.0 113/ 73 55 0.5 /-13.0 2.0

1 1 -3 -72.75 109.0/62.5 50.0 121/ 75 56 -12.0 /-12.5 6.0

1 -1.33 103.5/64.5 46.5 119/ 77 68 -15.5 /-12.5 21.5

4.17 112.0/63.5 50.0 76/ 55 70 36.0(\*)/ 8.5 20.0

12.17 120.0/65.0 51.5 130/ 85 75 -10.0 /-20.0 23.5

2 24.17 123.0/71.5 49.5 126/ 74 73 -3.0 / -2.5 23.5

1004 Screen 1 119.5/72.0 86.0 119/ 84 102 0.5 /-12.0 16.0

1 1 -3 -72.75 124.0/76.5 82.5 128/ 88 97 -4.0 /-11.5 14.5

1 -1.33 114.0/71.0 68.5 113/ 73 96 1.0 / -2.0 27.5

4.17 111.5/71.0 86.0 95/ 39 121 16.5 / 32.0(^) 35.0(#)

12.17 123.5/74.0 87.0 121/ 77 126 2.5 / -3.0 39.0(#)

2 24.17 116.5/69.5 77.0 123/ 71 116 -6.5 / -1.5 39.0(#)

1005 Screen 1 110.5/56.5 57.0 106/ 60 75 4.5 / -3.5 18.0

Note: @ Change in pulse is calculated by subtracting supine measurement (averages) from standing measurement, and change in blood pressure

is calculated by subtracting standing measurement from supine measurement (averages).

\* = Systolic change is at least 20

^ = Diastolic change is at least 10

# = Pulse change is at least 30

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_orthostatic.sas 15SEP2016 18:57

Page 2 of 3

Table 1.6.3 Vital Signs - Supine Averages and Respective Orthostatic Changes

Average of Supine Standing Orthostatic Change@

Subject Study ------------------------ ------------------------ ---------------------------

Number Period Cohort Day Hour Systolic/Diastolic Pulse Systolic/Diastolic Pulse Systolic/Diastolic Pulse

--------------------------------------------------------------------------------------------------------------------

1005 1 1 -3 -72.75 113.0/58.0 70.5 116/ 66 74 -3.0 / -8.0 3.5

1 -1.33 122.0/64.5 65.0 123/ 57 91 -1.0 / 7.5 26.0

4.17 121.5/70.0 59.5 126/ 74 86 -4.5 / -4.0 26.5

12.17 112.5/56.0 69.5 110/ 85 98 2.5 /-29.0 28.5

2 24.17 111.0/57.5 62.0 120/ 68 107 -9.0 /-10.5 45.0(#)

1006 Screen 1 121.0/79.5 68.0 122/ 90 85 -1.0 /-10.5 17.0

1 1 -3 -72.75 114.5/78.0 58.5 134/ 96 84 -19.5 /-18.0 25.5

1 -1.33 108.0/72.5 56.0 116/ 87 78 -8.0 /-14.5 22.0

4.17 113.5/72.5 57.0 141/ 93 101 -27.5 /-20.5 44.0(#)

12.17 104.5/66.5 62.0 120/ 86 93 -15.5 /-19.5 31.0(#)

2 24.17 107.0/68.0 63.0 123/ 78 102 -16.0 /-10.0 39.0(#)

1007 Screen 1 105.0/63.0 52.0 112/ 74 78 -7.0 /-11.0 26.0

1 1 -3 -72.75 106.0/60.0 52.5 118/ 79 76 -12.0 /-19.0 23.5

1 -1.33 106.5/60.0 51.0 121/ 79 85 -14.5 /-19.0 34.0(#)

4.17 117.5/65.5 55.0 139/ 82 93 -21.5 /-16.5 38.0(#)

12.17 121.5/65.0 60.0 124/ 77 91 -2.5 /-12.0 31.0(#)

2 24.17 114.5/64.5 56.0 108/ 68 92 6.5 / -3.5 36.0(#)

1008 Screen 1 114.0/66.0 63.0 125/ 77 78 -11.0 /-11.0 15.0

1 1 -3 -72.70 123.0/75.0 67.5 125/ 79 84 -2.0 / -4.0 16.5

1 -1.33 118.0/67.5 63.0 107/ 76 87 11.0 / -8.5 24.0

4.17 118.5/72.0 69.0 130/ 76 117 -11.5 / -4.0 48.0(#)

12.17 113.5/66.5 85.5 131/ 84 113 -17.5 /-17.5 27.5

2 24.17 113.0/67.5 67.5 121/ 85 89 -8.0 /-17.5 21.5

1009 Screen 1 115.0/68.5 62.5 123/ 73 78 -8.0 / -4.5 15.5

1 1 -3 -72.75 109.0/71.0 57.5 118/ 83 68 -9.0 /-12.0 10.5

Note: @ Change in pulse is calculated by subtracting supine measurement (averages) from standing measurement, and change in blood pressure

is calculated by subtracting standing measurement from supine measurement (averages).

\* = Systolic change is at least 20

^ = Diastolic change is at least 10

# = Pulse change is at least 30

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_orthostatic.sas 15SEP2016 18:57

Page 3 of 3

Table 1.6.3 Vital Signs - Supine Averages and Respective Orthostatic Changes

Average of Supine Standing Orthostatic Change@

Subject Study ------------------------ ------------------------ ---------------------------

Number Period Cohort Day Hour Systolic/Diastolic Pulse Systolic/Diastolic Pulse Systolic/Diastolic Pulse

--------------------------------------------------------------------------------------------------------------------

1009 1 1 1 -1.33 115.5/64.5 59.5 117/ 72 83 -1.5 / -7.5 23.5

4.17 112.5/72.5 62.0 121/ 72 98 -8.5 / 0.5 36.0(#)

12.17 114.0/69.0 67.0 128/ 81 103 -14.0 /-12.0 36.0(#)

2 24.17 112.0/64.5 63.5 116/ 86 91 -4.0 /-21.5 27.5

1010 Screen 1 123.5/69.0 74.5 141/ 84 92 -17.5 /-15.0 17.5

1 1 -3 -72.75 110.0/63.0 67.5 136/ 75 76 -26.0 /-12.0 8.5

1 -1.33 121.5/65.5 67.0 127/ 70 85 -5.5 / -4.5 18.0

4.17 121.0/71.5 68.0 108/ 79 106 13.0 / -7.5 38.0(#)

12.17 117.5/65.5 67.5 125/ 78 93 -7.5 /-12.5 25.5

2 24.17 118.0/63.5 60.0 120/ 68 94 -2.0 / -4.5 34.0(#)

Note: @ Change in pulse is calculated by subtracting supine measurement (averages) from standing measurement, and change in blood pressure

is calculated by subtracting standing measurement from supine measurement (averages).

\* = Systolic change is at least 20

^ = Diastolic change is at least 10

# = Pulse change is at least 30

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_orthostatic.sas 15SEP2016 18:57

Page 1 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1001 Screen 1 M 1 0.00 16AUG2016 NO 12:28:19 NORMAL 54 126 100 430 415

0.02 16AUG2016 NO 12:29:28 NORMAL 54 130 98 426 411

0.03 16AUG2016 NO 12:30:32 NORMAL 58 130 98 422 417

1 1 M -3 -73.00 26AUG2016 NO 6:48:22 NORMAL 62 132 100 416 421

-72.98 26AUG2016 NO 6:49:25 NORMAL 61 132 100 418 420 SINUS ARRHYTHMIA

-72.97 26AUG2016 NO 6:50:27 NORMAL 57 130 102 416 409

1 -1.48 29AUG2016 NO 5:45:57 NORMAL 54 132 102 439 424

-1.47 29AUG2016 NO 5:46:59 NORMAL 58 131 102 434 429

-1.45 29AUG2016 NO 5:48:07 NORMAL 60 132 100 427 427

-0.98 29AUG2016 NO 6:16:02 NORMAL 54 130 102 436 421

-0.97 29AUG2016 NO 6:17:03 NORMAL 52 131 88 439 419

-0.95 29AUG2016 NO 6:18:01 NORMAL 55 131 101 439 426

-0.48 29AUG2016 YES 6:46:01 NORMAL 65 134 87 419 430

-0.47 29AUG2016 YES 6:48:07 NORMAL 82 131 84 392 435 d

-0.45 29AUG2016 YES 6:49:16 NORMAL 62 127 101 402 406

0.17 29AUG2016 YES 7:25:02 NORMAL 57 131 101 422 415

0.18 29AUG2016 YES 7:26:05 NORMAL 57 129 100 424 417 SINUS ARRHYTHMIA

0.20 29AUG2016 YES 7:27:08 NORMAL 63 129 101 419 426 SINUS ARRHYTHMIA

0.42 29AUG2016 YES 7:39:57 NORMAL 58 130 101 415 410

0.43 29AUG2016 YES 7:41:02 NORMAL 58 129 86 419 414

0.45 29AUG2016 YES 7:42:01 NORMAL 70 129 100 411 433 d

0.92 29AUG2016 YES 8:10:02 NORMAL 63 129 102 421 428

0.93 29AUG2016 YES 8:11:03 NORMAL 55 131 102 437 425

0.95 29AUG2016 YES 8:12:08 NORMAL 54 132 101 434 419

1.92 29AUG2016 YES 9:10:01 NORMAL 88 125 78 393 447 d

29AUG2016 NO 9:11:05 NORMAL 74 125 98 398 427 SINUS ARRHYTHMIA.

RECHECK DONE IN

ERROR

1.93 29AUG2016 YES 9:11:46 NORMAL 81 125 83 395 437 d SINUS ARRHYTHMIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 2 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1001 1 1 M 1 1.93 29AUG2016 NO 9:12:19 NORMAL 78 123 97 388 423 SINUS ARRHYTHMIA.

RECHECK DONE IN

ERROR

1.95 29AUG2016 YES 9:13:01 NORMAL 70 124 84 397 418 SINUS ARRHYTHMIA

2.92 29AUG2016 YES 10:10:01 NORMAL 64 125 100 410 419

2.93 29AUG2016 YES 10:11:01 NORMAL 59 129 97 404 402

2.95 29AUG2016 YES 10:12:01 NORMAL 61 129 83 409 411

3.92 29AUG2016 YES 11:10:03 NORMAL 67 124 85 404 419

3.93 29AUG2016 YES 11:11:03 NORMAL 61 127 82 408 410

3.95 29AUG2016 YES 11:12:03 NORMAL 63 126 82 407 414

5.92 29AUG2016 YES 13:10:02 NORMAL 65 126 83 392 403

5.93 29AUG2016 YES 13:11:02 NORMAL 65 127 82 395 406

5.95 29AUG2016 YES 13:12:01 NORMAL 63 127 82 400 407

7.92 29AUG2016 YES 15:10:01 NORMAL 60 124 82 406 406

7.93 29AUG2016 YES 15:11:11 NORMAL 64 129 81 398 407

7.95 29AUG2016 YES 15:12:05 NORMAL 58 130 79 403 398

11.92 29AUG2016 YES 19:10:02 NORMAL 63 127 80 405 412

11.93 29AUG2016 YES 19:10:34 NORMAL 65 127 81 403 414 SINUS ARRHYTHMIA

11.95 29AUG2016 YES 19:11:03 NORMAL 64 128 80 405 414

2 23.92 30AUG2016 YES 7:10:03 NORMAL 55 126 86 421 409

23.93 30AUG2016 YES 7:11:03 NORMAL 60 125 87 425 425 SINUS ARRHYTHMIA

23.95 30AUG2016 YES 7:11:52 NORMAL 56 127 101 423 413

36.17 30AUG2016 YES 19:26:32 NORMAL 65 126 84 398 409 SINUS ARRHYTHMIA

36.18 30AUG2016 YES 19:27:34 NORMAL 67 128 82 396 411

36.20 30AUG2016 YES 19:28:22 NORMAL 61 128 84 400 402 SINUS ARRHYTHMIA

3 48.17 31AUG2016 YES 7:25:01 NORMAL 61 130 100 420 422

48.18 31AUG2016 YES 7:26:01 NORMAL 59 130 100 420 418

48.20 31AUG2016 YES 7:27:01 NORMAL 59 130 100 422 420

4 72.17 01SEP2016 YES 7:25:00 NORMAL 70 128 100 406 427

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 3 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1001 1 1 M 4 72.18 01SEP2016 YES 7:26:09 NORMAL 60 130 100 412 412

72.20 01SEP2016 YES 7:27:11 NORMAL 58 128 100 418 413

10 215.92 07SEP2016 YES 7:10:00 NORMAL 56 132 102 428 418

215.93 07SEP2016 YES 7:11:11 NORMAL 57 130 108 430 423

215.95 07SEP2016 YES 7:12:01 NORMAL 57 132 104 428 421

1002 Screen 1 M 1 0.00 16AUG2016 NO 12:11:05 NORMAL 55 158 92 420 408

0.02 16AUG2016 NO 12:12:10 NORMAL 50 158 90 430 405

0.03 16AUG2016 NO 12:13:14 NORMAL 51 158 92 430 407

1 1 M -3 -73.00 26AUG2016 NO 6:17:58 NORMAL 64 158 92 400 409

-72.98 26AUG2016 NO 6:18:51 NORMAL 66 158 92 400 413

-72.97 26AUG2016 NO 6:19:47 NORMAL 65 160 90 400 411

1 -1.48 29AUG2016 NO 5:48:58 NORMAL 55 159 91 416 404

-1.47 29AUG2016 NO 5:49:58 NORMAL 65 153 90 408 419

-1.45 29AUG2016 NO 5:50:57 NORMAL 56 159 90 408 399

-0.98 29AUG2016 NO 6:18:59 NORMAL 57 157 90 411 404

-0.97 29AUG2016 NO 6:20:08 NORMAL 63 152 92 409 416

-0.95 29AUG2016 NO 6:21:25 NORMAL 63 153 91 409 416

-0.48 29AUG2016 YES 6:49:02 NORMAL 61 151 91 404 406

-0.47 29AUG2016 YES 6:50:04 NORMAL 63 152 91 407 414

-0.45 29AUG2016 YES 6:51:06 NORMAL 61 150 90 408 410

0.17 29AUG2016 YES 7:28:02 NORMAL 62 150 90 403 407

0.18 29AUG2016 YES 7:29:04 NORMAL 65 148 89 400 411

0.20 29AUG2016 YES 7:30:06 NORMAL 65 151 90 401 412

0.42 29AUG2016 YES 7:43:01 NORMAL 61 152 89 396 398

0.43 29AUG2016 YES 7:44:30 NORMAL 65 150 89 399 410

0.45 29AUG2016 YES 7:45:32 NORMAL 67 150 90 397 412

0.92 29AUG2016 YES 8:13:15 NORMAL 61 149 89 400 402

0.93 29AUG2016 YES 8:14:17 NORMAL 64 150 90 406 415

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 4 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1002 1 1 M 1 0.95 29AUG2016 YES 8:15:21 NORMAL 64 152 88 401 410

1.92 29AUG2016 YES 9:13:02 NORMAL 59 152 88 404 402

1.93 29AUG2016 YES 9:14:04 NORMAL 62 153 89 407 411

1.95 29AUG2016 YES 9:15:07 NORMAL 61 153 89 405 407

2.92 29AUG2016 YES 10:13:03 NORMAL 60 148 89 408 408

2.93 29AUG2016 YES 10:14:06 NORMAL 62 148 89 406 410

2.95 29AUG2016 YES 10:15:09 NORMAL 60 149 89 407 407

3.92 29AUG2016 YES 11:13:01 NORMAL 61 151 89 401 403

3.93 29AUG2016 YES 11:13:46 NORMAL 61 146 90 406 408

3.95 29AUG2016 YES 11:14:20 NORMAL 62 146 89 403 407

5.92 29AUG2016 YES 13:13:02 NORMAL 60 146 90 400 400

5.93 29AUG2016 YES 13:14:02 NORMAL 65 144 90 398 409

5.95 29AUG2016 YES 13:15:02 NORMAL 63 142 90 396 402 ARTIFACT

7.92 29AUG2016 YES 15:13:03 NORMAL 65 151 87 391 402

7.93 29AUG2016 YES 15:14:04 NORMAL 67 142 87 395 410

7.95 29AUG2016 YES 15:15:10 NORMAL 67 142 85 392 407

11.92 29AUG2016 YES 19:13:01 NORMAL 64 140 86 391 400

11.93 29AUG2016 YES 19:14:30 NORMAL 67 147 87 390 405

11.95 29AUG2016 YES 19:15:38 NORMAL 65 140 88 392 403

2 23.92 30AUG2016 YES 7:13:00 NORMAL 65 143 89 399 410

23.93 30AUG2016 YES 7:14:12 NORMAL 69 154 88 395 414

23.95 30AUG2016 YES 7:15:01 NORMAL 63 156 88 396 402

36.17 30AUG2016 YES 19:29:44 NORMAL 68 144 86 380 396

36.18 30AUG2016 YES 19:30:25 NORMAL 64 146 86 382 390

36.20 30AUG2016 YES 19:31:10 NORMAL 68 142 88 382 398

3 48.17 31AUG2016 YES 7:29:11 NORMAL 65 150 88 388 398

48.18 31AUG2016 YES 7:30:12 NORMAL 61 152 88 396 398

48.20 31AUG2016 YES 7:31:12 NORMAL 65 150 90 392 403

4 72.17 01SEP2016 YES 7:28:01 NORMAL 65 148 92 396 407

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 5 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1002 1 1 M 4 72.18 01SEP2016 YES 7:28:38 NORMAL 66 148 92 398 411

72.20 01SEP2016 YES 7:29:11 NORMAL 64 148 92 398 407

10 215.92 07SEP2016 YES 7:13:01 NORMAL 65 154 90 404 415

215.93 07SEP2016 YES 7:14:16 NORMAL 67 154 90 408 423

215.95 07SEP2016 YES 7:15:04 NORMAL 64 156 90 404 413

1003 Screen 1 M 1 0.00 18AUG2016 NO 9:55:17 NORMAL 52 156 92 440 420

0.02 18AUG2016 NO 9:56:18 NORMAL 52 156 96 440 420

0.03 18AUG2016 NO 9:57:20 NORMAL 56 158 92 438 428

1 1 M -3 -73.00 29AUG2016 NO 7:10:13 NORMAL 50 162 100 458 431 d

-72.98 29AUG2016 NO 7:11:15 NORMAL 51 162 100 460 436 d

-72.97 29AUG2016 NO 7:12:18 NORMAL 46 156 102 468 428 SINUS BRADYCARDIA

1 -1.48 01SEP2016 NO 6:31:10 NORMAL 45 175 100 466 423 SINUS BRADYCARDIA

-1.47 01SEP2016 NO 6:32:06 NORMAL 44 173 101 466 420 SINUS BRADYCARDIA

-1.45 01SEP2016 NO 6:32:59 NORMAL 45 160 100 472 429 SINUS BRADYCARDIA

-0.98 01SEP2016 NO 7:01:01 NORMAL 47 174 100 461 425 SINUS BRADYCARDIA

-0.97 01SEP2016 NO 7:02:12 NORMAL 46 174 100 462 423 SINUS BRADYCARDIA

-0.95 01SEP2016 NO 7:03:06 NORMAL 47 151 100 468 431 d SINUS BRADYCARDIA

-0.48 01SEP2016 YES 7:31:01 NORMAL 48 167 100 459 426 SINUS BRADYCARDIA

-0.47 01SEP2016 YES 7:31:58 NORMAL 50 174 100 457 430

-0.45 01SEP2016 YES 7:33:02 NORMAL 49 174 100 458 428 SINUS BRADYCARDIA

0.17 01SEP2016 YES 8:10:01 NORMAL 48 156 100 464 431 d SINUS BRADYCARDIA

0.18 01SEP2016 YES 8:10:53 NORMAL 47 149 100 470 433 d SINUS BRADYCARDIA

0.20 01SEP2016 YES 8:11:37 NORMAL 48 148 100 471 437 d SINUS BRADYCARDIA

0.42 01SEP2016 YES 8:25:00 NORMAL 52 156 100 456 435 d

0.43 01SEP2016 YES 8:25:35 NORMAL 49 173 100 454 424 SINUS BRADYCARDIA

0.45 01SEP2016 YES 8:26:05 NORMAL 48 173 100 462 429 SINUS BRADYCARDIA

0.92 01SEP2016 YES 8:55:01 NORMAL 47 173 100 464 428 SINUS BRADYCARDIA

0.93 01SEP2016 YES 8:55:32 NORMAL 46 174 100 459 420 SINUS BRADYCARDIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 6 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1003 1 1 M 1 0.95 01SEP2016 YES 8:55:59 NORMAL 47 172 101 458 422 SINUS BRADYCARDIA

1.92 01SEP2016 YES 9:55:01 NORMAL 47 176 99 457 421 SINUS BRADYCARDIA

1.93 01SEP2016 YES 9:55:36 NORMAL 48 176 99 461 428 SINUS BRADYCARDIA

1.95 01SEP2016 YES 9:56:16 NORMAL 49 175 99 464 434 d SINUS BRADYCARDIA

2.92 01SEP2016 YES 10:55:01 NORMAL 46 169 100 451 413 SINUS BRADYCARDIA

2.93 01SEP2016 YES 10:55:43 NORMAL 48 174 100 452 420 SINUS BRADYCARDIA

2.95 01SEP2016 YES 10:56:31 NORMAL 49 175 99 446 417 SINUS BRADYCARDIA

3.92 01SEP2016 YES 11:55:04 NORMAL 50 175 99 445 419

3.93 01SEP2016 YES 11:56:37 NORMAL 48 175 99 450 418 SINUS BRADYCARDIA

3.95 01SEP2016 YES 11:57:42 NORMAL 50 174 100 448 422

5.92 01SEP2016 YES 13:55:01 NORMAL 62 169 99 418 423

5.93 01SEP2016 YES 13:56:06 NORMAL 57 170 99 420 413

5.95 01SEP2016 YES 13:56:59 NORMAL 56 171 103 427 417

7.92 01SEP2016 YES 15:55:01 NORMAL 57 168 104 411 404

7.93 01SEP2016 YES 15:56:15 NORMAL 58 167 98 411 406

7.95 01SEP2016 YES 15:56:57 NORMAL 59 167 106 416 414

11.92 01SEP2016 YES 19:54:02 NORMAL 52 172 98 435 415

11.93 01SEP2016 YES 19:54:43 NORMAL 54 171 98 438 423

11.95 01SEP2016 YES 19:55:45 NORMAL 55 169 103 437 425

2 23.92 02SEP2016 YES 7:55:01 NORMAL 51 175 100 451 427

23.93 02SEP2016 YES 7:55:59 NORMAL 48 176 99 454 421 SINUS BRADYCARDIA

23.95 02SEP2016 YES 7:56:42 NORMAL 50 175 99 455 428

36.17 02SEP2016 YES 20:10:08 NORMAL 59 160 108 420 418

36.18 02SEP2016 YES 20:11:32 NORMAL 58 158 98 418 413

36.20 02SEP2016 YES 20:12:40 NORMAL 59 156 102 420 418

3 48.17 03SEP2016 YES 8:10:01 NORMAL 53 158 102 444 426

48.18 03SEP2016 YES 8:10:56 NORMAL 53 160 100 444 426

48.20 03SEP2016 YES 8:11:34 NORMAL 53 160 100 444 426

4 72.17 04SEP2016 YES 8:10:09 NORMAL 58 162 98 424 419

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 7 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1003 1 1 M 4 72.18 04SEP2016 YES 8:10:54 NORMAL 57 162 100 428 421

72.20 04SEP2016 YES 8:11:56 NORMAL 58 164 98 424 419

10 215.92 10SEP2016 YES 7:55:02 NORMAL 56 160 100 442 432 d

215.93 10SEP2016 YES 7:56:05 NORMAL 55 160 100 444 431 d

215.95 10SEP2016 YES 7:57:11 NORMAL 52 158 100 448 427

1004 Screen 1 M 1 0.00 18AUG2016 NO 13:00:32 NORMAL 86 134 104 346 390

0.02 18AUG2016 NO 13:01:33 ANCS 90 132 110 342 391 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

0.03 18AUG2016 NO 13:02:34 NORMAL 86 134 108 344 388

1 1 M -3 -73.00 29AUG2016 NO 7:39:29 NORMAL 74 140 108 358 384

-72.98 29AUG2016 NO 7:40:41 ANCS 87 138 110 352 398 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-72.97 29AUG2016 NO 7:41:31 NORMAL 80 146 106 352 387

29AUG2016 NO 7:42:48 NORMAL 82 142 104 346 384

1 -1.48 01SEP2016 NO 6:34:02 NORMAL 64 130 105 363 371

-1.47 01SEP2016 NO 6:34:48 NORMAL 66 129 104 368 380

-1.45 01SEP2016 NO 6:35:25 NORMAL 67 128 107 368 382

-0.98 01SEP2016 NO 7:04:01 NORMAL 69 132 103 359 376

-0.97 01SEP2016 NO 7:04:34 NORMAL 69 130 106 364 381

-0.95 01SEP2016 NO 7:05:09 NORMAL 71 130 104 361 382

-0.48 01SEP2016 YES 7:34:03 NORMAL 67 128 104 370 384

-0.47 01SEP2016 YES 7:34:51 NORMAL 65 128 106 368 378

-0.45 01SEP2016 YES 7:35:29 NORMAL 67 128 104 372 386

0.17 01SEP2016 YES 8:13:02 NORMAL 79 131 105 355 389

0.18 01SEP2016 YES 8:13:50 NORMAL 78 131 104 356 389

0.20 01SEP2016 YES 8:14:44 NORMAL 83 130 104 349 389

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 8 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1004 1 1 M 1 0.42 01SEP2016 YES 8:28:02 NORMAL 72 130 106 350 372

0.43 01SEP2016 YES 8:28:39 NORMAL 68 131 103 355 370

0.45 01SEP2016 YES 8:29:22 NORMAL 74 131 103 354 380

0.92 01SEP2016 YES 8:58:01 NORMAL 71 127 106 361 382

0.93 01SEP2016 YES 8:58:48 NORMAL 71 133 104 364 385

0.95 01SEP2016 YES 8:59:26 NORMAL 69 132 104 362 379

1.92 01SEP2016 YES 9:58:01 NORMAL 86 131 104 335 378

1.93 01SEP2016 YES 9:59:13 NORMAL 82 130 103 335 372

1.95 01SEP2016 YES 10:00:08 NORMAL 85 134 102 337 378

2.92 01SEP2016 YES 10:58:05 ANCS 111 124 102 322 395 SINUS TACHYCARDIA;

SINUS ARRHYTHMIA

2.93 01SEP2016 YES 10:58:32 NORMAL 83 130 105 335 373

2.95 01SEP2016 YES 10:58:59 NORMAL 81 133 104 335 370

3.92 01SEP2016 YES 11:58:01 NORMAL 81 132 103 342 378

3.93 01SEP2016 YES 11:59:06 NORMAL 94 130 103 334 388

3.95 01SEP2016 YES 12:00:58 NORMAL 92 131 103 333 384

5.92 01SEP2016 YES 13:57:01 NORMAL 91 128 104 325 373

5.93 01SEP2016 YES 13:57:52 NORMAL 94 129 106 331 384

5.95 01SEP2016 YES 13:58:24 NORMAL 91 129 105 328 377

7.92 01SEP2016 YES 15:58:03 NORMAL 100 124 102 322 382

7.93 01SEP2016 YES 15:58:38 NORMAL 91 127 103 331 380

7.95 01SEP2016 YES 15:59:07 NORMAL 87 127 105 329 372

11.92 01SEP2016 YES 19:58:05 NORMAL 90 128 103 327 374

11.93 01SEP2016 YES 19:58:46 NORMAL 91 126 102 328 377

11.95 01SEP2016 YES 19:59:29 NORMAL 94 125 100 327 380

2 23.92 02SEP2016 YES 7:58:01 NORMAL 69 129 103 362 379

23.93 02SEP2016 YES 7:58:56 NORMAL 70 129 105 366 385

23.95 02SEP2016 YES 7:59:47 NORMAL 72 128 102 364 387

36.17 02SEP2016 YES 22:40:02 NORMAL 86 138 102 338 381

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 9 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1004 1 1 M 2 36.18 02SEP2016 YES 22:41:32 NORMAL 85 138 102 342 384

36.20 02SEP2016 YES 22:42:21 NORMAL 85 140 104 342 384

3 48.17 03SEP2016 YES 12:04:02 NORMAL 90 132 104 322 369

48.18 03SEP2016 YES 12:04:58 NORMAL 91 132 102 324 372

48.20 03SEP2016 YES 12:06:04 NORMAL 100 132 104 320 379

4 72.17 04SEP2016 YES 8:13:01 NORMAL 82 134 104 340 377

72.18 04SEP2016 YES 8:13:40 NORMAL 83 134 106 340 379

72.20 04SEP2016 YES 8:15:21 NORMAL 88 136 106 336 382

10 215.92 10SEP2016 YES 8:13:04 ANCS 71 122 112 362 383 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

215.93 10SEP2016 YES 8:14:10 ANCS 72 124 110 362 385 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

215.95 10SEP2016 YES 8:14:51 NORMAL 72 128 110 364 387

1005 Screen 1 F 1 0.00 26AUG2016 NO 11:55:09 NORMAL 65 144 82 398 409

0.02 26AUG2016 NO 11:56:11 NORMAL 65 140 84 400 411

0.03 26AUG2016 NO 11:57:13 NORMAL 65 142 82 400 411

1 1 F -3 -73.00 29AUG2016 NO 8:07:07 NORMAL 70 140 92 400 421

-72.98 29AUG2016 NO 8:08:10 NORMAL 70 136 86 402 423

-72.97 29AUG2016 NO 8:09:13 NORMAL 70 138 88 400 421

1 -1.48 01SEP2016 NO 6:37:02 NORMAL 59 147 83 412 410

-1.47 01SEP2016 NO 6:37:53 NORMAL 61 139 83 421 423

-1.45 01SEP2016 NO 6:38:46 NORMAL 58 153 82 424 419

-0.98 01SEP2016 NO 7:07:04 NORMAL 61 140 89 416 418

-0.97 01SEP2016 NO 7:07:56 NORMAL 58 140 88 413 408

-0.95 01SEP2016 NO 7:08:39 NORMAL 59 141 91 422 420

-0.48 01SEP2016 YES 7:37:01 NORMAL 57 145 81 420 413

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 10 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1005 1 1 F 1 -0.47 01SEP2016 YES 7:38:05 NORMAL 63 141 83 419 426

-0.45 01SEP2016 YES 7:39:07 NORMAL 61 149 82 419 421

0.17 01SEP2016 YES 8:16:01 NORMAL 58 138 82 414 409

0.18 01SEP2016 YES 8:16:46 NORMAL 58 136 81 413 408

0.20 01SEP2016 YES 8:17:24 NORMAL 59 139 79 412 410

0.42 01SEP2016 YES 8:31:03 NORMAL 64 142 82 412 421

0.43 01SEP2016 YES 8:31:37 NORMAL 64 139 83 410 419

0.45 01SEP2016 YES 8:32:08 NORMAL 67 141 82 403 418

0.92 01SEP2016 YES 9:01:01 NORMAL 58 140 79 401 396

0.93 01SEP2016 YES 9:01:29 NORMAL 58 142 79 414 409

0.95 01SEP2016 YES 9:01:54 NORMAL 59 137 82 419 417

1.92 01SEP2016 YES 10:01:01 NORMAL 71 138 82 404 427

1.93 01SEP2016 YES 10:01:41 NORMAL 65 146 84 399 410

1.95 01SEP2016 YES 10:02:25 NORMAL 63 140 85 406 413

2.92 01SEP2016 YES 11:01:01 NORMAL 65 138 85 400 411

2.93 01SEP2016 YES 11:01:43 NORMAL 59 141 84 407 405

2.95 01SEP2016 YES 11:02:18 NORMAL 63 137 83 407 414

3.92 01SEP2016 YES 12:01:02 NORMAL 58 137 84 415 410

3.93 01SEP2016 YES 12:02:16 NORMAL 59 137 83 418 416

3.95 01SEP2016 YES 12:03:17 NORMAL 54 137 84 424 409

5.92 01SEP2016 YES 14:01:02 NORMAL 74 135 85 380 408

5.93 01SEP2016 YES 14:02:05 NORMAL 82 130 82 375 416

5.95 01SEP2016 YES 14:02:57 NORMAL 68 127 83 378 394

7.92 01SEP2016 YES 16:01:01 NORMAL 74 136 81 380 408

7.93 01SEP2016 YES 16:01:38 NORMAL 74 130 80 378 405

7.95 01SEP2016 YES 16:02:15 NORMAL 76 133 82 382 413

11.92 01SEP2016 YES 20:01:02 NORMAL 69 128 86 384 402

11.93 01SEP2016 YES 20:01:35 NORMAL 71 129 84 389 411

11.95 01SEP2016 YES 20:02:23 NORMAL 73 128 84 386 412

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 11 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1005 1 1 F 2 23.92 02SEP2016 YES 8:01:09 NORMAL 64 137 81 404 413

23.93 02SEP2016 YES 8:03:06 NORMAL 62 136 83 413 418

23.95 02SEP2016 YES 8:03:53 NORMAL 70 141 82 397 418

36.17 02SEP2016 YES 20:17:08 NORMAL 80 134 92 380 418

02SEP2016 NO 20:18:24 NORMAL 75 130 82 374 403 RECHECK DONE IN

ERROR

36.18 02SEP2016 YES 20:19:11 NORMAL 78 130 84 372 406

36.20 02SEP2016 YES 20:19:51 NORMAL 77 130 84 372 404

3 48.17 03SEP2016 YES 8:19:09 NORMAL 68 142 82 408 425

48.18 03SEP2016 YES 8:19:48 NORMAL 65 138 84 408 419

48.20 03SEP2016 YES 8:20:29 NORMAL 67 142 80 402 417

4 72.17 04SEP2016 YES 8:16:09 NORMAL 63 134 90 396 402

72.18 04SEP2016 YES 8:17:12 NORMAL 67 134 86 396 411

72.20 04SEP2016 YES 8:17:58 NORMAL 63 138 86 396 402

10 215.92 10SEP2016 YES 7:55:30 NORMAL 69 140 88 400 419

215.93 10SEP2016 YES 7:56:46 NORMAL 69 142 84 394 413

215.95 10SEP2016 YES 7:58:00 NORMAL 70 140 88 396 417

1006 Screen 1 F 1 0.00 18AUG2016 NO 11:27:17 ANCS 59 132 96 406 404 PREMATURE ATRIAL

COMPLEXES

0.02 18AUG2016 NO 11:28:56 NORMAL 62 130 96 406 410

0.03 18AUG2016 NO 11:30:00 NORMAL 63 126 100 406 413

1 1 F -3 -73.00 29AUG2016 NO 7:40:02 NORMAL 59 136 106 406 404

-72.98 29AUG2016 NO 7:41:05 NORMAL 65 132 100 408 419

-72.97 29AUG2016 NO 7:42:07 NORMAL 63 138 96 402 409

1 -1.48 01SEP2016 NO 6:40:04 NORMAL 56 142 105 440 430

-1.47 01SEP2016 NO 6:40:43 ANCS 55 142 117 437 425 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 12 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1006 1 1 F 1 -1.45 01SEP2016 NO 6:41:12 ANCS 56 145 117 433 423

-0.98 01SEP2016 NO 7:10:01 ANCS 56 139 119 434 424 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-0.97 01SEP2016 NO 7:10:50 ANCS 54 144 117 441 426 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-0.95 01SEP2016 NO 7:11:45 ANCS 55 137 118 443 430 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-0.48 01SEP2016 YES 7:40:03 ANCS 53 144 115 439 421 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-0.47 01SEP2016 YES 7:40:39 ANCS 57 142 116 442 435 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-0.45 01SEP2016 YES 7:41:15 ANCS 55 139 117 444 431 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

0.17 01SEP2016 YES 8:19:04 NORMAL 57 131 104 437 430

0.18 01SEP2016 YES 8:20:00 NORMAL 58 132 104 438 433

0.20 01SEP2016 YES 8:20:57 ANCS 58 130 111 432 427 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

0.42 01SEP2016 YES 8:34:02 ANCS 63 138 114 432 439 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

0.43 01SEP2016 YES 8:34:34 NORMAL 58 133 106 432 427 SINUS ARRHYTHMIA

0.45 01SEP2016 YES 8:35:08 NORMAL 60 132 106 435 435

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 13 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1006 1 1 F 1 0.92 01SEP2016 YES 9:03:59 ANCS 57 132 116 436 429 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

0.93 01SEP2016 YES 9:04:39 NORMAL 55 146 95 435 423

0.95 01SEP2016 YES 9:05:13 ANCS 57 140 116 438 431 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

1.92 01SEP2016 YES 10:04:01 NORMAL 55 141 103 439 426

1.93 01SEP2016 YES 10:04:50 NORMAL 54 142 98 437 422

1.95 01SEP2016 YES 10:05:50 NORMAL 56 139 101 441 431

2.92 01SEP2016 YES 11:04:03 NORMAL 59 127 100 427 425

2.93 01SEP2016 YES 11:04:34 NORMAL 60 120 100 425 425

2.95 01SEP2016 YES 11:05:07 ANCS 59 132 112 427 425 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

3.92 01SEP2016 YES 12:04:02 NORMAL 57 141 97 430 423

3.93 01SEP2016 YES 12:04:58 NORMAL 61 138 104 434 436

3.95 01SEP2016 YES 12:05:51 NORMAL 64 139 106 427 436

5.92 01SEP2016 YES 14:03:01 NORMAL 68 127 105 396 413

5.93 01SEP2016 YES 14:03:50 NORMAL 73 126 107 388 414

5.95 01SEP2016 YES 14:04:35 NORMAL 73 120 103 392 418

7.92 01SEP2016 YES 16:04:01 ANCS 71 121 115 402 425 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

7.93 01SEP2016 YES 16:04:32 ANCS 61 121 113 407 409 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 14 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1006 1 1 F 1 7.95 01SEP2016 YES 16:05:01 ANCS 65 122 115 411 422 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

11.92 01SEP2016 YES 20:04:14 NORMAL 59 137 103 413 411

11.93 01SEP2016 YES 20:04:52 NORMAL 62 134 106 419 424

11.95 01SEP2016 YES 20:05:28 NORMAL 63 134 105 421 428

2 23.92 02SEP2016 YES 8:04:01 ANCS 67 136 113 416 432 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

23.93 02SEP2016 YES 8:04:52 ANCS 62 146 113 420 425 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

23.95 02SEP2016 YES 8:05:43 ANCS 61 144 111 426 428

36.17 02SEP2016 YES 20:20:25 NORMAL 70 132 100 398 419

36.18 02SEP2016 YES 20:21:12 NORMAL 71 136 96 402 425

36.20 02SEP2016 YES 20:22:04 NORMAL 65 134 106 400 411

3 48.17 03SEP2016 YES 12:10:54 ANCS 65 136 110 412 423 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

48.18 03SEP2016 YES 12:11:59 NORMAL 66 138 106 412 425

48.20 03SEP2016 YES 12:13:06 NORMAL 69 130 106 410 430

4 72.17 04SEP2016 YES 8:19:06 NORMAL 65 136 106 410 421

72.18 04SEP2016 YES 8:19:37 NORMAL 67 140 108 412 427

72.20 04SEP2016 YES 8:20:08 NORMAL 66 140 98 412 425

10 215.92 10SEP2016 YES 8:00:40 NORMAL 59 142 98 420 418

215.93 10SEP2016 YES 8:01:20 NORMAL 59 136 98 414 412

215.95 10SEP2016 YES 8:01:57 NORMAL 59 136 94 414 412

1007 Screen 1 M 1 0.00 28AUG2016 NO 8:22:23 NORMAL 53 150 96 434 416

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 15 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1007 Screen 1 M 1 0.02 28AUG2016 NO 8:23:25 NORMAL 55 146 98 434 422

0.03 28AUG2016 NO 8:24:27 NORMAL 54 150 92 430 415

1 1 M -3 -73.00 29AUG2016 NO 7:23:35 NORMAL 53 150 96 432 415

-72.98 29AUG2016 NO 7:24:37 NORMAL 55 152 98 434 422

-72.97 29AUG2016 NO 7:25:38 NORMAL 60 146 98 428 428

1 -1.48 01SEP2016 NO 6:43:05 NORMAL 50 134 98 435 409

-1.47 01SEP2016 NO 6:43:53 NORMAL 50 133 91 436 410

-1.45 01SEP2016 NO 6:44:44 NORMAL 53 131 87 434 416

-0.98 01SEP2016 NO 7:13:01 NORMAL 49 129 100 435 407 SINUS BRADYCARDIA

-0.97 01SEP2016 NO 7:13:41 NORMAL 52 131 87 433 413

-0.95 01SEP2016 NO 7:14:24 NORMAL 53 132 97 427 410

-0.48 01SEP2016 NO 7:43:01 NORMAL 49 138 89 433 405 SINUS BRADYCARDIA

-0.47 01SEP2016 YES 7:44:01 NORMAL 52 131 89 428 408

-0.45 01SEP2016 YES 7:45:04 NORMAL 50 136 89 437 411

01SEP2016 YES 7:45:50 NORMAL 54 130 97 432 417 ECG TAKEN IN ERROR

0.17 01SEP2016 YES 8:22:03 NORMAL 48 132 96 437 406 SINUS BRADYCARDIA

0.18 01SEP2016 YES 8:22:52 NORMAL 54 124 100 433 418

0.20 01SEP2016 YES 8:23:36 NORMAL 56 121 100 434 424

0.42 01SEP2016 YES 8:37:49 NORMAL 55 121 101 426 414

0.43 01SEP2016 YES 8:38:23 NORMAL 50 129 96 427 402

0.45 01SEP2016 YES 8:38:50 NORMAL 54 127 99 426 411

0.92 01SEP2016 YES 9:07:01 NORMAL 50 138 99 432 407

0.93 01SEP2016 YES 9:07:33 NORMAL 51 137 97 431 408

0.95 01SEP2016 YES 9:08:03 NORMAL 51 134 98 429 406

1.92 01SEP2016 YES 10:07:01 NORMAL 56 127 99 416 407

1.93 01SEP2016 YES 10:07:52 NORMAL 55 131 99 405 393

1.95 01SEP2016 YES 10:08:46 NORMAL 55 141 95 404 392

2.92 01SEP2016 YES 11:07:01 NORMAL 57 136 98 405 398

2.93 01SEP2016 YES 11:07:41 NORMAL 57 120 99 409 402

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 16 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1007 1 1 M 1 2.95 01SEP2016 YES 11:08:20 NORMAL 81 132 101 401 443 d

3.92 01SEP2016 YES 12:07:02 NORMAL 59 132 100 419 417

3.93 01SEP2016 YES 12:08:18 NORMAL 53 127 100 426 409

3.95 01SEP2016 YES 12:09:31 NORMAL 56 120 100 420 410

5.92 01SEP2016 YES 14:07:02 NORMAL 61 133 100 391 393

5.93 01SEP2016 YES 14:08:06 NORMAL 62 133 100 394 398

5.95 01SEP2016 YES 14:08:59 NORMAL 65 133 98 386 396

7.92 01SEP2016 YES 16:07:01 NORMAL 63 130 100 387 393

7.93 01SEP2016 YES 16:07:46 NORMAL 64 131 100 389 397

7.95 01SEP2016 YES 16:08:29 NORMAL 64 131 100 394 403

11.92 01SEP2016 YES 20:07:02 NORMAL 60 115 102 415 415

11.93 01SEP2016 YES 20:07:44 NORMAL 58 121 99 414 409

11.95 01SEP2016 YES 20:08:30 NORMAL 60 136 95 413 413

2 23.92 02SEP2016 YES 8:07:01 NORMAL 54 117 87 403 389

23.93 02SEP2016 YES 8:07:55 NORMAL 55 111 86 413 401

23.95 02SEP2016 YES 8:08:43 NORMAL 55 110 87 420 408

36.17 02SEP2016 YES 20:23:24 NORMAL 60 146 90 406 406

36.18 02SEP2016 YES 20:24:10 NORMAL 60 148 90 408 408

36.20 02SEP2016 YES 20:24:56 NORMAL 70 148 98 406 427

3 48.17 03SEP2016 YES 8:26:05 NORMAL 59 144 96 424 422

48.18 03SEP2016 YES 8:26:43 NORMAL 63 146 100 428 435 d

48.20 03SEP2016 YES 8:27:24 NORMAL 61 142 104 432 434 d

4 72.17 04SEP2016 YES 8:22:01 NORMAL 66 142 102 420 434 d

72.18 04SEP2016 YES 8:22:41 NORMAL 60 146 100 424 424

72.20 04SEP2016 YES 8:23:20 NORMAL 63 146 94 422 429

10 215.92 10SEP2016 YES 8:09:07 NORMAL 51 148 96 436 413

215.93 10SEP2016 YES 8:09:53 NORMAL 52 156 90 438 418

215.95 10SEP2016 YES 8:10:28 NORMAL 53 148 94 442 424

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 17 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1008 Screen 1 F 1 0.00 16AUG2016 NO 11:29:31 NORMAL 71 134 86 378 400

0.02 16AUG2016 NO 11:30:35 NORMAL 70 134 84 378 398

0.03 16AUG2016 NO 11:31:34 NORMAL 67 132 88 384 398

1 1 F -3 -72.95 08SEP2016 NO 6:40:51 NORMAL 63 134 88 400 407

-72.93 08SEP2016 NO 6:41:32 NORMAL 70 136 94 394 415

-72.92 08SEP2016 NO 6:42:09 NORMAL 67 138 86 388 403

1 -1.48 11SEP2016 NO 5:42:59 NORMAL 63 134 98 406 413

-1.47 11SEP2016 NO 5:44:00 NORMAL 63 133 79 408 415

-1.45 11SEP2016 NO 5:45:00 NORMAL 61 135 97 401 403

-0.98 11SEP2016 NO 6:13:12 NORMAL 57 134 97 426 419

-0.97 11SEP2016 NO 6:14:14 NORMAL 59 133 97 424 422

-0.95 11SEP2016 NO 6:15:19 NORMAL 62 137 96 416 421

-0.48 11SEP2016 YES 6:43:57 NORMAL 74 140 97 406 435

-0.47 11SEP2016 YES 6:45:30 NORMAL 74 136 80 396 425

-0.45 11SEP2016 YES 6:46:27 NORMAL 67 139 92 398 413

0.17 11SEP2016 YES 7:22:01 NORMAL 66 131 95 408 421

0.18 11SEP2016 YES 7:22:44 NORMAL 59 129 96 414 412

0.20 11SEP2016 YES 7:23:25 NORMAL 63 127 80 417 424

0.42 11SEP2016 YES 7:37:01 NORMAL 57 130 77 409 402

0.43 11SEP2016 YES 7:38:11 NORMAL 66 130 77 406 419

0.45 11SEP2016 YES 7:39:12 NORMAL 62 131 96 407 411

0.92 11SEP2016 YES 8:07:00 NORMAL 63 129 95 404 411

0.93 11SEP2016 YES 8:07:45 NORMAL 68 127 97 403 420

0.95 11SEP2016 YES 8:08:19 NORMAL 65 127 81 410 421

1.92 11SEP2016 YES 9:07:00 NORMAL 57 130 81 415 408

1.93 11SEP2016 YES 9:08:14 NORMAL 65 131 80 408 419

1.95 11SEP2016 YES 9:08:44 NORMAL 63 131 80 408 415

2.92 11SEP2016 YES 10:07:01 NORMAL 66 129 79 394 407

2.93 11SEP2016 YES 10:07:53 NORMAL 58 128 96 402 397

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 18 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1008 1 1 F 1 2.95 11SEP2016 YES 10:08:46 NORMAL 71 121 79 396 419

3.92 11SEP2016 YES 11:07:00 NORMAL 65 131 80 392 403

3.93 11SEP2016 YES 11:07:42 NORMAL 69 128 80 398 417

3.95 11SEP2016 YES 11:08:20 NORMAL 59 129 80 410 408

5.92 11SEP2016 YES 13:07:04 NORMAL 92 120 78 349 402

5.93 11SEP2016 YES 13:07:58 NORMAL 78 128 86 353 385

5.95 11SEP2016 YES 13:08:49 NORMAL 79 127 78 367 402

7.92 11SEP2016 YES 15:07:01 NORMAL 87 119 89 356 403

7.93 11SEP2016 YES 15:07:45 NORMAL 87 117 88 355 402

7.95 11SEP2016 YES 15:08:38 NORMAL 76 127 87 366 396

11.92 11SEP2016 YES 19:09:27 NORMAL 88 122 87 353 401

11.93 11SEP2016 YES 19:10:06 NORMAL 86 122 88 357 403

11.95 11SEP2016 YES 19:10:44 NORMAL 83 120 87 358 399

2 23.92 12SEP2016 NO 7:07:01 NORMAL 62 130 98 409 413 INCOMPLETE

TRIPLICATE

12SEP2016 YES 7:17:40 NORMAL 66 130 80 399 412

23.93 12SEP2016 NO 7:07:41 NORMAL 61 132 80 411 413 INCOMPLETE

TRIPLICATE

12SEP2016 YES 7:18:10 NORMAL 68 130 80 400 417

23.95 12SEP2016 YES 7:18:39 NORMAL 67 130 96 401 416

36.17 12SEP2016 YES 19:22:01 NORMAL 82 130 88 364 404

36.18 12SEP2016 YES 19:22:38 NORMAL 82 126 88 362 402

36.20 12SEP2016 YES 19:23:06 NORMAL 79 130 86 364 399

3 48.17 13SEP2016 YES 7:22:00 NORMAL 67 134 92 406 421

48.18 13SEP2016 YES 7:23:28 NORMAL 59 134 94 416 414

48.20 13SEP2016 YES 7:24:27 NORMAL 60 134 92 412 412

1009 Screen 1 M 1 0.00 24AUG2016 NO 9:26:31 NORMAL 61 142 96 406 408

0.02 24AUG2016 NO 9:27:33 NORMAL 60 138 100 408 408

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 19 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1009 Screen 1 M 1 0.03 24AUG2016 NO 9:28:35 NORMAL 65 148 96 402 413

1 1 M -3 -73.00 29AUG2016 NO 7:10:01 NORMAL 59 146 100 414 412

-72.98 29AUG2016 NO 7:10:39 NORMAL 57 140 102 420 413

-72.97 29AUG2016 NO 7:11:13 NORMAL 56 142 104 424 414

1 -1.48 01SEP2016 NO 6:49:03 NORMAL 61 154 103 410 412

-1.47 01SEP2016 NO 6:49:40 NORMAL 57 156 99 407 400

-1.45 01SEP2016 NO 6:50:13 NORMAL 60 155 101 409 409

-0.98 01SEP2016 NO 7:16:01 NORMAL 57 152 102 413 406

-0.97 01SEP2016 NO 7:17:57 NORMAL 58 156 101 412 407

-0.95 01SEP2016 NO 7:19:00 NORMAL 61 157 101 408 410

-0.48 01SEP2016 YES 7:46:02 NORMAL 65 156 102 405 416

-0.47 01SEP2016 YES 7:46:36 NORMAL 55 152 98 408 396

-0.45 01SEP2016 YES 7:47:46 NORMAL 62 157 100 407 411

0.17 01SEP2016 YES 8:28:02 NORMAL 57 151 103 409 402

0.18 01SEP2016 YES 8:28:57 NORMAL 57 150 100 411 404

0.20 01SEP2016 YES 8:29:40 NORMAL 59 155 100 409 407

0.42 01SEP2016 YES 8:43:02 NORMAL 64 156 100 401 410

0.43 01SEP2016 YES 8:43:45 NORMAL 65 156 100 396 407

0.45 01SEP2016 YES 8:44:17 NORMAL 59 152 102 403 401

0.92 01SEP2016 YES 9:13:08 NORMAL 56 154 101 412 403

0.93 01SEP2016 YES 9:13:50 NORMAL 57 150 101 413 406

0.95 01SEP2016 YES 9:14:26 NORMAL 57 150 100 412 405

1.92 01SEP2016 YES 10:13:01 NORMAL 64 153 100 407 416

1.93 01SEP2016 YES 10:13:47 NORMAL 59 154 99 401 399

1.95 01SEP2016 YES 10:14:39 NORMAL 60 155 100 410 410

2.92 01SEP2016 YES 11:13:03 NORMAL 61 150 100 401 403

2.93 01SEP2016 YES 11:13:34 NORMAL 65 155 100 394 405

2.95 01SEP2016 YES 11:14:02 NORMAL 65 154 100 394 405

3.92 01SEP2016 YES 12:13:01 NORMAL 61 153 100 397 399

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 20 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1009 1 1 M 1 3.93 01SEP2016 YES 12:14:09 NORMAL 65 153 100 393 404

3.95 01SEP2016 YES 12:15:15 NORMAL 63 151 101 398 405

5.92 01SEP2016 YES 14:12:01 NORMAL 80 144 102 357 393

5.93 01SEP2016 YES 14:12:45 NORMAL 81 143 103 357 395

5.95 01SEP2016 YES 14:13:13 NORMAL 85 143 102 355 399

7.92 01SEP2016 YES 16:13:01 NORMAL 77 141 102 363 394

7.93 01SEP2016 YES 16:13:34 NORMAL 77 142 102 366 398

7.95 01SEP2016 YES 16:14:18 NORMAL 79 144 102 365 400

11.92 01SEP2016 YES 20:13:01 NORMAL 73 145 102 381 407

11.93 01SEP2016 YES 20:13:43 NORMAL 72 145 102 379 403

11.95 01SEP2016 YES 20:14:21 NORMAL 71 145 101 378 400

2 23.92 02SEP2016 YES 8:13:01 NORMAL 74 142 88 396 425

23.93 02SEP2016 YES 8:13:57 NORMAL 69 149 100 385 403

23.95 02SEP2016 YES 8:14:47 NORMAL 70 147 101 390 411

36.17 02SEP2016 YES 20:28:28 NORMAL 69 148 102 376 394

36.18 02SEP2016 YES 20:29:16 NORMAL 71 148 100 378 400

36.20 02SEP2016 YES 20:29:58 NORMAL 71 148 102 378 400

3 48.17 03SEP2016 YES 8:28:03 NORMAL 66 152 102 396 409

48.18 03SEP2016 YES 8:28:49 NORMAL 65 150 102 398 409

48.20 03SEP2016 YES 8:29:30 NORMAL 66 150 102 402 415

4 72.17 04SEP2016 YES 8:28:56 NORMAL 64 152 100 390 398

72.18 04SEP2016 YES 8:29:30 NORMAL 64 152 100 394 403

72.20 04SEP2016 YES 8:30:00 NORMAL 65 152 98 396 407

10 215.92 10SEP2016 YES 8:02:41 NORMAL 54 144 102 416 402

215.93 10SEP2016 YES 8:03:36 NORMAL 53 144 102 420 403

215.95 10SEP2016 YES 8:04:13 NORMAL 60 150 102 414 414

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 21 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1010 Screen 1 M 1 0.00 28AUG2016 NO 8:14:42 ANCS 74 154 110 376 403 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

0.02 28AUG2016 NO 8:15:45 NORMAL 71 156 108 380 402

0.03 28AUG2016 NO 8:17:33 ANCS 63 154 110 382 388 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

1 1 M -3 -73.00 29AUG2016 NO 7:15:07 ANCS 71 158 110 382 404 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-72.98 29AUG2016 NO 7:16:16 ANCS 68 156 112 382 398 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

-72.97 29AUG2016 NO 7:17:16 ANCS 70 156 110 380 400 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

1 -1.48 01SEP2016 NO 6:52:02 NORMAL 61 155 106 386 388

-1.47 01SEP2016 NO 6:52:49 NORMAL 59 154 105 391 389

-1.45 01SEP2016 NO 6:53:33 NORMAL 65 155 107 392 403

-0.98 01SEP2016 NO 7:22:01 NORMAL 59 153 106 396 394

-0.97 01SEP2016 NO 7:22:39 NORMAL 62 155 105 389 393

-0.95 01SEP2016 NO 7:23:46 NORMAL 70 156 107 379 399

-0.48 01SEP2016 YES 7:52:01 NORMAL 65 153 107 386 396

-0.47 01SEP2016 YES 7:53:01 NORMAL 65 155 106 388 398

-0.45 01SEP2016 YES 7:54:02 NORMAL 65 153 107 390 401

0.17 01SEP2016 YES 8:31:02 NORMAL 69 152 105 377 395

0.18 01SEP2016 YES 8:31:40 NORMAL 66 155 105 376 388

0.20 01SEP2016 YES 8:32:28 NORMAL 63 155 105 384 390 SINUS ARRHYTHMIA

0.42 01SEP2016 YES 8:46:01 NORMAL 71 154 105 374 396

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 22 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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1010 1 1 M 1 0.43 01SEP2016 YES 8:46:29 NORMAL 65 152 106 376 386

0.45 01SEP2016 YES 8:46:57 NORMAL 71 155 105 380 402

0.92 01SEP2016 YES 9:16:28 NORMAL 69 154 105 377 395

0.93 01SEP2016 YES 9:16:56 NORMAL 69 153 105 373 391

0.95 01SEP2016 YES 9:17:24 NORMAL 66 154 105 378 390

1.92 01SEP2016 YES 10:16:14 NORMAL 70 154 106 377 397

1.93 01SEP2016 YES 10:17:48 NORMAL 65 151 105 380 390

1.95 01SEP2016 YES 10:18:39 NORMAL 63 154 105 378 384

2.92 01SEP2016 YES 11:16:01 NORMAL 63 155 106 378 384

2.93 01SEP2016 YES 11:16:41 NORMAL 71 157 106 375 397

2.95 01SEP2016 YES 11:17:26 NORMAL 62 153 104 377 381

3.92 01SEP2016 YES 12:16:05 NORMAL 77 146 104 374 406

3.93 01SEP2016 YES 12:17:36 NORMAL 73 152 105 371 396

3.95 01SEP2016 YES 12:18:43 NORMAL 69 151 106 373 391

5.92 01SEP2016 YES 14:16:01 NORMAL 85 151 105 348 391

5.93 01SEP2016 YES 14:16:51 NORMAL 85 151 104 352 395

5.95 01SEP2016 YES 14:17:49 NORMAL 83 151 105 346 386

7.92 01SEP2016 YES 16:16:01 NORMAL 69 149 105 359 376

7.93 01SEP2016 YES 16:16:43 NORMAL 72 150 104 362 385

7.95 01SEP2016 YES 16:17:21 NORMAL 72 149 105 361 384

11.92 01SEP2016 YES 20:16:03 NORMAL 67 155 104 369 383

11.93 01SEP2016 YES 20:16:39 NORMAL 67 155 104 366 380

11.95 01SEP2016 YES 20:17:12 NORMAL 68 153 104 372 388

2 23.92 02SEP2016 YES 8:16:02 NORMAL 63 152 105 387 393

23.93 02SEP2016 YES 8:16:57 NORMAL 67 152 103 386 400

23.95 02SEP2016 YES 8:17:43 NORMAL 68 153 104 383 399

36.17 02SEP2016 YES 20:31:25 NORMAL 67 152 108 378 392

36.18 02SEP2016 YES 20:32:11 NORMAL 67 152 108 376 390

36.20 02SEP2016 YES 20:33:00 NORMAL 65 150 108 380 390

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 23 of 23

Table 1.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

1010 1 1 M 3 48.17 03SEP2016 YES 8:31:01 NORMAL 61 156 106 380 382

48.18 03SEP2016 YES 8:31:40 NORMAL 65 154 108 390 401

48.20 03SEP2016 YES 8:32:39 NORMAL 67 152 108 384 398

4 72.17 04SEP2016 YES 8:31:01 NORMAL 71 150 108 370 391

72.18 04SEP2016 YES 8:31:44 NORMAL 71 152 106 374 396

72.20 04SEP2016 YES 8:32:35 NORMAL 71 152 106 374 396

10 215.92 10SEP2016 YES 8:12:19 NORMAL 64 154 108 384 392

215.93 10SEP2016 YES 8:13:02 ANCS 64 160 110 386 394 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC

215.95 10SEP2016 YES 8:13:38 NORMAL 61 158 108 388 390

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 1 of 6

Table 1.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

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1001 1 1 M 1 Baseline 69.7 130.7 90.7 404.3 423.7

0.25 hr 59.0 129.7 100.7 421.7 419.3 -10.7 -1.0 10.0 17.3 -4.3

0.5 hr 62.0 129.3 95.7 415.0 419.0 -7.7 -1.3 5.0 10.7 -4.7

1 hr 57.3 130.7 101.7 430.7 424.0 -12.3 0.0 11.0 26.3 0.3

2 hr 79.7 124.7 81.7 395.0 434.0 d 10.0 -6.0 -9.0 -9.3 10.3

3 hr 61.3 127.7 93.3 407.7 410.7 -8.3 -3.0 2.7 3.3 -13.0

4 hr 63.7 125.7 83.0 406.3 414.3 -6.0 -5.0 -7.7 2.0 -9.3

6 hr 64.3 126.7 82.3 395.7 405.3 -5.3 -4.0 -8.3 -8.7 -18.3

8 hr 60.7 127.7 80.7 402.3 403.7 -9.0 -3.0 -10.0 -2.0 -20.0

12 hr 64.0 127.3 80.3 404.3 413.3 -5.7 -3.3 -10.3 0.0 -10.3

2 24 hr 57.0 126.0 91.3 423.0 415.7 -12.7 -4.7 0.7 18.7 -8.0

36 hr 64.3 127.3 83.3 398.0 407.3 -5.3 -3.3 -7.3 -6.3 -16.3

3 48 hr 59.7 130.0 100.0 420.7 420.0 -10.0 -0.7 9.3 16.3 -3.7

4 72 hr 62.7 128.7 100.0 412.0 417.3 -7.0 -2.0 9.3 7.7 -6.3

10 56.7 131.3 104.7 428.7 420.7 -13.0 0.7 14.0 24.3 -3.0

1002 1 1 M 1 Baseline 61.7 151.0 90.7 406.3 410.0

0.25 hr 64.0 149.7 89.7 401.3 410.0 2.3 -1.3 -1.0 -5.0 0.0

0.5 hr 64.3 150.7 89.3 397.3 406.7 2.7 -0.3 -1.3 -9.0 -3.3

1 hr 63.0 150.3 89.0 402.3 409.0 1.3 -0.7 -1.7 -4.0 -1.0

2 hr 60.7 152.7 88.7 405.3 406.7 -1.0 1.7 -2.0 -1.0 -3.3

3 hr 60.7 148.3 89.0 407.0 408.3 -1.0 -2.7 -1.7 0.7 -1.7

4 hr 61.3 147.7 89.3 403.3 406.0 -0.3 -3.3 -1.3 -3.0 -4.0

6 hr 62.7 144.0 90.0 398.0 403.7 1.0 -7.0 -0.7 -8.3 -6.3

8 hr 66.3 145.0 86.3 392.7 406.3 4.7 -6.0 -4.3 -13.7 -3.7

12 hr 65.3 142.3 87.0 391.0 402.7 3.7 -8.7 -3.7 -15.3 -7.3

2 24 hr 65.7 151.0 88.3 396.7 408.7 4.0 0.0 -2.3 -9.7 -1.3

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 2 of 6

Table 1.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

1002 1 1 M 2 36 hr 66.7 144.0 86.7 381.3 394.7 5.0 -7.0 -4.0 -25.0 -15.3

3 48 hr 63.7 150.7 88.7 392.0 399.7 2.0 -0.3 -2.0 -14.3 -10.3

4 72 hr 65.0 148.0 92.0 397.3 408.3 3.3 -3.0 1.3 -9.0 -1.7

10 65.3 154.7 90.0 405.3 417.0 3.7 3.7 -0.7 -1.0 7.0

1003 1 1 M 1 Baseline 49.0 171.7 100.0 458.0 428.0

0.25 hr 47.7 151.0 100.0 468.3 433.7 d -1.3 -20.7 0.0 10.3 5.7

0.5 hr 49.7 167.3 100.0 457.3 429.3 0.7 -4.3 0.0 -0.7 1.3

1 hr 46.7 173.0 100.3 460.3 423.3 -2.3 1.3 0.3 2.3 -4.7

2 hr 48.0 175.7 99.0 460.7 427.7 -1.0 4.0 -1.0 2.7 -0.3

3 hr 47.7 172.7 99.7 449.7 416.7 -1.3 1.0 -0.3 -8.3 -11.3

4 hr 49.3 174.7 99.3 447.7 419.7 0.3 3.0 -0.7 -10.3 -8.3

6 hr 58.3 170.0 100.3 421.7 417.7 9.3 -1.7 0.3 -36.3 -10.3

8 hr 58.0 167.3 102.7 412.7 408.0 9.0 -4.3 2.7 -45.3 -20.0

12 hr 53.7 170.7 99.7 436.7 421.0 4.7 -1.0 -0.3 -21.3 -7.0

2 24 hr 49.7 175.3 99.3 453.3 425.3 0.7 3.7 -0.7 -4.7 -2.7

36 hr 58.7 158.0 102.7 419.3 416.3 9.7 -13.7 2.7 -38.7 -11.7

3 48 hr 53.0 159.3 100.7 444.0 426.0 4.0 -12.3 0.7 -14.0 -2.0

4 72 hr 57.7 162.7 98.7 425.3 419.7 8.7 -9.0 -1.3 -32.7 -8.3

10 54.3 159.3 100.0 444.7 430.0 5.3 -12.3 0.0 -13.3 2.0

1004 1 1 M 1 Baseline 66.3 128.0 104.7 370.0 382.7

0.25 hr 80.0 130.7 104.3 353.3 389.0 13.7 2.7 -0.3 -16.7 6.3

0.5 hr 71.3 130.7 104.0 353.0 374.0 5.0 2.7 -0.7 -17.0 -8.7

1 hr 70.3 130.7 104.7 362.3 382.0 4.0 2.7 0.0 -7.7 -0.7

2 hr 84.3 131.7 103.0 335.7 376.0 18.0 3.7 -1.7 -34.3 -6.7

3 hr 91.7 129.0 103.7 330.7 379.3 25.3 i 1.0 -1.0 -39.3 -3.3

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 3 of 6

Table 1.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

1004 1 1 M 1 4 hr 89.0 131.0 103.0 336.3 383.3 22.7 i 3.0 -1.7 -33.7 0.7

6 hr 92.0 128.7 105.0 328.0 378.0 25.7 i 0.7 0.3 -42.0 -4.7

8 hr 92.7 126.0 103.3 327.3 378.0 26.3 i -2.0 -1.3 -42.7 -4.7

12 hr 91.7 126.3 101.7 327.3 377.0 25.3 i -1.7 -3.0 -42.7 -5.7

2 24 hr 70.3 128.7 103.3 364.0 383.7 4.0 0.7 -1.3 -6.0 1.0

36 hr 85.3 138.7 102.7 340.7 383.0 19.0 10.7 -2.0 -29.3 0.3

3 48 hr 93.7 132.0 103.3 322.0 373.3 27.3 i 4.0 -1.3 -48.0 -9.3

4 72 hr 84.3 134.7 105.3 338.7 379.3 18.0 6.7 0.7 -31.3 -3.3

10 71.7 124.7 110.7 362.7 385.0 5.3 -3.3 6.0 -7.3 2.3

1005 1 1 F 1 Baseline 60.3 145.0 82.0 419.3 420.0

0.25 hr 58.3 137.7 80.7 413.0 409.0 -2.0 -7.3 -1.3 -6.3 -11.0

0.5 hr 65.0 140.7 82.3 408.3 419.3 4.7 -4.3 0.3 -11.0 -0.7

1 hr 58.3 139.7 80.0 411.3 407.3 -2.0 -5.3 -2.0 -8.0 -12.7

2 hr 66.3 141.3 83.7 403.0 416.7 6.0 -3.7 1.7 -16.3 -3.3

3 hr 62.3 138.7 84.0 404.7 410.0 2.0 -6.3 2.0 -14.7 -10.0

4 hr 57.0 137.0 83.7 419.0 411.7 -3.3 -8.0 1.7 -0.3 -8.3

6 hr 74.7 130.7 83.3 377.7 406.0 14.3 -14.3 1.3 -41.7 -14.0

8 hr 74.7 133.0 81.0 380.0 408.7 14.3 -12.0 -1.0 -39.3 -11.3

12 hr 71.0 128.3 84.7 386.3 408.3 10.7 -16.7 2.7 -33.0 -11.7

2 24 hr 65.3 138.0 82.0 404.7 416.3 5.0 -7.0 0.0 -14.7 -3.7

36 hr 78.3 131.3 86.7 374.7 409.3 18.0 -13.7 4.7 -44.7 -10.7

3 48 hr 66.7 140.7 82.0 406.0 420.3 6.3 -4.3 0.0 -13.3 0.3

4 72 hr 64.3 135.3 87.3 396.0 405.0 4.0 -9.7 5.3 -23.3 -15.0

10 69.3 140.7 86.7 396.7 416.3 9.0 -4.3 4.7 -22.7 -3.7

1006 1 1 F 1 Baseline 55.0 141.7 116.0 441.7 429.0

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 4 of 6

Table 1.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

1006 1 1 F 1 0.25 hr 57.7 131.0 106.3 435.7 430.0 2.7 -10.7 -9.7 -6.0 1.0

0.5 hr 60.3 134.3 108.7 433.0 433.7 5.3 -7.3 -7.3 -8.7 4.7

1 hr 56.3 139.3 109.0 436.3 427.7 1.3 -2.3 -7.0 -5.3 -1.3

2 hr 55.0 140.7 100.7 439.0 426.3 0.0 -1.0 -15.3 -2.7 -2.7

3 hr 59.3 126.3 104.0 426.3 425.0 4.3 -15.3 -12.0 -15.3 -4.0

4 hr 60.7 139.3 102.3 430.3 431.7 5.7 -2.3 -13.7 -11.3 2.7

6 hr 71.3 124.3 105.0 392.0 415.0 16.3 -17.3 -11.0 -49.7 -14.0

8 hr 65.7 121.3 114.3 406.7 418.7 10.7 -20.3 -1.7 -35.0 -10.3

12 hr 61.3 135.0 104.7 417.7 421.0 6.3 -6.7 -11.3 -24.0 -8.0

2 24 hr 63.3 142.0 112.3 420.7 428.3 8.3 0.3 -3.7 -21.0 -0.7

36 hr 68.7 134.0 100.7 400.0 418.3 13.7 -7.7 -15.3 -41.7 -10.7

3 48 hr 66.7 134.7 107.3 411.3 426.0 11.7 -7.0 -8.7 -30.3 -3.0

4 72 hr 66.0 138.7 104.0 411.3 424.3 11.0 -3.0 -12.0 -30.3 -4.7

10 59.0 138.0 96.7 416.0 414.0 4.0 -3.7 -19.3 -25.7 -15.0

1007 1 1 M 1 Baseline 52.0 132.3 91.7 432.3 412.0

0.25 hr 52.7 125.7 98.7 434.7 416.0 0.7 -6.7 7.0 2.3 4.0

0.5 hr 53.0 125.7 98.7 426.3 409.0 1.0 -6.7 7.0 -6.0 -3.0

1 hr 50.7 136.3 98.0 430.7 407.0 -1.3 4.0 6.3 -1.7 -5.0

2 hr 55.3 133.0 97.7 408.3 397.3 3.3 0.7 6.0 -24.0 -14.7

3 hr 65.0 129.3 99.3 405.0 414.3 13.0 -3.0 7.7 -27.3 2.3

4 hr 56.0 126.3 100.0 421.7 412.0 4.0 -6.0 8.3 -10.7 0.0

6 hr 62.7 133.0 99.3 390.3 395.7 10.7 0.7 7.7 -42.0 -16.3

8 hr 63.7 130.7 100.0 390.0 397.7 11.7 -1.7 8.3 -42.3 -14.3

12 hr 59.3 124.0 98.7 414.0 412.3 7.3 -8.3 7.0 -18.3 0.3

2 24 hr 54.7 112.7 86.7 412.0 399.3 2.7 -19.7 -5.0 -20.3 -12.7

36 hr 63.3 147.3 92.7 406.7 413.7 11.3 15.0 1.0 -25.7 1.7

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 5 of 6

Table 1.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

1007 1 1 M 3 48 hr 61.0 144.0 100.0 428.0 430.3 d 9.0 11.7 8.3 -4.3 18.3

4 72 hr 63.0 144.7 98.7 422.0 429.0 11.0 12.3 7.0 -10.3 17.0

10 52.0 150.7 93.3 438.7 418.3 0.0 18.3 h 1.7 6.3 6.3

1008 1 1 F 1 Baseline 71.7 138.3 89.7 400.0 424.3

0.25 hr 62.7 129.0 90.3 413.0 419.0 -9.0 -9.3 0.7 13.0 -5.3

0.5 hr 61.7 130.3 83.3 407.3 410.7 -10.0 -8.0 -6.3 7.3 -13.7

1 hr 65.3 127.7 91.0 405.7 417.3 -6.3 -10.7 1.3 5.7 -7.0

2 hr 61.7 130.7 80.3 410.3 414.0 -10.0 -7.7 -9.3 10.3 -10.3

3 hr 65.0 126.0 84.7 397.3 407.7 -6.7 -12.3 -5.0 -2.7 -16.7

4 hr 64.3 129.3 80.0 400.0 409.3 -7.3 -9.0 -9.7 0.0 -15.0

6 hr 83.0 125.0 80.7 356.3 396.3 11.3 -13.3 -9.0 -43.7 -28.0

8 hr 83.3 121.0 88.0 359.0 400.3 11.7 -17.3 -1.7 -41.0 -24.0

12 hr 85.7 121.3 87.3 356.0 401.0 14.0 -17.0 -2.3 -44.0 -23.3

2 24 hr 67.0 130.0 85.3 400.0 415.0 -4.7 -8.3 -4.3 0.0 -9.3

36 hr 81.0 128.7 87.3 363.3 401.7 9.3 -9.7 -2.3 -36.7 -22.7

3 48 hr 62.0 134.0 92.7 411.3 415.7 -9.7 -4.3 3.0 11.3 -8.7

1009 1 1 M 1 Baseline 60.7 155.0 100.0 406.7 407.7

0.25 hr 57.7 152.0 101.0 409.7 404.3 -3.0 -3.0 1.0 3.0 -3.3

0.5 hr 62.7 154.7 100.7 400.0 406.0 2.0 -0.3 0.7 -6.7 -1.7

1 hr 56.7 151.3 100.7 412.3 404.7 -4.0 -3.7 0.7 5.7 -3.0

2 hr 61.0 154.0 99.7 406.0 408.3 0.3 -1.0 -0.3 -0.7 0.7

3 hr 63.7 153.0 100.0 396.3 404.3 3.0 -2.0 0.0 -10.3 -3.3

4 hr 63.0 152.3 100.3 396.0 402.7 2.3 -2.7 0.3 -10.7 -5.0

6 hr 82.0 143.3 102.3 356.3 395.7 21.3 i -11.7 2.3 -50.3 -12.0

8 hr 77.7 142.3 102.0 364.7 397.3 17.0 -12.7 2.0 -42.0 -10.3

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 6 of 6

Table 1.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

1009 1 1 M 1 12 hr 72.0 145.0 101.7 379.3 403.3 11.3 -10.0 1.7 -27.3 -4.3

2 24 hr 71.0 146.0 96.3 390.3 413.0 10.3 -9.0 -3.7 -16.3 5.3

36 hr 70.3 148.0 101.3 377.3 398.0 9.7 -7.0 1.3 -29.3 -9.7

3 48 hr 65.7 150.7 102.0 398.7 411.0 5.0 -4.3 2.0 -8.0 3.3

4 72 hr 64.3 152.0 99.3 393.3 402.7 3.7 -3.0 -0.7 -13.3 -5.0

10 55.7 146.0 102.0 416.7 406.3 -5.0 -9.0 2.0 10.0 -1.3

1010 1 1 M 1 Baseline 65.0 153.7 106.7 388.0 398.3

0.25 hr 66.0 154.0 105.0 379.0 391.0 1.0 0.3 -1.7 -9.0 -7.3

0.5 hr 69.0 153.7 105.3 376.7 394.7 4.0 0.0 -1.3 -11.3 -3.7

1 hr 68.0 153.7 105.0 376.0 392.0 3.0 0.0 -1.7 -12.0 -6.3

2 hr 66.0 153.0 105.3 378.3 390.3 1.0 -0.7 -1.3 -9.7 -8.0

3 hr 65.3 155.0 105.3 376.7 387.3 0.3 1.3 -1.3 -11.3 -11.0

4 hr 73.0 149.7 105.0 372.7 397.7 8.0 -4.0 -1.7 -15.3 -0.7

6 hr 84.3 151.0 104.7 348.7 390.7 19.3 -2.7 -2.0 -39.3 -7.7

8 hr 71.0 149.3 104.7 360.7 381.7 6.0 -4.3 -2.0 -27.3 -16.7

12 hr 67.3 154.3 104.0 369.0 383.7 2.3 0.7 -2.7 -19.0 -14.7

2 24 hr 66.0 152.3 104.0 385.3 397.3 1.0 -1.3 -2.7 -2.7 -1.0

36 hr 66.3 151.3 108.0 378.0 390.7 1.3 -2.3 1.3 -10.0 -7.7

3 48 hr 64.3 154.0 107.3 384.7 393.7 -0.7 0.3 0.7 -3.3 -4.7

4 72 hr 71.0 151.3 106.7 372.7 394.3 6.0 -2.3 0.0 -15.3 -4.0

10 63.0 157.3 108.7 386.0 392.0 -2.0 3.7 2.0 -2.0 -6.3

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 1 = 50 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 1 of 1

Table 1.7.3 Electrocardiogram Outlier Summary

Cohort 1

Hour Measurement (Number of Subjects)

------------------------------------------------------------------------

Day 1 (0.25 hr) 430 < QTcF (Male Only) <= 450 1

Day 1 (2 hr) 430 < QTcF (Male Only) <= 450 1

Day 3 (48 hr) 430 < QTcF (Male Only) <= 450 1

Note: QTcF\* = QTc corrected for Fridericia equation. This table is based on the averages of the triplicates.

Cohort 1 = 50 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_Outlier.sas 15SEP2016 18:57

Page 1 of 1

Table 1.8 Prior and Concomitant Medications

Prior

Subject Any Start Start Stop Stop to

Number Med? Medication Dosage Route Date Time Date Time Frequency Indication Continuing? Study?

------------------------------------------------------------------------------------------------------------------------------------

1001 NO None

1002 NO None

1003 NO None

1004 YES ADVIL MIGRAINE 400 MG BY MOUTH 14AUG2016 UNK 14AUG2016 UNK ONCE MIGRAINE NO X

ZZZQUIL 50 MG BY MOUTH 14AUG2016 UNK 14AUG2016 UNK ONCE SLEEP AID NO X

1005 NO None

1006 NO None

1007 NO None

1008 NO None

1009 NO None

1010 NO None

Note: UNK = Unknown

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_con.sas 15SEP2016 18:57

Page 1 of 1

Table 1.9 Demographics

Body Mass

Subject Date Of Age\* Height Weight Index

Number Birth (yrs) Gender Race Ethnicity (cm) (kg) (kg/m²)

--------------------------------------------------------------------------------------------------------------------------------------

1001 11FEB1987 29 Male Black or African American Not Hispanic or Latino 174 87.8 29.08

1002 26SEP1991 24 Male White Not Hispanic or Latino 172 67.0 22.71

1003 09DEC1983 32 Male White Not Hispanic or Latino 174 74.4 24.52

1004 12JAN1980 36 Male White Not Hispanic or Latino 168 68.4 24.12

1005 22DEC1995 20 Female White Hispanic or Latino 161 58.7 22.58

1006 30DEC1989 26 Female White Not Hispanic or Latino 176 76.4 24.65

1007 06DEC1992 23 Male Black or African American Not Hispanic or Latino 181 104.1 31.75

1008 19JUL1989 27 Female White Not Hispanic or Latino 158 75.1 29.88

1009 19JUN1970 46 Male Black or African American Not Hispanic or Latino 172 62.9 21.20

1010 10MAR1994 22 Male White Not Hispanic or Latino 189 83.4 23.23

Note: \* Age is calculated from the date of first dosing.

BMI (body mass index) and weight are based on the CRF data collected at admission (Day -3).

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_dem.sas 15SEP2016 18:57

Page 1 of 2

Table 2.3 Demographic Summary

Trait Cohort 2

--------------------------------------------------------------------------------

Gender Female 3 ( 38%)

Male 5 ( 63%)

Race Black or African American 3 ( 38%)

White 4 ( 50%)

White, Black or African American 1 ( 13%)

Age\* (yrs) N 8

Mean 35.6

SD 12.41

Minimum 20

Median 33.5

Maximum 55

Weight (kg) N 8

Mean 79.09

SD 10.616

Minimum 66.1

Median 74.45

Maximum 92.6

Height (cm) N 8

Mean 173.5

SD 3.85

Minimum 167

Median 173.0

Maximum 179

Note: Cohort 2 = 100 mg TD-1439 or placebo

\* Age is based on date of first dose.

BMI (body mass index) and weight are based on the CRF data collected at admission (Day -3).

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_demsummary.sas 15SEP2016 19:01

Page 2 of 2

Table 2.3 Demographic Summary

Trait Cohort 2

--------------------------------------------------------------------------------

BMI (kg/m²) N 8

Mean 26.248

SD 3.1047

Minimum 22.99

Median 24.870

Maximum 31.17

Note: Cohort 2 = 100 mg TD-1439 or placebo

\* Age is based on date of first dose.

BMI (body mass index) and weight are based on the CRF data collected at admission (Day -3).

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_demsummary.sas 15SEP2016 19:01

Page 1 of 1

Table 2.4.1 Adverse Events (I of II)

Time From

Last Dose Onset Resolved Duration

Subject ---------- --------------- --------------- ----------

Number Cohort TE?^ Adverse Event (DD:HH:MM) Date Time Date Time (DD:HH:MM)

-------------------------------------------------------------------------------------------------------

2001 2 Yes LIGHTHEADEDNESS 00:02:45 11SEP2016 10:00 11SEP2016 11:00 00:01:00

2002 2 Yes EARS FEEL PLUGGED 01:12:42 12SEP2016 20:00

2003 2 None

2004 2 None

2006 2 Yes SORE THROAT 01:12:30 12SEP2016 20:00

2007 2 Yes TEMPORAL HEADACHE 00:10:27 11SEP2016 18:00 12SEP2016 3:00 00:09:00

2008 2 No DIAPHORESIS 11SEP2016 6:23 11SEP2016 6:33 00:00:10

No POSTURAL DIZZINESS 11SEP2016 6:23 11SEP2016 6:33 00:00:10

2009 2 Yes NAUSEA 00:06:21 11SEP2016 14:00 11SEP2016 16:00 00:02:00

Note: Cohort 2 = 100 mg TD-1439 or placebo

^ = Abbreviation for treatment-emergent.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae1.sas 15SEP2016 18:57

Page 1 of 1

Table 2.4.2 Adverse Events (II of II)

Action Action

Relation- Taken Taken

Onset ship to With With

Subject --------------- Study Study Study

Number Cohort Adverse Event Date Time Frequency Severity Serious Outcome Drug Treatment Drug

-------------------------------------------------------------------------------------------------------------------------------------

2001 2 LIGHTHEADEDNESS 11SEP2016 10:00 Intermittent Mild Not Unknown 99 None Dose

serious not

changed

2002 2 EARS FEEL PLUGGED 12SEP2016 20:00 Continuous Mild 99

2003 2 None

2004 2 None

2006 2 SORE THROAT 12SEP2016 20:00 Continuous Mild 99

2007 2 TEMPORAL HEADACHE 11SEP2016 18:00 Continuous Mild Not Recovered/ 99 None Dose

serious Resolved not

changed

2008 2 DIAPHORESIS 11SEP2016 6:23 Intermittent Mild Not Recovered/ 99 None Dose

serious Resolved not

changed

POSTURAL DIZZINESS 11SEP2016 6:23 Intermittent Mild Not Recovered/ 99 None Dose

serious Resolved not

changed

2009 2 NAUSEA 11SEP2016 14:00 Intermittent Mild Not Recovered/ 99 None Dose

serious Resolved not

changed

Note: Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae2.sas 15SEP2016 18:57

Page 1 of 1

Table 2.4.3 Adverse Event Non Drug Therapy

Onset Therapy

Subject --------------- ------------------------------------

Number Cohort Adverse Event Date Time Date Time Description

---------------------------------------------------------------------------------------------------

2008 2 POSTURAL DIZZINESS 11SEP2016 6:23 11SEP2016 6:23 SUPINE POSITION

WITH FEET ELEVATED

Note: Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ae3.sas 15SEP2016 18:57

Page 1 of 4

Table 2.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Calcium (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Chloride (mEq/L) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 5 3 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Bicarbonate (mmol/L) Day 2 0 1 0 0 7 0 0 0 0

Day 3 0 1 0 0 7 0 0 0 0

Day 4 0 1 0 0 7 0 0 0 0

2 Magnesium (mg/dL) Day 2 1 0 0 0 7 0 0 0 0

Day 3 1 0 0 1 6 0 0 0 0

Day 4 1 0 0 0 7 0 0 0 0

2 Potassium (mEq/L) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Sodium (mEq/L) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Albumin (g/dL) Day 2 1 0 0 0 7 0 0 0 0

Day 3 1 0 0 1 6 0 0 0 0

Day 4 1 0 0 0 7 0 0 0 0

2 Blood Urea Nitrogen (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 2 of 4

Table 2.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Blood Urea Nitrogen (mg/dL) Day 4 0 0 0 0 8 0 0 0 0

2 Creatinine (mg/dL) Day 2 0 0 0 0 7 1 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Glucose (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Alkaline Phosphatase (U/L) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Alanine Aminotransferase (U/L) Day 2 1 0 0 0 7 0 0 0 0

Day 3 1 0 0 0 7 0 0 0 0

Day 4 0 1 0 0 7 0 0 0 0

2 Aspartate Aminotransferase (U/L) Day 2 1 0 0 0 7 0 0 0 0

Day 3 1 0 0 0 7 0 0 0 0

Day 4 1 0 0 0 7 0 0 0 0

2 Direct Bilirubin (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Indirect Bilirubin (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 3 of 4

Table 2.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Total Bilirubin (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 GGT (U/L) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Cholesterol (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 HDL Cholesterol (mg/dL) Day 2 0 0 0 0 7 0 0 0 1

Day 3 0 0 0 0 7 0 0 0 1

Day 4 0 0 0 0 7 0 0 0 1

2 LDL Cholesterol (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Creatine Kinase (U/L) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 1 7 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Lactate Dehydrogenase (U/L) Day 2 1 1 0 1 5 0 0 0 0

Day 3 1 1 0 0 6 0 0 0 0

Day 4 1 1 0 0 6 0 0 0 0

2 Triglycerides (mg/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 4 of 4

Table 2.5.1 Clinical Laboratory Shift From Baseline - Serum Chemistry

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Triglycerides (mg/dL) Day 4 0 0 0 0 8 0 0 0 0

2 Lipase (U/L) Day 2 0 0 0 0 6 1 0 1 0

Day 3 0 0 0 0 7 0 0 1 0

Day 4 0 0 0 0 7 0 0 1 0

2 Amylase (U/L) Day 2 0 0 0 0 7 0 0 0 1

Day 3 0 0 0 0 7 0 0 1 0

Day 4 0 0 0 0 7 0 0 1 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 1 of 3

Table 2.5.2 Clinical Laboratory Shift From Baseline - Hematology

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Hemoglobin (g/dL) Day 2 1 1 0 0 6 0 0 0 0

Day 3 2 0 0 0 6 0 0 0 0

Day 4 2 0 0 0 6 0 0 0 0

2 Hematocrit (%) Day 2 0 1 0 1 6 0 0 0 0

Day 3 1 0 0 1 6 0 0 0 0

Day 4 1 0 0 0 7 0 0 0 0

2 Platelet Count (Thou/uL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Red Blood Cell Count (Mil/uL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 MCH (pg) Day 2 2 0 0 0 6 0 0 0 0

Day 3 2 0 0 0 6 0 0 0 0

Day 4 2 0 0 0 6 0 0 0 0

2 MCHC (g/dL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 1 7 0 0 0 0

Day 4 0 0 0 1 7 0 0 0 0

2 MCV (fL) Day 2 2 0 0 0 6 0 0 0 0

Day 3 2 0 0 0 6 0 0 0 0

Day 4 2 0 0 0 6 0 0 0 0

2 White Blood Cell Count (Thou/uL) Day 2 1 0 0 0 7 0 0 0 0

Day 3 0 1 0 0 7 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 2 of 3

Table 2.5.2 Clinical Laboratory Shift From Baseline - Hematology

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 White Blood Cell Count (Thou/uL) Day 4 0 1 0 0 7 0 0 0 0

2 Basophils (%) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Absolute Basophils (Thou/uL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Eosinophils (%) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 7 1 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Absolute Eosinophils (Thou/uL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Lymphocytes (%) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Absolute Lymphocytes (Thou/uL) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Monocytes (%) Day 2 0 1 0 0 6 1 0 0 0

Day 3 1 0 0 0 6 1 0 0 0

Day 4 0 1 0 0 7 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 3 of 3

Table 2.5.2 Clinical Laboratory Shift From Baseline - Hematology

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Absolute Monocytes (Thou/uL) Day 2 1 0 0 0 7 0 0 0 0

Day 3 0 1 0 0 7 0 0 0 0

Day 4 0 1 0 0 7 0 0 0 0

2 Neutrophils (%) Day 2 0 0 0 0 8 0 0 0 0

Day 3 0 0 0 0 8 0 0 0 0

Day 4 0 0 0 0 8 0 0 0 0

2 Absolute Neutrophils (Thou/uL) Day 2 1 0 0 0 7 0 0 0 0

Day 3 0 1 0 0 7 0 0 0 0

Day 4 0 1 0 0 7 0 0 0 0

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 1 of 2

Table 2.5.3 Clinical Laboratory Shift From Baseline - Urinalysis

Baseline\* N Baseline\* O

----------------- -----------------

Postdose Postdose

----------------- -----------------

Cohort Laboratory Test (units) Time Point N O N O

--------------------------------------------------------------------------------------------

2 Blood Day 2 6 1 0 1

Day 3 7 0 0 1

Day 4 6 1 0 1

2 pH, Urine Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Specific Gravity Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Glucose Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Ketones Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Leukocyte Esterase Day 2 6 2 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Nitrite Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Protein Day 2 8 0 0 0

Day 3 8 0 0 0

Note: N = Within Reference Range, O = Outside Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 2 of 2

Table 2.5.3 Clinical Laboratory Shift From Baseline - Urinalysis

Baseline\* N Baseline\* O

----------------- -----------------

Postdose Postdose

----------------- -----------------

Cohort Laboratory Test (units) Time Point N O N O

--------------------------------------------------------------------------------------------

2 Protein Day 4 8 0 0 0

2 Bilirubin Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

2 Urobilinogen Day 2 8 0 0 0

Day 3 8 0 0 0

Day 4 8 0 0 0

Note: N = Within Reference Range, O = Outside Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshift.sas 15SEP2016 18:57

Page 1 of 1

Table 2.5.4 Clinical Laboratory Shift From Baseline - Coagulation

Baseline\* L Baseline\* N Baseline\* H

-------------------------- -------------------------- --------------------------

Postdose Postdose Postdose

-------------------------- -------------------------- --------------------------

Cohort Laboratory Test (units) Time Point L N H L N H L N H

-----------------------------------------------------------------------------------------------------------------------------------------

2 Prothrombin Time/INR Day 2 0 0 0 0 8 0 0 0 0

2 Prothrombin Time (seconds) Day 2 1 0 0 0 7 0 0 0 0

2 Partial Thromboplastin Time Day 2 0 0 0 0 8 0 0 0 0

(seconds)

Note: N = Within Reference Range, L = Below Reference Range, H = Above Reference Range

\* Baseline is the last predose measurement.

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_labshiftcoag.sas 15SEP2016 18:57

Page 1 of 2

Table 2.5.5.1.1 Unscheduled and Out-of-Range Results - Serum Chemistry (I of III)

Chloride Bicarbonate Magnesium Albumin

Subject Study 97-105 24-33.2 1.9-2.4 3.9-5

Number Period Cohort Day Hour Date (mEq/L) (mmol/L) (mg/dL) (g/dL)

-----------------------------------------------------------------------------------------------

2001 Screen 2 16AUG2016 1.8 LN 4.2

1 2 -3 -73.5 08SEP2016 1.7 LN 3.7 LN

1 -0.2 11SEP2016 1.8 LN 3.6 LN

2 24.0 12SEP2016 1.8 LN 3.6 LN

3 48.0 13SEP2016 1.8 LN 3.7 LN

2004 Screen 2 30AUG2016 104 4.2

1 2 -3 -73.5 08SEP2016 99 4.1

1 -0.2 11SEP2016 103 4.0

2 24.0 12SEP2016 104 3.9

3 48.0 13SEP2016 106 HN 3.7 LN

2006 Screen 2 30AUG2016 4.2

1 2 -3 -73.5 08SEP2016 3.8 LN

1 -0.2 11SEP2016 4.2

2 24.0 12SEP2016 4.0

3 48.0 13SEP2016 3.9

2007 Screen 2 06SEP2016 104 24.3

1 2 -3 -73.5 08SEP2016 103 24.2

1 -0.2 11SEP2016 104 23.8 LN

2 24.0 12SEP2016 103 25.5

3 48.0 13SEP2016 106 HN 24.2

2008 Screen 2 07SEP2016 2.0

1 2 -3 -73.5 08SEP2016 1.9

1 -0.2 11SEP2016 2.0

2 24.0 12SEP2016 2.0

3 48.0 13SEP2016 1.8 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 2 of 2

Table 2.5.5.1.1 Unscheduled and Out-of-Range Results - Serum Chemistry (I of III)

Chloride Bicarbonate Magnesium Albumin

Subject Study 97-105 24-33.2 1.9-2.4 3.9-5

Number Period Cohort Day Hour Date (mEq/L) (mmol/L) (mg/dL) (g/dL)

-----------------------------------------------------------------------------------------------

2009 Screen 2 07SEP2016 105

1 2 -3 -73.5 08SEP2016 103

1 -0.2 11SEP2016 103

2 24.0 12SEP2016 104

3 48.0 13SEP2016 106 HN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 1 of 1

Table 2.5.5.1.2 Unscheduled and Out-of-Range Results - Serum Chemistry (II of III)

Blood

Urea Alkaline Alanine

Nitrogen Creatinine Phosphatase Amino-

F: 6-17 F: .5-.9 38-104, 37-115 # transferase

Subject Study M: 7-20 M: .69-1.2 48-131, 45-120 @ 10-67

Number Period Cohort Day Hour Date (mg/dL) (mg/dL) (U/L) (U/L)

--------------------------------------------------------------------------------------------------------------

2001 Screen 2 16AUG2016 .87 12

1 2 -3 -73.5 08SEP2016 .96 HN 9 LN

1 -0.2 11SEP2016 .88 9 LN

2 24.0 12SEP2016 .90 9 LN

3 48.0 13SEP2016 .88 9 LN

2003 Screen 2 28AUG2016 44 LN

1 2 -3 -73.5 08SEP2016 52

1 -0.2 11SEP2016 45

2 24.0 12SEP2016 47

3 48.0 13SEP2016 48

2007 Screen 2 06SEP2016 5 LN

1 2 -3 -73.5 08SEP2016 6

1 -0.2 11SEP2016 11

2 24.0 12SEP2016 12

3 48.0 13SEP2016 10

2008 Screen 2 07SEP2016 1.14

1 2 -3 -73.5 08SEP2016 1.14

1 -0.2 11SEP2016 1.17

2 24.0 12SEP2016 1.23 HN

3 48.0 13SEP2016 1.18

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

# = 0-25/F: 38-104 26-99/F: 37-115, @ = 0-25/M: 48-131 26-99/M: 45-120

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 1 of 2

Table 2.5.5.1.3 Unscheduled and Out-of-Range Results - Serum Chemistry (III of III)

Aspartate Creatine

Amino- HDL Kinase Lactate

transferase Cholesterol F: 28-207 Dehydrogenase Lipase Amylase

Subject Study 14-48 34-96 M: 43-350 131-249 14-70 29-119

Number Period Cohort Day Hour Date (U/L) (mg/dL) (U/L) (U/L) (U/L) (U/L)

-------------------------------------------------------------------------------------------------------------------------------------

2001 Screen 2 16AUG2016 121 HN

1 2 -3 -73.5 08SEP2016 102 HN

1 -0.2 11SEP2016 104 HN

2 24.0 12SEP2016 107 HN

3 48.0 13SEP2016 107 HN

2002 Screen 2 16AUG2016 73 HN

1 2 -3 -73.5 08SEP2016 50

1 -0.2 11SEP2016 49

2 24.0 12SEP2016 44

3 48.0 13SEP2016 50

2004 Screen 2 30AUG2016 36

1 2 -3 -73.5 08SEP2016 37

1 -0.2 11SEP2016 37

2 24.0 12SEP2016 99 HY^

3 48.0 13SEP2016 44

2006 Screen 2 30AUG2016 29

1 2 -3 -73.5 08SEP2016 21

1 -0.2 11SEP2016 110 HY-

2 24.0 12SEP2016 32

3 48.0 13SEP2016 22

2007 Screen 2 06SEP2016 151

1 2 -3 -73.5 08SEP2016 158

1 -0.2 11SEP2016 132

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 2 = 100 mg TD-1439 or placebo

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Page 2 of 2

Table 2.5.5.1.3 Unscheduled and Out-of-Range Results - Serum Chemistry (III of III)

Aspartate Creatine

Amino- HDL Kinase Lactate

transferase Cholesterol F: 28-207 Dehydrogenase Lipase Amylase

Subject Study 14-48 34-96 M: 43-350 131-249 14-70 29-119

Number Period Cohort Day Hour Date (U/L) (mg/dL) (U/L) (U/L) (U/L) (U/L)

-------------------------------------------------------------------------------------------------------------------------------------

2007 1 2 2 24.0 12SEP2016 128 LN

3 48.0 13SEP2016 132

2008 Screen 2 07SEP2016 168 145 HY-

1 2 -3 -73.5 08SEP2016 138 147 HYR

Recheck 2 -3 -73.5 09SEP2016 145 HY-

1 2 1 -0.2 11SEP2016 127 LN 141 HY-

2 24.0 12SEP2016 134 126 HN

3 48.0 13SEP2016 133 110

2009 Screen 2 07SEP2016 12 LN 54 125 LN

1 2 -3 -73.5 08SEP2016 12 LN 51 124 LN

1 -0.2 11SEP2016 12 LN 52 111 LN

2 24.0 12SEP2016 13 LN 47 118 LN

3 48.0 13SEP2016 12 LN 42 LN 114 LN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 2 = 100 mg TD-1439 or placebo

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Page 1 of 1

Table 2.5.5.2.1 Unscheduled and Out-of-Range Results - Hematology (I of III)

Hemoglobin Hematocrit

F: 12-15.9 F: 35.3-47 MCH MCHC

Subject Study M: 13.6-17.4 M: 40.6-52.3 25.7-34.9 32.2-36.5

Number Period Cohort Day Hour Date (g/dL) (%) (pg) (g/dL)

---------------------------------------------------------------------------------------------------------------

2003 Screen 2 28AUG2016 13.2 LNR 38.9 LNR

Recheck 2 31AUG2016 13.4 LN 40.2 LN

1 2 -3 -73.5 08SEP2016 13.6 40.0 LN-

1 -0.2 11SEP2016 12.8 LN 38.1 LN

2 24.0 12SEP2016 13.8 40.6

3 48.0 13SEP2016 12.9 LN 38.7 LN

2004 Screen 2 30AUG2016 13.4 LN 24.2 LY- 31.7 LN

1 2 -3 -73.5 08SEP2016 13.9 25.0 LN 32.4

1 -0.2 11SEP2016 14.1 25.4 LN 33.2

2 24.0 12SEP2016 14.6 25.2 LN 33.1

3 48.0 13SEP2016 13.9 24.7 LY- 32.3

2006 Screen 2 30AUG2016 42.5

1 2 -3 -73.5 08SEP2016 40.2 LN-

1 -0.2 11SEP2016 43.6

2 24.0 12SEP2016 43.1

3 48.0 13SEP2016 42.3

2007 Screen 2 06SEP2016 12.6 38.9 25.4 LN 32.4

1 2 -3 -73.5 08SEP2016 12.9 39.6 25.5 LN 32.6

1 -0.2 11SEP2016 11.7 LY- 36.1 25.1 LN 32.4

2 24.0 12SEP2016 10.8 LY^ 33.5 LN 25.2 LN 32.2

3 48.0 13SEP2016 10.6 LY^ 33.3 LN 25.1 LN 31.8 LN

Note: L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked, ^ = Will be Retested at a Later Event

Cohort 2 = 100 mg TD-1439 or placebo

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Page 1 of 1

Table 2.5.5.2.2 Unscheduled and Out-of-Range Results - Hematology (II of III)

White Blood

MCV Cell Count Eosinophils Lymphocytes

Subject Study 80-98 3.7-11.5 .5-7.4 15.8-45.8

Number Period Cohort Day Hour Date (fL) (Thou/uL) (%) (%)

---------------------------------------------------------------------------------------------------

2001 Screen 2 16AUG2016 5.1 39.5

1 2 -3 -73.5 08SEP2016 4.4 48.9 HN

1 -0.2 11SEP2016 3.5 LN 44.9

2 24.0 12SEP2016 3.5 LN 44.4

3 48.0 13SEP2016 4.0 43.3

2004 Screen 2 30AUG2016 77 LY-

1 2 -3 -73.5 08SEP2016 77 LY-

1 -0.2 11SEP2016 76 LY-

2 24.0 12SEP2016 76 LY-

3 48.0 13SEP2016 76 LY-

2007 Screen 2 06SEP2016 78 LN 7.9 HN

1 2 -3 -73.5 08SEP2016 78 LN 6.7

1 -0.2 11SEP2016 77 LY- 6.5

2 24.0 12SEP2016 78 LN 6.8

3 48.0 13SEP2016 79 LN 7.7 HN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant

Cohort 2 = 100 mg TD-1439 or placebo

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Page 1 of 1

Table 2.5.5.2.3 Unscheduled and Out-of-Range Results - Hematology (III of III)

Absolute Absolute

Monocytes Monocytes Neutrophils Neutrophils

Subject Study 4.9-12.8 .3-.9 38.4-74.2 1.6-7.7

Number Period Cohort Day Hour Date (%) (Thou/uL) (%) (Thou/uL)

----------------------------------------------------------------------------------------------------

2001 Screen 2 16AUG2016 3.7 LN .2 LN 49.7 2.5

1 2 -3 -73.5 08SEP2016 7.3 .3 37.1 LN 1.6

1 -0.2 11SEP2016 6.8 .2 LN 42.6 1.5 LN

2 24.0 12SEP2016 6.6 .2 LN 43.0 1.5 LN

3 48.0 13SEP2016 6.3 .3 44.7 1.8

2002 Screen 2 16AUG2016 4.2 LN

1 2 -3 -73.5 08SEP2016 4.4 LN

1 -0.2 11SEP2016 4.4 LN

2 24.0 12SEP2016 6.3

3 48.0 13SEP2016 4.8 LN

2006 Screen 2 30AUG2016 12.6

1 2 -3 -73.5 08SEP2016 11.7

1 -0.2 11SEP2016 9.9

2 24.0 12SEP2016 13.8 HN

3 48.0 13SEP2016 12.2

2009 Screen 2 07SEP2016 12.3

1 2 -3 -73.5 08SEP2016 13.4 HN

1 -0.2 11SEP2016 12.0

2 24.0 12SEP2016 11.1

3 48.0 13SEP2016 15.0 HN

Note: H = Above Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 1 of 2

Table 2.5.5.3.1 Unscheduled and Out-of-Range Results - Urinalysis (I of III)

Blood Specific

Subject Study F: NEG, TRACE pH, Urine Gravity Glucose

Number Period Cohort Day Hour Date M: NEGATIVE 5.0-8.0 1.005-1.030 NEGATIVE

----------------------------------------------------------------------------------------------------------

2002 Screen 2 16AUG2016 NEGATIVE 1.007

1 2 -3 -73.5 08SEP2016 NEGATIVE 1.002 LN

1 -2.5 11SEP2016 NEGATIVE 1.015

2 22.5 12SEP2016 NEGATIVE 1.012

3 46.5 13SEP2016 NEGATIVE 1.018

2003 Screen 2 28AUG2016 1.001 LY-

1 2 -3 -73.5 08SEP2016 1.004 LN

1 -2.5 11SEP2016 1.014

2 22.5 12SEP2016 1.015

3 46.5 13SEP2016 1.013

2004 Screen 2 30AUG2016 1.003 LN

1 2 -3 -73.5 08SEP2016 1.014

1 -2.5 11SEP2016 1.011

2 22.5 12SEP2016 1.016

3 46.5 13SEP2016 1.011

2006 Screen 2 30AUG2016 NEGATIVE 6.5 1.005 NEGATIVE

1 2 -3 -73.5 08SEP2016 NEGATIVE 7.0 1.006 NEGATIVE

1 -2.5 11SEP2016 NEGATIVE 6.0 1.013 NEGATIVE

2 22.5 12SEP2016 TRACE \*YR 5.0 1.017 NEGATIVE

3 46.5 13SEP2016 NEGATIVE 5.0 1.023 NEGATIVE

Recheck 2 2 22.5 13SEP2016 NEGATIVE 5.0 1.023 NEGATIVE

2007 Screen 2 06SEP2016 NEGATIVE 1.004 LN

1 2 -3 -73.5 08SEP2016 1+ \*Y- 1.004 LN

1 -2.5 11SEP2016 4+ \*Y+ 1.014

Note: \* = No Match to Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: + = Clinically Significant, - = Not Clinically Significant, R = To be rechecked

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 2 of 2

Table 2.5.5.3.1 Unscheduled and Out-of-Range Results - Urinalysis (I of III)

Blood Specific

Subject Study F: NEG, TRACE pH, Urine Gravity Glucose

Number Period Cohort Day Hour Date M: NEGATIVE 5.0-8.0 1.005-1.030 NEGATIVE

----------------------------------------------------------------------------------------------------------

2007 1 2 2 22.5 12SEP2016 4+ \*Y- 1.011

3 46.5 13SEP2016 4+ \*Y- 1.014

2008 Screen 2 07SEP2016 1.004 LN

1 2 -3 -73.5 08SEP2016 1.003 LN

1 -2.5 11SEP2016 1.016

2 22.5 12SEP2016 1.011

3 46.5 13SEP2016 1.014

2009 Screen 2 07SEP2016 1.003 LN

1 2 -3 -73.5 08SEP2016 1.005

1 -2.5 11SEP2016 1.014

2 22.5 12SEP2016 1.017

3 46.5 13SEP2016 1.016

Note: \* = No Match to Reference Range, L = Below Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: + = Clinically Significant, - = Not Clinically Significant, R = To be rechecked

Cohort 2 = 100 mg TD-1439 or placebo

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Page 1 of 1

Table 2.5.5.3.2 Unscheduled and Out-of-Range Results - Urinalysis (II of III)

Leukocyte

Subject Study Ketones Esterase Nitrite Protein

Number Period Cohort Day Hour Date NEG, TRACE NEG, TRACE NEGATIVE NEG, TRACE

-----------------------------------------------------------------------------------------------------------

2002 Screen 2 16AUG2016 NEGATIVE

1 2 -3 -73.5 08SEP2016 1+ \*Y-

1 -2.5 11SEP2016 NEGATIVE

2 22.5 12SEP2016 1+ \*Y-

3 46.5 13SEP2016 NEGATIVE

2003 Screen 2 28AUG2016 NEGATIVE

1 2 -3 -73.5 08SEP2016 NEGATIVE

1 -2.5 11SEP2016 NEGATIVE

2 22.5 12SEP2016 1+ \*YR

3 46.5 13SEP2016 NEGATIVE

2006 Screen 2 30AUG2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1 2 -3 -73.5 08SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

1 -2.5 11SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

2 22.5 12SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

3 46.5 13SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

Recheck 2 2 22.5 13SEP2016 NEGATIVE NEGATIVE NEGATIVE NEGATIVE

Note: \* = No Match to Reference Range

Computer: Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked

Cohort 2 = 100 mg TD-1439 or placebo

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Page 1 of 1

Table 2.5.5.3.3 Unscheduled and Out-of-Range Results - Urinalysis (III of III)

RBC WBC

Subject Study Bilirubin Urobilinogen Bacteria 0-3 0-7

Number Period Cohort Day Hour Date NEGATIVE NEGATIVE NEGATIVE (/hpf) (/hpf)

-----------------------------------------------------------------------------------------------------------

2002 1 2 -3 -73.5 08SEP2016 1+ \*N

2 22.5 12SEP2016 NEGATIVE

2003 1 2 2 22.5 12SEP2016 10-15 HYR

2006 Screen 2 30AUG2016 NEGATIVE NEGATIVE

1 2 -3 -73.5 08SEP2016 NEGATIVE NEGATIVE

1 -2.5 11SEP2016 NEGATIVE NEGATIVE

2 22.5 12SEP2016 NEGATIVE NEGATIVE 2-4 HYR

3 46.5 13SEP2016 NEGATIVE NEGATIVE

Recheck 2 2 22.5 13SEP2016 NEGATIVE NEGATIVE

2007 1 2 -3 -73.5 08SEP2016 0

1 -2.5 11SEP2016 2-4 HY-

2 22.5 12SEP2016 0

3 46.5 13SEP2016 0-1

Note: \* = No Match to Reference Range, H = Above Reference Range

Computer: N = Not Clinically Significant, Y = Clinically Significant

PI interpretation: - = Not Clinically Significant, R = To be rechecked

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 1 of 1

Table 2.5.5.4 Unscheduled and Out-of-Range Results - Coagulation

Prothrombin

Time

Subject Study 9.7-12.6

Number Period Cohort Day Hour Date (seconds)

--------------------------------------------------------------

2001 Screen 2 16AUG2016 9.5 LN

1 2 2 24.0 12SEP2016 9.5 LN

Note: L = Below Reference Range

Computer: N = Not Clinically Significant

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lab\_oor2.sas 15SEP2016 18:57

Page 1 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2001 Screen 2 16AUG2016 11:47:08 91.5 30.86

SUP10 RIGHT 114 / 62 59 12 36.9

11:48:17 SUP1 RIGHT 107 / 58 59

11:51:32 STD3 RIGHT 115 / 79 71

1 2 -3 -73.50 08SEP2016 5:59:23 92.4 31.17

-72.75 08SEP2016 6:32:37 SUP10 RIGHT 110 / 63 59 20 37.1

6:33:59 SUP1 RIGHT 108 / 59 62

6:37:31 STD3 RIGHT 124 / 83 71

-2 -48.17 09SEP2016 7:05:10 SUP5 RIGHT 108 / 69 65 14 37.1

7:06:24 SUP1 RIGHT 103 / 62 66

-1 -25.33 10SEP2016 5:55:00 SUP5 RIGHT 103 / 57 60 16 37.6

5:56:05 SUP1 RIGHT 100 / 57 60

1 -1.33 11SEP2016 5:55:21 SUP10 RIGHT 109 / 58 65 14 37.1

5:57:15 SUP1 RIGHT 106 / 61 74

6:00:22 STD3 RIGHT 110 / 68 87

0.33 11SEP2016 7:36:09 SUP5 RIGHT 119 / 62 68

7:37:21 SUP1 RIGHT 106 / 66 76

0.58 11SEP2016 7:50:38 SUP5 RIGHT 106 / 62 66

7:52:02 SUP1 RIGHT 105 / 62 66

1.08 11SEP2016 8:19:50 SUP5 RIGHT 106 / 59 69

8:22:44 SUP1 RIGHT 108 / 55 66

2.08 11SEP2016 9:20:13 SUP5 RIGHT 111 / 59 67

9:21:24 SUP1 RIGHT 111 / 56 68

3.08 11SEP2016 10:21:06 SUP5 RIGHT 115 / 67 65

10:22:07 SUP1 RIGHT 103 / 70 72

4.17 11SEP2016 11:25:08 SUP10 RIGHT 105 / 67 66 16 37.1

11:26:36 SUP1 RIGHT 111 / 57 66

11:29:57 STD3 RIGHT 112 / 73 82

6.08 11SEP2016 13:20:26 SUP5 RIGHT 108 / 58 68

13:21:28 SUP1 RIGHT 105 / 63 70

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 2 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2001 1 2 1 8.08 11SEP2016 15:22:13 SUP5 RIGHT 108 / 56 78

15:24:02 SUP1 RIGHT 109 / 56 78

12.17 11SEP2016 19:25:01 SUP10 RIGHT 105 / 63 72 16 37.6

19:26:02 SUP1 RIGHT 106 / 57 76

19:30:09 STD3 RIGHT 112 / 71 86

2 24.17 12SEP2016 7:25:05 SUP10 RIGHT 103 / 65 64 16 37.1

7:26:23 SUP1 RIGHT 104 / 61 65

7:29:52 STD3 RIGHT 100 / 60 84

36.08 12SEP2016 19:20:11 SUP5 RIGHT 108 / 60 74 14 37.1

19:21:28 SUP1 RIGHT 106 / 59 75

3 48.08 13SEP2016 7:22:13 SUP5 RIGHT 115 / 68 63 12 37

7:23:54 SUP1 RIGHT 106 / 60 64

4 72.08 14SEP2016 7:20:42 SUP5 RIGHT 95 / 50 69 18 37.6

7:22:04 SUP1 RIGHT 93 / 49 66

2002 Screen 2 16AUG2016 11:54:05 75.8 25.35

SUP10 RIGHT 118 / 68 62 12 35.9

11:55:08 SUP1 RIGHT 118 / 63 64

11:58:17 STD3 RIGHT 126 / 75 84

1 2 -3 -73.50 08SEP2016 6:00:02 75.2 25.12

-72.75 08SEP2016 7:01:20 SUP10 RIGHT 131 / 67 67 16 37

7:02:46 SUP1 RIGHT 124 / 69 70

7:06:06 STD3 RIGHT 140 / 77 90

-2 -48.17 09SEP2016 7:08:00 SUP5 RIGHT 115 / 59 74 14 36.6

7:09:01 SUP1 RIGHT 123 / 60 69

-1 -25.33 10SEP2016 5:58:02 SUP5 RIGHT 112 / 62 69 12 36.4

5:59:06 SUP1 RIGHT 112 / 60 75

1 -1.33 11SEP2016 5:57:27 SUP10 RIGHT 111 / 71 64 14 36.8

5:58:56 SUP1 RIGHT 119 / 58 67

6:02:20 STD3 RIGHT 123 / 71 86

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 3 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2002 1 2 1 0.33 11SEP2016 7:38:23 SUP5 RIGHT 121 / 70 64

7:39:26 SUP1 RIGHT 122 / 59 66

0.58 11SEP2016 7:53:52 SUP5 RIGHT 114 / 60 61

7:54:58 SUP1 RIGHT 110 / 60 62

1.08 11SEP2016 8:25:24 SUP5 RIGHT 118 / 61 67

8:26:37 SUP1 RIGHT 120 / 62 66

2.08 11SEP2016 9:23:10 SUP5 RIGHT 120 / 67 63

9:24:28 SUP1 RIGHT 125 / 64 67

3.08 11SEP2016 10:23:04 SUP5 RIGHT 119 / 67 68

10:24:26 SUP1 RIGHT 121 / 60 67

4.17 11SEP2016 11:27:20 SUP10 RIGHT 118 / 68 69 18 37.1

11:28:39 SUP1 RIGHT 117 / 57 65

11:32:09 STD3 RIGHT 110 / 69 104(#)

6.08 11SEP2016 13:22:01 SUP5 RIGHT 120 / 62 83

13:23:03 SUP1 RIGHT 100 / 59 76

8.08 11SEP2016 15:23:00 SUP5 RIGHT 102 / 60 72

15:24:17 SUP1 RIGHT 105 / 61 71

12.17 11SEP2016 19:28:05 SUP10 RIGHT 116 / 61 68 16 37.1

19:29:13 SUP1 RIGHT 124 / 61 76

19:32:28 STD3 RIGHT 121 / 65 98

2 24.17 12SEP2016 7:38:58 SUP10 RIGHT 134 / 72 70 20 36

7:40:28 SUP1 RIGHT 129 / 76 70

7:43:32 STD3 RIGHT 133 / 68 105(#)

36.08 12SEP2016 19:23:41 SUP5 RIGHT 101 / 57 67 18 36

19:24:42 SUP1 RIGHT 100 / 56 66

3 48.08 13SEP2016 7:23:58 SUP5 RIGHT 124 / 61 71 14 36.9

7:25:31 SUP1 RIGHT 121 / 67 69

4 72.08 14SEP2016 7:27:43 SUP5 RIGHT 124 / 71 68 14 37.1

7:29:12 SUP1 RIGHT 119 / 72 68

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 4 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2003 Screen 2 28AUG2016 8:15:51 75.6 23.84

SUP10 RIGHT 111 / 70 73 16 37.1

8:16:55 SUP1 RIGHT 110 / 77 71

8:20:06 STD3 RIGHT 120 / 75 86

1 2 -3 -73.50 08SEP2016 6:00:51 72.9 22.99

-72.75 08SEP2016 6:54:59 SUP10 RIGHT 112 / 68 78 12 36.3

6:56:31 SUP1 RIGHT 114 / 74 77

6:59:46 STD3 RIGHT 129 / 84 85

-2 -48.17 09SEP2016 7:11:05 SUP5 RIGHT 114 / 74 70 12 37

7:12:06 SUP1 RIGHT 116 / 72 71

-1 -25.33 10SEP2016 6:00:56 SUP5 RIGHT 116 / 71 67 14 36.9

6:02:04 SUP1 RIGHT 120 / 70 66

1 -1.33 11SEP2016 6:01:06 SUP10 RIGHT 114 / 72 74 10 37.6

6:02:24 SUP1 RIGHT 116 / 65 69

6:05:33 STD3 RIGHT 119 / 80 85

0.33 11SEP2016 7:43:11 SUP5 RIGHT 92 / 65 74

7:44:20 SUP1 RIGHT 96 / 64 70

0.58 11SEP2016 7:56:22 SUP5 RIGHT 120 / 77 68

7:57:33 SUP1 RIGHT 119 / 67 66

1.08 11SEP2016 8:26:02 SUP5 RIGHT 113 / 79 71

8:27:18 SUP1 RIGHT 111 / 73 67

2.08 11SEP2016 9:30:19 SUP5 RIGHT 123 / 76 77

9:31:27 SUP1 RIGHT 118 / 69 70

3.08 11SEP2016 10:26:33 SUP5 RIGHT 128 / 77 69

10:27:42 SUP1 RIGHT 116 / 72 67

4.17 11SEP2016 11:33:02 SUP10 RIGHT 115 / 68 73 20 37

11:34:33 SUP1 RIGHT 113 / 65 70

11:37:40 STD3 RIGHT 123 / 65 92

6.08 11SEP2016 13:26:02 SUP5 RIGHT 120 / 64 88

13:27:14 SUP1 RIGHT 112 / 49 84

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 5 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2003 1 2 1 8.08 11SEP2016 15:26:04 SUP5 RIGHT 110 / 66 70

15:27:22 SUP1 RIGHT 111 / 73 70

12.17 11SEP2016 19:31:14 SUP10 RIGHT 124 / 71 75 20 37.4

19:32:19 SUP1 RIGHT 118 / 69 72

19:35:28 STD3 RIGHT 118 / 82 99

2 24.17 12SEP2016 7:31:30 SUP10 RIGHT 112 / 72 73 24 37

7:33:18 SUP1 RIGHT 115 / 67 71

7:36:47 STD3 RIGHT 116 / 68 97

36.08 12SEP2016 19:26:04 SUP5 RIGHT 103 / 61 85 20 37.2

19:27:10 SUP1 RIGHT 113 / 58 86

3 48.08 13SEP2016 7:25:47 SUP5 RIGHT 115 / 68 75 14 36.8

7:27:19 SUP1 RIGHT 111 / 64 70

4 72.08 14SEP2016 7:27:05 SUP5 RIGHT 131 / 77 80 16 37.2

7:28:42 SUP1 RIGHT 121 / 70 74

2004 Screen 2 30AUG2016 7:04:54 92.9 30.24

SUP10 RIGHT 111 / 64 44 18 36.9

7:05:58 SUP1 RIGHT 118 / 69 48

7:09:01 STD3 RIGHT 120 / 88 56

1 2 -3 -73.50 08SEP2016 5:55:33 92.6 30.14

-72.75 08SEP2016 6:40:49 SUP10 RIGHT 119 / 71 46 16 36.1

6:42:13 SUP1 RIGHT 111 / 69 45

6:45:31 STD3 RIGHT 124 / 75 57

-2 -48.17 09SEP2016 7:11:15 SUP5 RIGHT 129 / 73 50 10 36.9

7:12:20 SUP1 RIGHT 123 / 76 47

-1 -25.33 10SEP2016 6:04:05 SUP5 RIGHT 107 / 65 45 14 36.9

6:05:32 SUP1 RIGHT 110 / 63 44

1 -1.33 11SEP2016 6:03:43 SUP10 RIGHT 100 / 64 44 12 36.4

6:05:36 SUP1 RIGHT 95 / 68 44

6:09:56 STD3 RIGHT 99 / 70 58

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 6 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2004 1 2 1 0.33 11SEP2016 7:44:14 SUP5 RIGHT 125 / 68 46

7:45:18 SUP1 RIGHT 107 / 67 46

0.58 11SEP2016 7:59:30 SUP5 RIGHT 116 / 70 46

8:00:40 SUP1 RIGHT 114 / 75 45

1.08 11SEP2016 8:30:12 SUP5 RIGHT 117 / 70 42

8:31:22 SUP1 RIGHT 113 / 71 44

2.08 11SEP2016 9:28:48 SUP5 RIGHT 113 / 68 45

9:30:10 SUP1 RIGHT 100 / 69 45

3.08 11SEP2016 10:28:36 SUP5 RIGHT 106 / 67 46

10:30:24 SUP1 RIGHT 113 / 67 46

4.17 11SEP2016 11:34:06 SUP10 RIGHT 121 / 69 46 12 36.6

11:35:14 SUP1 RIGHT 113 / 69 47

11:38:55 STD3 RIGHT 121 / 80 73

6.08 11SEP2016 13:29:08 SUP5 RIGHT 110 / 71 58

13:30:32 SUP1 RIGHT 101 / 66 57

8.08 11SEP2016 15:29:22 SUP5 RIGHT 100 / 66 50

15:30:29 SUP1 RIGHT 101 / 60 51

12.17 11SEP2016 19:34:49 SUP10 RIGHT 105 / 69 53 20 37.1

19:35:58 SUP1 RIGHT 117 / 64 50

19:39:44 STD3 RIGHT 110 / 72 75

2 24.17 12SEP2016 7:38:33 SUP10 RIGHT 102 / 66 44 16 36.6

7:40:10 SUP1 RIGHT 105 / 67 45

7:44:31 STD3 RIGHT 120 / 87 66

36.08 12SEP2016 19:29:04 SUP5 RIGHT 80(\*) / 48 51 18 36.6

19:32:57 SUP1 RIGHT 85 / 55 53

R 19:34:17 SUP5 RIGHT 107 / 66

R 19:36:35 SUP1 RIGHT 114 / 67

3 48.08 13SEP2016 7:29:10 SUP5 RIGHT 114 / 69 51 12 36.6

7:30:11 SUP1 RIGHT 111 / 65 49

4 72.08 14SEP2016 7:31:50 SUP5 RIGHT 108 / 60 49 14 36.7

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 7 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2004 1 2 4 72.08 14SEP2016 7:34:47 SUP1 RIGHT 95 / 59 48

2006 Screen 2 30AUG2016 7:12:52 88.2 27.67

SUP10 RIGHT 118 / 61 51 10 36.8

7:13:59 SUP1 RIGHT 108 / 67 53

7:17:08 STD3 RIGHT 117 / 80 67

1 2 -3 -73.50 08SEP2016 5:58:31 89.3 28.00

-72.75 08SEP2016 6:39:43 SUP10 RIGHT 118 / 74 60 14 36.8

6:41:18 SUP1 RIGHT 118 / 66 59

6:44:39 STD3 RIGHT 136 / 89 71

-2 -48.17 09SEP2016 7:17:19 SUP5 RIGHT 104 / 70 58 12 37

7:18:30 SUP1 RIGHT 113 / 62 60

-1 -25.33 10SEP2016 6:06:47 SUP5 RIGHT 104 / 60 52 16 36.6

6:08:07 SUP1 RIGHT 102 / 63 52

1 -1.33 11SEP2016 6:09:38 SUP10 RIGHT 109 / 65 49 18 36.6

6:10:59 SUP1 RIGHT 103 / 60 51

6:14:31 STD3 RIGHT 119 / 71 63

0.33 11SEP2016 7:49:28 SUP5 RIGHT 102 / 55 45

7:51:03 SUP1 RIGHT 106 / 60 49

0.58 11SEP2016 8:05:04 SUP5 RIGHT 116 / 63 49

8:06:10 SUP1 RIGHT 117 / 67 54

1.08 11SEP2016 8:35:04 SUP5 RIGHT 120 / 67 49

8:36:37 SUP1 RIGHT 118 / 62 50

2.08 11SEP2016 9:35:01 SUP5 RIGHT 114 / 67 52

9:36:02 SUP1 RIGHT 119 / 66 50

3.08 11SEP2016 10:35:18 SUP5 RIGHT 112 / 62 49

10:36:18 SUP1 RIGHT 112 / 64 49

4.17 11SEP2016 11:34:15 SUP10 RIGHT 115 / 66 51 12 36.9

11:35:38 SUP1 RIGHT 120 / 64 51

11:38:45 STD3 RIGHT 149(\*)/ 86 76

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 8 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2006 1 2 1 6.08 11SEP2016 13:35:02 SUP5 RIGHT 115 / 63 64

13:36:05 SUP1 RIGHT 109 / 69 71

8.08 11SEP2016 15:34:50 SUP5 RIGHT 107 / 59 63

15:36:05 SUP1 RIGHT 102 / 64 64

12.17 11SEP2016 19:40:49 SUP10 RIGHT 111 / 63 62 16 37

19:42:25 SUP1 RIGHT 116 / 58 65

19:45:34 STD3 RIGHT 126 / 90 102(#)

2 24.17 12SEP2016 7:45:43 SUP10 RIGHT 124 / 73 54 16 36.2

7:47:32 SUP1 RIGHT 123 / 73 53

7:52:29 STD3 RIGHT 133 / 78 87

36.08 12SEP2016 19:36:10 SUP5 RIGHT 106 / 56 61 12 36.7

19:37:23 SUP1 RIGHT 103 / 60 60

3 48.08 13SEP2016 7:35:11 SUP5 RIGHT 115 / 61 53 10 36.6

7:36:19 SUP1 RIGHT 109 / 64 53

4 72.08 14SEP2016 7:36:13 SUP5 RIGHT 113 / 56 54 14 37.1

7:37:50 SUP1 RIGHT 101 / 60 50

2007 Screen 2 06SEP2016 8:00:49 66.7 23.96

SUP10 RIGHT 119 / 70 68 18 36.1

8:02:58 SUP1 RIGHT 115 / 70 68

8:06:22 STD3 RIGHT 104 / 72 75

1 2 -3 -73.50 08SEP2016 5:57:25 66.1 23.73

-72.75 08SEP2016 6:32:01 SUP10 RIGHT 115 / 72 64 10 37

6:33:34 SUP1 RIGHT 118 / 73 62

6:36:54 STD3 RIGHT 105 / 74 73

-2 -48.17 09SEP2016 7:20:01 SUP5 RIGHT 118 / 70 67 16 37.4

7:21:08 SUP1 RIGHT 113 / 66 71

-1 -25.33 10SEP2016 6:10:44 SUP5 RIGHT 119 / 74 66 14 36.8

6:12:07 SUP1 RIGHT 125 / 65 60

1 -1.33 11SEP2016 6:25:01 SUP10 RIGHT 112 / 65 68 10 37.1

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 9 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2007 1 2 1 -1.33 11SEP2016 6:26:34 SUP1 RIGHT 115 / 73 71

6:29:31 STD3 RIGHT 111 / 74 85

0.33 11SEP2016 7:53:01 SUP5 RIGHT 125 / 71 73

7:54:02 SUP1 RIGHT 112 / 66 64

0.58 11SEP2016 8:08:00 SUP5 RIGHT 114 / 76 67

8:09:01 SUP1 RIGHT 110 / 72 66

1.08 11SEP2016 8:38:04 SUP5 RIGHT 111 / 70 69

8:39:13 SUP1 RIGHT 111 / 76 68

2.08 11SEP2016 9:38:27 SUP5 RIGHT 109 / 71 65

9:39:36 SUP1 RIGHT 110 / 74 68

3.08 11SEP2016 10:37:39 SUP5 RIGHT 112 / 72 68

10:38:58 SUP1 RIGHT 115 / 74 65

4.17 11SEP2016 11:42:58 SUP10 RIGHT 117 / 77 67 14 37.1

11:44:40 SUP1 RIGHT 110 / 76 67

11:47:47 STD3 RIGHT 117 / 71 110(#)

6.08 11SEP2016 13:38:01 SUP5 RIGHT 113 / 66 83

13:39:03 SUP1 RIGHT 109 / 68 83

8.08 11SEP2016 15:38:56 SUP5 RIGHT 113 / 65 76

15:39:58 SUP1 RIGHT 114 / 73 75

12.17 11SEP2016 19:43:02 SUP10 RIGHT 113 / 68 70 18 37.3

19:44:10 SUP1 RIGHT 115 / 69 70

19:47:11 STD3 RIGHT 106 / 69 101(#)

2 24.17 12SEP2016 7:42:25 SUP10 RIGHT 129 / 71 63 14 37.1

7:44:08 SUP1 RIGHT 116 / 67 73

7:47:09 STD3 RIGHT 121 / 73 92

36.08 12SEP2016 19:39:10 SUP5 RIGHT 108 / 65 65 20 37.1

19:40:11 SUP1 RIGHT 109 / 70 70

3 48.08 13SEP2016 7:38:00 SUP5 RIGHT 122 / 65 64 16 37

7:39:07 SUP1 RIGHT 118 / 70 61

4 72.08 14SEP2016 7:38:36 SUP5 RIGHT 115 / 72 64 12 37.1

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 10 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2007 1 2 4 72.08 14SEP2016 7:40:01 SUP1 RIGHT 112 / 77 66

2008 Screen 2 07SEP2016 10:16:19 73.8 24.65

SUP10 RIGHT 132 / 74 52 10 36.7

10:17:36 SUP1 RIGHT 132 / 74 50

10:20:42 STD3 RIGHT 133 / 82 62

1 2 -3 -73.50 08SEP2016 6:01:53 73.7 24.62

-72.75 08SEP2016 6:48:03 SUP10 RIGHT 131 / 75 45 16 36.1

6:49:43 SUP1 RIGHT 131 / 79 45

6:52:45 STD3 RIGHT 137 / 82 63

-2 -48.17 09SEP2016 7:23:09 SUP5 RIGHT 121 / 67 48 14 36.8

7:24:13 SUP1 RIGHT 118 / 59 48

-1 -25.33 10SEP2016 6:13:01 SUP5 RIGHT 128 / 68 47 12 36.8

6:14:05 SUP1 RIGHT 125 / 70 47

1 -1.33 11SEP2016 6:16:24 SUP10 RIGHT 112 / 60 48 16 36.6

6:18:38 SUP1 RIGHT 116 / 62 49

6:23:40 STD3 RIGHT 89 / 53 68

0.33 11SEP2016 7:56:06 SUP5 RIGHT 112 / 61 54

7:57:44 SUP1 RIGHT 113 / 57 51

0.58 11SEP2016 8:11:09 SUP5 RIGHT 124 / 70 51

8:12:26 SUP1 RIGHT 116 / 63 50

1.08 11SEP2016 8:40:49 SUP5 RIGHT 123 / 72 50

8:42:05 SUP1 RIGHT 127 / 73 51

2.08 11SEP2016 9:45:20 SUP5 RIGHT 119 / 62 56

9:46:25 SUP1 RIGHT 123 / 69 56

3.08 11SEP2016 10:41:42 SUP5 RIGHT 130 / 70 56

10:42:56 SUP1 RIGHT 123 / 64 54

4.17 11SEP2016 11:41:14 SUP10 RIGHT 121 / 68 59 16 36.9

11:43:19 SUP1 RIGHT 116 / 68 54

11:46:27 STD3 RIGHT 137 / 77 88

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 11 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2008 1 2 1 6.08 11SEP2016 13:41:00 SUP5 RIGHT 125 / 65 59

13:42:04 SUP1 RIGHT 123 / 62 61

8.08 11SEP2016 15:41:00 SUP5 RIGHT 123 / 69 62

15:42:01 SUP1 RIGHT 122 / 64 58

12.17 11SEP2016 19:46:42 SUP10 RIGHT 126 / 68 60 14 37.6

19:47:57 SUP1 RIGHT 123 / 68 59

19:50:59 STD3 RIGHT 131 / 71 93

2 24.17 12SEP2016 7:48:08 SUP10 RIGHT 124 / 69 52 14 36.9

7:49:27 SUP1 RIGHT 124 / 70 57

7:52:56 STD3 RIGHT 125 / 74 115(#)

36.08 12SEP2016 19:41:00 SUP5 RIGHT 122 / 65 56 18 37

19:42:09 SUP1 RIGHT 124 / 66 57

3 48.08 13SEP2016 7:41:42 SUP5 RIGHT 130 / 65 55 12 36.7

7:42:42 SUP1 RIGHT 125 / 75 53

4 72.08 14SEP2016 7:42:43 SUP5 RIGHT 126 / 75 53 18 36.8

7:44:03 SUP1 RIGHT 119 / 63 56

2009 Screen 2 07SEP2016 7:08:14 70.6 24.24

SUP10 RIGHT 110 / 62 48 10 36.6

7:09:28 SUP1 RIGHT 110 / 67 47

7:12:34 STD3 RIGHT 113 / 70 70

1 2 -3 -73.50 08SEP2016 6:08:54 70.5 24.21

-72.75 08SEP2016 7:01:54 SUP10 RIGHT 107 / 62 50 14 36.3

7:02:58 SUP1 RIGHT 108 / 66 48

7:06:32 STD3 RIGHT 107 / 71 66

-2 -48.17 09SEP2016 7:26:00 SUP5 RIGHT 111 / 65 48 8 36.9

7:27:02 SUP1 RIGHT 110 / 71 51

-1 -25.33 10SEP2016 6:18:00 SUP5 RIGHT 108 / 68 48 16 36.9

6:19:11 SUP1 RIGHT 115 / 66 47

1 -1.33 11SEP2016 6:18:59 SUP10 RIGHT 106 / 64 48 12 36.8

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 12 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2009 1 2 1 -1.33 11SEP2016 6:20:33 SUP1 RIGHT 108 / 67 45

6:24:06 STD3 RIGHT 112 / 74 89

0.33 11SEP2016 7:59:00 SUP5 RIGHT 116 / 73 55

8:00:02 SUP1 RIGHT 113 / 71 57

0.58 11SEP2016 8:14:12 SUP5 RIGHT 117 / 78 49

8:15:23 SUP1 RIGHT 120 / 72 58

1.08 11SEP2016 8:44:05 SUP5 RIGHT 119 / 74 49

8:45:24 SUP1 RIGHT 124 / 72 50

2.08 11SEP2016 9:43:36 SUP5 RIGHT 107 / 75 52

9:44:52 SUP1 RIGHT 107 / 70 50

3.08 11SEP2016 10:43:44 SUP5 RIGHT 113 / 72 53

10:45:10 SUP1 RIGHT 109 / 79 55

4.17 11SEP2016 11:49:18 SUP10 RIGHT 110 / 73 49 10 36.6

11:50:24 SUP1 RIGHT 110 / 69 55

11:53:43 STD3 RIGHT 127 / 72 117(#)

6.08 11SEP2016 13:43:59 SUP5 RIGHT 111 / 70 60

13:45:00 SUP1 RIGHT 107 / 72 59

8.08 11SEP2016 15:43:57 SUP5 RIGHT 108 / 68 61

15:44:59 SUP1 RIGHT 112 / 68 64

12.17 11SEP2016 19:49:04 SUP10 RIGHT 109 / 69 56 14 37

19:50:22 SUP1 RIGHT 110 / 69 61

19:53:31 STD3 RIGHT 120 / 75 111(#)

2 24.17 12SEP2016 7:54:50 SUP10 RIGHT 126 / 70 50 12 36.4

7:56:01 SUP1 RIGHT 122 / 73 52

7:59:11 STD3 RIGHT 125 / 71 106(#)

36.08 12SEP2016 19:43:40 SUP5 RIGHT 97 / 54 66 12 37.1

19:45:45 SUP1 RIGHT 106 / 66 68

3 48.08 13SEP2016 7:44:00 SUP5 RIGHT 109 / 68 55 12 37

7:45:01 SUP1 RIGHT 110 / 70 57

4 72.08 14SEP2016 7:46:16 SUP5 RIGHT 108 / 67 52 12 36.7

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 13 of 13

Table 2.6.1 Vital Signs

Blood Pressure (mmHg) Respir- Temper-

Subject Study ----------------------------------- Pulse ation ature Weight BMI

Number Period Cohort Day Hour Date Time Test Arm Systolic/Diastolic (bpm) (rpm) (°C) (kg) (kg/m²)

-------------------------------------------------------------------------------------------------------------------------------------

2009 1 2 4 72.08 14SEP2016 7:47:30 SUP1 RIGHT 106 / 70 51

Note: SUP1 = 1-minute supine, SUP5 = 5-minute supine, SUP10 = 10-minute supine, STD3 = 3-minute standing, R = Recheck value

Cohort 2 = 100 mg TD-1439 or placebo

\* = Systolic is less than 85 or greater than 140

^ = Diastolic is less than 45 or greater than 90

# = Pulse is less than 40 or greater than 100

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit.sas 15SEP2016 18:57

Page 1 of 5

Table 2.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

2001 1 2 1 Baseline 11SEP2016 SUP RIGHT 107.5/ 59.5 69.5 14 37.1

STD RIGHT 110.0/ 68.0 87.0

0.33 11SEP2016 SUP RIGHT 5.0/ 4.5 2.5

0.58 11SEP2016 SUP RIGHT -2.0/ 2.5 -3.5

1.08 11SEP2016 SUP RIGHT -0.5/ -2.5 -2.0

2.08 11SEP2016 SUP RIGHT 3.5/ -2.0 -2.0

3.08 11SEP2016 SUP RIGHT 1.5/ 9.0 -1.0

4.17 11SEP2016 SUP RIGHT 0.5/ 2.5 -3.5 2 0.0

STD RIGHT 2.0/ 5.0 -5.0

6.08 11SEP2016 SUP RIGHT -1.0/ 1.0 -0.5

8.08 11SEP2016 SUP RIGHT 1.0/ -3.5 8.5

12.17 11SEP2016 SUP RIGHT -2.0/ 0.5 4.5 2 0.5

STD RIGHT 2.0/ 3.0 -1.0

2 24.17 12SEP2016 SUP RIGHT -4.0/ 3.5 -5.0 2 0.0

STD RIGHT -10.0/ -8.0 -3.0

36.08 12SEP2016 SUP RIGHT -0.5/ 0.0 5.0 0 0.0

3 48.08 13SEP2016 SUP RIGHT 3.0/ 4.5 -6.0 -2 -0.1

4 72.08 14SEP2016 SUP RIGHT -13.5/-10.0 -2.0 4 0.5

2002 1 2 1 Baseline 11SEP2016 SUP RIGHT 115.0/ 64.5 65.5 14 36.8

STD RIGHT 123.0/ 71.0 86.0

0.33 11SEP2016 SUP RIGHT 6.5/ 0.0 -0.5

0.58 11SEP2016 SUP RIGHT -3.0/ -4.5 -4.0

1.08 11SEP2016 SUP RIGHT 4.0/ -3.0 1.0

2.08 11SEP2016 SUP RIGHT 7.5/ 1.0 -0.5

3.08 11SEP2016 SUP RIGHT 5.0/ -1.0 2.0

4.17 11SEP2016 SUP RIGHT 2.5/ -2.0 1.5 4 0.3

STD RIGHT -13.0/ -2.0 18.0

6.08 11SEP2016 SUP RIGHT -5.0/ -4.0 14.0

8.08 11SEP2016 SUP RIGHT -11.5/ -4.0 6.0

12.17 11SEP2016 SUP RIGHT 5.0/ -3.5 6.5 2 0.3

Note: SUP = Supine, STD = Standing

Cohort 2 = 100 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 2 of 5

Table 2.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

2002 1 2 1 12.17 11SEP2016 STD RIGHT -2.0/ -6.0 12.0

2 24.17 12SEP2016 SUP RIGHT 16.5/ 9.5 4.5 6 -0.8

STD RIGHT 10.0/ -3.0 19.0

36.08 12SEP2016 SUP RIGHT -14.5/ -8.0 1.0 4 -0.8

3 48.08 13SEP2016 SUP RIGHT 7.5/ -0.5 4.5 0 0.1

4 72.08 14SEP2016 SUP RIGHT 6.5/ 7.0 2.5 0 0.3

2003 1 2 1 Baseline 11SEP2016 SUP RIGHT 115.0/ 68.5 71.5 10 37.6

STD RIGHT 119.0/ 80.0 85.0

0.33 11SEP2016 SUP RIGHT -21.0/ -4.0 0.5

0.58 11SEP2016 SUP RIGHT 4.5/ 3.5 -4.5

1.08 11SEP2016 SUP RIGHT -3.0/ 7.5 -2.5

2.08 11SEP2016 SUP RIGHT 5.5/ 4.0 2.0

3.08 11SEP2016 SUP RIGHT 7.0/ 6.0 -3.5

4.17 11SEP2016 SUP RIGHT -1.0/ -2.0 0.0 10 -0.6

STD RIGHT 4.0/-15.0 7.0

6.08 11SEP2016 SUP RIGHT 1.0/-12.0 14.5

8.08 11SEP2016 SUP RIGHT -4.5/ 1.0 -1.5

12.17 11SEP2016 SUP RIGHT 6.0/ 1.5 2.0 10 -0.2

STD RIGHT -1.0/ 2.0 14.0

2 24.17 12SEP2016 SUP RIGHT -1.5/ 1.0 0.5 14 -0.6

STD RIGHT -3.0/-12.0 12.0

36.08 12SEP2016 SUP RIGHT -7.0/ -9.0 14.0 10 -0.4

3 48.08 13SEP2016 SUP RIGHT -2.0/ -2.5 1.0 4 -0.8

4 72.08 14SEP2016 SUP RIGHT 11.0/ 5.0 5.5 6 -0.4

2004 1 2 1 Baseline 11SEP2016 SUP RIGHT 97.5/ 66.0 44.0 12 36.4

STD RIGHT 99.0/ 70.0 58.0

0.33 11SEP2016 SUP RIGHT 18.5/ 1.5 2.0

0.58 11SEP2016 SUP RIGHT 17.5/ 6.5 1.5

1.08 11SEP2016 SUP RIGHT 17.5/ 4.5 -1.0

Note: SUP = Supine, STD = Standing

Cohort 2 = 100 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 3 of 5

Table 2.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

2004 1 2 1 2.08 11SEP2016 SUP RIGHT 9.0/ 2.5 1.0

3.08 11SEP2016 SUP RIGHT 12.0/ 1.0 2.0

4.17 11SEP2016 SUP RIGHT 19.5/ 3.0 2.5 0 0.2

STD RIGHT 22.0/ 10.0 15.0

6.08 11SEP2016 SUP RIGHT 8.0/ 2.5 13.5

8.08 11SEP2016 SUP RIGHT 3.0/ -3.0 6.5

12.17 11SEP2016 SUP RIGHT 13.5/ 0.5 7.5 8 0.7

STD RIGHT 11.0/ 2.0 17.0

2 24.17 12SEP2016 SUP RIGHT 6.0/ 0.5 0.5 4 0.2

STD RIGHT 21.0/ 17.0 8.0

36.08 12SEP2016 SUP RIGHT -15.0/-14.5 8.0 6 0.2

3 48.08 13SEP2016 SUP RIGHT 15.0/ 1.0 6.0 0 0.2

4 72.08 14SEP2016 SUP RIGHT 4.0/ -6.5 4.5 2 0.3

2006 1 2 1 Baseline 11SEP2016 SUP RIGHT 106.0/ 62.5 50.0 18 36.6

STD RIGHT 119.0/ 71.0 63.0

0.33 11SEP2016 SUP RIGHT -2.0/ -5.0 -3.0

0.58 11SEP2016 SUP RIGHT 10.5/ 2.5 1.5

1.08 11SEP2016 SUP RIGHT 13.0/ 2.0 -0.5

2.08 11SEP2016 SUP RIGHT 10.5/ 4.0 1.0

3.08 11SEP2016 SUP RIGHT 6.0/ 0.5 -1.0

4.17 11SEP2016 SUP RIGHT 11.5/ 2.5 1.0 -6 0.3

STD RIGHT 30.0/ 15.0 13.0

6.08 11SEP2016 SUP RIGHT 6.0/ 3.5 17.5

8.08 11SEP2016 SUP RIGHT -1.5/ -1.0 13.5

12.17 11SEP2016 SUP RIGHT 7.5/ -2.0 13.5 -2 0.4

STD RIGHT 7.0/ 19.0 39.0

2 24.17 12SEP2016 SUP RIGHT 17.5/ 10.5 3.5 -2 -0.4

STD RIGHT 14.0/ 7.0 24.0

36.08 12SEP2016 SUP RIGHT -1.5/ -4.5 10.5 -6 0.1

3 48.08 13SEP2016 SUP RIGHT 6.0/ 0.0 3.0 -8 0.0

Note: SUP = Supine, STD = Standing

Cohort 2 = 100 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 4 of 5

Table 2.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

2006 1 2 4 72.08 14SEP2016 SUP RIGHT 1.0/ -4.5 2.0 -4 0.5

2007 1 2 1 Baseline 11SEP2016 SUP RIGHT 113.5/ 69.0 69.5 10 37.1

STD RIGHT 111.0/ 74.0 85.0

0.33 11SEP2016 SUP RIGHT 5.0/ -0.5 -1.0

0.58 11SEP2016 SUP RIGHT -1.5/ 5.0 -3.0

1.08 11SEP2016 SUP RIGHT -2.5/ 4.0 -1.0

2.08 11SEP2016 SUP RIGHT -4.0/ 3.5 -3.0

3.08 11SEP2016 SUP RIGHT 0.0/ 4.0 -3.0

4.17 11SEP2016 SUP RIGHT 0.0/ 7.5 -2.5 4 0.0

STD RIGHT 6.0/ -3.0 25.0

6.08 11SEP2016 SUP RIGHT -2.5/ -2.0 13.5

8.08 11SEP2016 SUP RIGHT 0.0/ 0.0 6.0

12.17 11SEP2016 SUP RIGHT 0.5/ -0.5 0.5 8 0.2

STD RIGHT -5.0/ -5.0 16.0

2 24.17 12SEP2016 SUP RIGHT 9.0/ 0.0 -1.5 4 0.0

STD RIGHT 10.0/ -1.0 7.0

36.08 12SEP2016 SUP RIGHT -5.0/ -1.5 -2.0 10 0.0

3 48.08 13SEP2016 SUP RIGHT 6.5/ -1.5 -7.0 6 -0.1

4 72.08 14SEP2016 SUP RIGHT 0.0/ 5.5 -4.5 2 0.0

2008 1 2 1 Baseline 11SEP2016 SUP RIGHT 114.0/ 61.0 48.5 16 36.6

STD RIGHT 89.0/ 53.0 68.0

0.33 11SEP2016 SUP RIGHT -1.5/ -2.0 4.0

0.58 11SEP2016 SUP RIGHT 6.0/ 5.5 2.0

1.08 11SEP2016 SUP RIGHT 11.0/ 11.5 2.0

2.08 11SEP2016 SUP RIGHT 7.0/ 4.5 7.5

3.08 11SEP2016 SUP RIGHT 12.5/ 6.0 6.5

4.17 11SEP2016 SUP RIGHT 4.5/ 7.0 8.0 0 0.3

STD RIGHT 48.0/ 24.0 20.0

6.08 11SEP2016 SUP RIGHT 10.0/ 2.5 11.5

Note: SUP = Supine, STD = Standing

Cohort 2 = 100 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 5 of 5

Table 2.6.2 Vital Signs - Change From Baseline

Blood Pressure (mmHg) Respir- Temper-

Subject Study --------------------------------- Pulse ation ature

Number Period Cohort Day Hour Date Test Arm Systolic/Diastolic (bpm) (rpm) (°C)

------------------------------------------------------------------------------------------------------------

2008 1 2 1 8.08 11SEP2016 SUP RIGHT 8.5/ 5.5 11.5

12.17 11SEP2016 SUP RIGHT 10.5/ 7.0 11.0 -2 1.0

STD RIGHT 42.0/ 18.0 25.0

2 24.17 12SEP2016 SUP RIGHT 10.0/ 8.5 6.0 -2 0.3

STD RIGHT 36.0/ 21.0 47.0

36.08 12SEP2016 SUP RIGHT 9.0/ 4.5 8.0 2 0.4

3 48.08 13SEP2016 SUP RIGHT 13.5/ 9.0 5.5 -4 0.1

4 72.08 14SEP2016 SUP RIGHT 8.5/ 8.0 6.0 2 0.2

2009 1 2 1 Baseline 11SEP2016 SUP RIGHT 107.0/ 65.5 46.5 12 36.8

STD RIGHT 112.0/ 74.0 89.0

0.33 11SEP2016 SUP RIGHT 7.5/ 6.5 9.5

0.58 11SEP2016 SUP RIGHT 11.5/ 9.5 7.0

1.08 11SEP2016 SUP RIGHT 14.5/ 7.5 3.0

2.08 11SEP2016 SUP RIGHT 0.0/ 7.0 4.5

3.08 11SEP2016 SUP RIGHT 4.0/ 10.0 7.5

4.17 11SEP2016 SUP RIGHT 3.0/ 5.5 5.5 -2 -0.2

STD RIGHT 15.0/ -2.0 28.0

6.08 11SEP2016 SUP RIGHT 2.0/ 5.5 13.0

8.08 11SEP2016 SUP RIGHT 3.0/ 2.5 16.0

12.17 11SEP2016 SUP RIGHT 2.5/ 3.5 12.0 2 0.2

STD RIGHT 8.0/ 1.0 22.0

2 24.17 12SEP2016 SUP RIGHT 17.0/ 6.0 4.5 0 -0.4

STD RIGHT 13.0/ -3.0 17.0

36.08 12SEP2016 SUP RIGHT -5.5/ -5.5 20.5 0 0.3

3 48.08 13SEP2016 SUP RIGHT 2.5/ 3.5 9.5 0 0.2

4 72.08 14SEP2016 SUP RIGHT 0.0/ 3.0 5.0 0 -0.1

Note: SUP = Supine, STD = Standing

Cohort 2 = 100 mg TD-1439 or placebo

Baseline is defined as the measurement collected closest and prior to dosing which will generally be the measurement obtained

predose on Day 1.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_Change.sas 15SEP2016 18:57

Page 1 of 2

Table 2.6.3 Vital Signs - Supine Averages and Respective Orthostatic Changes

Average of Supine Standing Orthostatic Change@

Subject Study ------------------------ ------------------------ ---------------------------

Number Period Cohort Day Hour Systolic/Diastolic Pulse Systolic/Diastolic Pulse Systolic/Diastolic Pulse

--------------------------------------------------------------------------------------------------------------------

2001 Screen 2 110.5/60.0 59.0 115/ 79 71 -4.5 /-19.0 12.0

1 2 -3 -72.75 109.0/61.0 60.5 124/ 83 71 -15.0 /-22.0 10.5

1 -1.33 107.5/59.5 69.5 110/ 68 87 -2.5 / -8.5 17.5

4.17 108.0/62.0 66.0 112/ 73 82 -4.0 /-11.0 16.0

12.17 105.5/60.0 74.0 112/ 71 86 -6.5 /-11.0 12.0

2 24.17 103.5/63.0 64.5 100/ 60 84 3.5 / 3.0 19.5

2002 Screen 2 118.0/65.5 63.0 126/ 75 84 -8.0 / -9.5 21.0

1 2 -3 -72.75 127.5/68.0 68.5 140/ 77 90 -12.5 / -9.0 21.5

1 -1.33 115.0/64.5 65.5 123/ 71 86 -8.0 / -6.5 20.5

4.17 117.5/62.5 67.0 110/ 69 104 7.5 / -6.5 37.0(#)

12.17 120.0/61.0 72.0 121/ 65 98 -1.0 / -4.0 26.0

2 24.17 131.5/74.0 70.0 133/ 68 105 -1.5 / 6.0 35.0(#)

2003 Screen 2 110.5/73.5 72.0 120/ 75 86 -9.5 / -1.5 14.0

1 2 -3 -72.75 113.0/71.0 77.5 129/ 84 85 -16.0 /-13.0 7.5

1 -1.33 115.0/68.5 71.5 119/ 80 85 -4.0 /-11.5 13.5

4.17 114.0/66.5 71.5 123/ 65 92 -9.0 / 1.5 20.5

12.17 121.0/70.0 73.5 118/ 82 99 3.0 /-12.0 25.5

2 24.17 113.5/69.5 72.0 116/ 68 97 -2.5 / 1.5 25.0

2004 Screen 2 114.5/66.5 46.0 120/ 88 56 -5.5 /-21.5 10.0

1 2 -3 -72.75 115.0/70.0 45.5 124/ 75 57 -9.0 / -5.0 11.5

1 -1.33 97.5/66.0 44.0 99/ 70 58 -1.5 / -4.0 14.0

4.17 117.0/69.0 46.5 121/ 80 73 -4.0 /-11.0 26.5

12.17 111.0/66.5 51.5 110/ 72 75 1.0 / -5.5 23.5

2 24.17 103.5/66.5 44.5 120/ 87 66 -16.5 /-20.5 21.5

2006 Screen 2 113.0/64.0 52.0 117/ 80 67 -4.0 /-16.0 15.0

Note: @ Change in pulse is calculated by subtracting supine measurement (averages) from standing measurement, and change in blood pressure

is calculated by subtracting standing measurement from supine measurement (averages).

\* = Systolic change is at least 20

^ = Diastolic change is at least 10

# = Pulse change is at least 30

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_orthostatic.sas 15SEP2016 18:57

Page 2 of 2

Table 2.6.3 Vital Signs - Supine Averages and Respective Orthostatic Changes

Average of Supine Standing Orthostatic Change@

Subject Study ------------------------ ------------------------ ---------------------------

Number Period Cohort Day Hour Systolic/Diastolic Pulse Systolic/Diastolic Pulse Systolic/Diastolic Pulse

--------------------------------------------------------------------------------------------------------------------

2006 1 2 -3 -72.75 118.0/70.0 59.5 136/ 89 71 -18.0 /-19.0 11.5

1 -1.33 106.0/62.5 50.0 119/ 71 63 -13.0 / -8.5 13.0

4.17 117.5/65.0 51.0 149/ 86 76 -31.5 /-21.0 25.0

12.17 113.5/60.5 63.5 126/ 90 102 -12.5 /-29.5 38.5(#)

2 24.17 123.5/73.0 53.5 133/ 78 87 -9.5 / -5.0 33.5(#)

2007 Screen 2 117.0/70.0 68.0 104/ 72 75 13.0 / -2.0 7.0

1 2 -3 -72.75 116.5/72.5 63.0 105/ 74 73 11.5 / -1.5 10.0

1 -1.33 113.5/69.0 69.5 111/ 74 85 2.5 / -5.0 15.5

4.17 113.5/76.5 67.0 117/ 71 110 -3.5 / 5.5 43.0(#)

12.17 114.0/68.5 70.0 106/ 69 101 8.0 / -0.5 31.0(#)

2 24.17 122.5/69.0 68.0 121/ 73 92 1.5 / -4.0 24.0

2008 Screen 2 132.0/74.0 51.0 133/ 82 62 -1.0 / -8.0 11.0

1 2 -3 -72.75 131.0/77.0 45.0 137/ 82 63 -6.0 / -5.0 18.0

1 -1.33 114.0/61.0 48.5 89/ 53 68 25.0(\*)/ 8.0 19.5

4.17 118.5/68.0 56.5 137/ 77 88 -18.5 / -9.0 31.5(#)

12.17 124.5/68.0 59.5 131/ 71 93 -6.5 / -3.0 33.5(#)

2 24.17 124.0/69.5 54.5 125/ 74 115 -1.0 / -4.5 60.5(#)

2009 Screen 2 110.0/64.5 47.5 113/ 70 70 -3.0 / -5.5 22.5

1 2 -3 -72.75 107.5/64.0 49.0 107/ 71 66 0.5 / -7.0 17.0

1 -1.33 107.0/65.5 46.5 112/ 74 89 -5.0 / -8.5 42.5(#)

4.17 110.0/71.0 52.0 127/ 72 117 -17.0 / -1.0 65.0(#)

12.17 109.5/69.0 58.5 120/ 75 111 -10.5 / -6.0 52.5(#)

2 24.17 124.0/71.5 51.0 125/ 71 106 -1.0 / 0.5 55.0(#)

Note: @ Change in pulse is calculated by subtracting supine measurement (averages) from standing measurement, and change in blood pressure

is calculated by subtracting standing measurement from supine measurement (averages).

\* = Systolic change is at least 20

^ = Diastolic change is at least 10

# = Pulse change is at least 30

Cohort 2 = 100 mg TD-1439 or placebo

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_vit\_orthostatic.sas 15SEP2016 18:57

Page 1 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

2001 Screen 2 F 1 0.00 16AUG2016 NO 11:41:33 NORMAL 60 140 90 420 420

0.02 16AUG2016 NO 11:42:37 NORMAL 61 140 92 418 420

0.03 16AUG2016 NO 11:43:39 NORMAL 63 140 92 420 427

1 2 F -3 -73.00 08SEP2016 NO 6:25:25 NORMAL 66 154 94 418 431

-72.98 08SEP2016 NO 6:26:40 NORMAL 59 152 96 422 420

-72.97 08SEP2016 NO 6:27:40 NORMAL 63 156 96 420 427

1 -1.48 11SEP2016 NO 5:46:02 NORMAL 65 146 93 404 415

-1.47 11SEP2016 NO 5:47:04 NORMAL 63 144 92 407 414

-1.45 11SEP2016 NO 5:48:06 NORMAL 69 144 92 406 425

-0.98 11SEP2016 NO 6:15:17 NORMAL 63 148 93 416 423

-0.97 11SEP2016 NO 6:16:11 NORMAL 61 147 93 419 421

-0.95 11SEP2016 NO 6:17:05 NORMAL 63 147 92 418 425

-0.48 11SEP2016 YES 6:46:03 NORMAL 62 144 94 420 425

-0.47 11SEP2016 YES 6:47:04 NORMAL 61 143 93 421 423

-0.45 11SEP2016 YES 6:48:06 NORMAL 67 137 93 420 436

0.17 11SEP2016 YES 7:25:03 NORMAL 65 141 93 415 426

0.18 11SEP2016 YES 7:25:44 NORMAL 66 143 92 415 428

0.20 11SEP2016 YES 7:26:21 NORMAL 68 146 92 415 433

0.42 11SEP2016 YES 7:40:07 NORMAL 72 148 92 402 427

0.43 11SEP2016 YES 7:41:03 NORMAL 71 144 94 406 429

0.45 11SEP2016 YES 7:41:51 NORMAL 78 143 92 399 435

0.92 11SEP2016 YES 8:10:02 NORMAL 65 147 92 413 424

0.93 11SEP2016 YES 8:10:41 NORMAL 65 148 93 414 425

0.95 11SEP2016 YES 8:11:18 NORMAL 67 145 94 413 428

1.92 11SEP2016 YES 9:10:03 NORMAL 64 146 93 419 428

1.93 11SEP2016 YES 9:10:39 NORMAL 63 147 91 419 426

1.95 11SEP2016 YES 9:11:18 NORMAL 65 143 94 422 433

2.92 11SEP2016 YES 10:10:08 NORMAL 66 144 92 412 425

2.93 11SEP2016 YES 10:11:04 NORMAL 67 149 92 411 426

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 2 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

2001 1 2 F 1 2.95 11SEP2016 YES 10:12:04 NORMAL 71 147 93 409 433

3.92 11SEP2016 YES 11:10:04 NORMAL 67 146 92 418 434

3.93 11SEP2016 YES 11:11:12 NORMAL 66 144 92 420 434

3.95 11SEP2016 YES 11:12:11 NORMAL 67 144 92 418 434

5.92 11SEP2016 YES 13:10:13 NORMAL 68 150 94 399 416

5.93 11SEP2016 YES 13:10:59 NORMAL 69 149 93 397 416

5.95 11SEP2016 YES 13:11:43 NORMAL 65 151 92 399 410

7.92 11SEP2016 YES 15:10:01 NORMAL 78 141 90 395 431

7.93 11SEP2016 YES 15:11:01 NORMAL 80 140 92 393 433

7.95 11SEP2016 YES 15:12:01 NORMAL 79 142 92 394 432

11.92 11SEP2016 YES 19:10:02 NORMAL 73 139 91 403 430

11.93 11SEP2016 YES 19:11:02 NORMAL 74 140 91 402 431

11.95 11SEP2016 YES 19:12:02 NORMAL 74 139 91 404 433

2 23.92 12SEP2016 YES 7:10:01 NORMAL 67 142 93 412 427

23.93 12SEP2016 YES 7:11:03 NORMAL 67 145 93 413 428

23.95 12SEP2016 YES 7:12:05 NORMAL 66 146 93 413 426

36.17 12SEP2016 YES 19:25:01 NORMAL 74 142 94 402 431

36.18 12SEP2016 YES 19:25:47 NORMAL 75 144 94 400 431

36.20 12SEP2016 YES 19:26:20 NORMAL 76 130 94 404 437

3 48.17 13SEP2016 YES 7:25:01 NORMAL 63 148 104 422 429

48.18 13SEP2016 YES 7:25:54 NORMAL 65 146 106 424 435

48.20 13SEP2016 YES 7:26:36 NORMAL 63 146 104 424 431

2002 Screen 2 F 1 0.00 16AUG2016 NO 11:25:18 NORMAL 63 158 102 412 419

0.02 16AUG2016 NO 11:26:40 NORMAL 66 166 102 410 423

0.03 16AUG2016 NO 11:27:39 NORMAL 67 168 102 410 425

1 2 F -3 -73.00 08SEP2016 NO 6:33:28 NORMAL 71 170 102 390 413

-72.98 08SEP2016 NO 6:34:06 NORMAL 71 172 102 394 417

-72.97 08SEP2016 NO 6:34:46 NORMAL 69 172 102 394 413

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 3 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

2002 1 2 F 1 -1.48 11SEP2016 NO 5:46:24 NORMAL 67 173 90 391 406 ECG TAKEN IN ERROR

11SEP2016 NO 5:49:00 NORMAL 67 165 91 392 407

-1.47 11SEP2016 NO 5:50:00 NORMAL 64 171 102 398 407

-1.45 11SEP2016 NO 5:51:00 NORMAL 64 170 103 400 409

-0.98 11SEP2016 NO 6:18:04 NORMAL 63 171 104 407 414

-0.97 11SEP2016 NO 6:20:04 NORMAL 61 172 105 411 413

-0.95 11SEP2016 NO 6:21:06 NORMAL 59 172 104 415 413

-0.48 11SEP2016 YES 6:49:00 NORMAL 63 167 103 406 413

-0.47 11SEP2016 YES 6:50:00 NORMAL 58 167 104 410 405

-0.45 11SEP2016 YES 6:51:00 NORMAL 63 173 104 411 418

0.17 11SEP2016 YES 7:28:00 NORMAL 64 166 93 402 411

0.18 11SEP2016 YES 7:28:37 NORMAL 59 163 90 403 401

0.20 11SEP2016 YES 7:29:17 NORMAL 64 167 103 403 412

0.42 11SEP2016 YES 7:43:01 NORMAL 67 168 92 398 413

0.43 11SEP2016 YES 7:44:02 NORMAL 61 164 92 403 405

0.45 11SEP2016 YES 7:45:03 NORMAL 61 166 89 405 407

0.92 11SEP2016 YES 8:13:10 NORMAL 65 168 90 396 407

0.93 11SEP2016 YES 8:13:45 NORMAL 70 168 104 398 419

0.95 11SEP2016 YES 8:14:29 NORMAL 68 169 90 397 414

1.92 11SEP2016 YES 9:13:18 NORMAL 64 167 89 405 414

1.93 11SEP2016 YES 9:14:10 NORMAL 61 163 90 409 411

1.95 11SEP2016 YES 9:14:45 NORMAL 62 167 103 410 415

2.92 11SEP2016 YES 10:13:06 NORMAL 66 158 89 393 406

2.93 11SEP2016 YES 10:13:47 NORMAL 63 164 89 392 398

2.95 11SEP2016 YES 10:14:21 NORMAL 67 166 89 396 411

3.92 11SEP2016 YES 11:12:53 NORMAL 67 169 102 397 412

3.93 11SEP2016 YES 11:13:47 NORMAL 77 167 88 387 421

3.95 11SEP2016 YES 11:14:30 NORMAL 64 167 90 395 404

5.92 11SEP2016 YES 13:13:01 NORMAL 75 162 90 372 401

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 4 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

2002 1 2 F 1 5.93 11SEP2016 YES 13:13:42 NORMAL 77 164 103 376 409

5.95 11SEP2016 YES 13:14:30 NORMAL 76 164 104 380 411

7.92 11SEP2016 YES 15:13:01 NORMAL 72 164 89 380 404

7.93 11SEP2016 YES 15:13:37 NORMAL 76 164 87 379 410

7.95 11SEP2016 YES 15:14:35 NORMAL 79 162 88 373 409

11.92 11SEP2016 YES 19:13:02 NORMAL 65 161 87 389 400

11.93 11SEP2016 YES 19:13:38 NORMAL 71 163 86 385 407

11.95 11SEP2016 YES 19:14:11 NORMAL 72 162 86 383 407

2 23.92 12SEP2016 YES 7:12:27 NORMAL 71 161 89 382 404

23.93 12SEP2016 YES 7:13:07 NORMAL 73 170 88 379 405

23.95 12SEP2016 YES 7:13:37 NORMAL 71 170 89 383 405

36.17 12SEP2016 YES 19:28:01 NORMAL 68 170 100 386 402

36.18 12SEP2016 YES 19:28:38 NORMAL 71 164 102 390 413

36.20 12SEP2016 YES 19:29:13 NORMAL 73 164 104 388 414

3 48.17 13SEP2016 YES 7:30:37 NORMAL 68 172 102 390 407

48.18 13SEP2016 YES 7:31:37 NORMAL 70 178 100 390 411

48.20 13SEP2016 YES 7:32:38 NORMAL 65 170 102 398 409

2003 Screen 2 M 1 0.00 28AUG2016 NO 8:50:09 NORMAL 71 152 90 392 415

0.02 28AUG2016 NO 8:51:11 NORMAL 71 152 90 390 413

0.03 28AUG2016 NO 8:52:13 NORMAL 73 154 88 390 416

1 2 M -3 -73.00 08SEP2016 NO 6:43:50 NORMAL 78 156 90 382 417

-72.98 08SEP2016 NO 6:44:38 NORMAL 77 158 86 382 415

-72.97 08SEP2016 NO 6:45:16 NORMAL 80 156 88 380 418

1 -1.48 11SEP2016 NO 5:53:16 NORMAL 69 154 90 379 397

-1.47 11SEP2016 NO 5:54:05 NORMAL 69 156 90 379 397

-1.45 11SEP2016 NO 5:55:07 NORMAL 67 155 89 385 399

-0.98 11SEP2016 NO 6:22:02 NORMAL 71 154 89 384 406

-0.97 11SEP2016 NO 6:23:34 NORMAL 68 155 89 384 400

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 5 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2003 1 2 M 1 -0.95 11SEP2016 NO 6:24:21 NORMAL 68 156 89 385 401

-0.48 11SEP2016 YES 6:52:03 NORMAL 72 149 90 383 407

-0.47 11SEP2016 YES 6:52:47 NORMAL 71 149 90 384 406

-0.45 11SEP2016 YES 6:53:30 NORMAL 73 150 90 384 410

0.17 11SEP2016 YES 7:31:06 NORMAL 68 153 89 379 395

0.18 11SEP2016 YES 7:31:50 NORMAL 69 153 89 381 399

0.20 11SEP2016 YES 7:32:24 NORMAL 71 155 90 385 407

0.42 11SEP2016 YES 7:46:08 NORMAL 71 154 90 379 401

0.43 11SEP2016 YES 7:46:57 NORMAL 76 151 90 381 412

0.45 11SEP2016 YES 7:47:46 NORMAL 71 155 89 381 403

0.92 11SEP2016 YES 8:16:04 NORMAL 74 145 89 372 399

0.93 11SEP2016 YES 8:16:37 NORMAL 70 146 88 373 393

0.95 11SEP2016 YES 8:17:10 NORMAL 71 145 90 378 400

1.92 11SEP2016 YES 9:16:03 NORMAL 78 144 90 373 407

1.93 11SEP2016 YES 9:16:36 NORMAL 72 143 88 372 395

1.95 11SEP2016 YES 9:17:11 NORMAL 77 144 90 372 404

2.92 11SEP2016 YES 10:15:58 NORMAL 76 144 89 368 398

2.93 11SEP2016 YES 10:17:11 NORMAL 65 143 81 375 385

2.95 11SEP2016 YES 10:18:28 NORMAL 76 148 88 372 402

3.92 11SEP2016 YES 11:16:07 NORMAL 72 143 89 377 401

3.93 11SEP2016 YES 11:17:07 NORMAL 69 146 78 382 400

3.95 11SEP2016 YES 11:18:05 NORMAL 73 141 88 372 397

5.92 11SEP2016 YES 13:16:02 NORMAL 92 132 77 335 386

5.93 11SEP2016 YES 13:16:54 NORMAL 94 133 77 335 389

5.95 11SEP2016 YES 13:17:28 NORMAL 90 138 73 334 382

7.92 11SEP2016 YES 15:16:01 NORMAL 74 138 80 368 395

7.93 11SEP2016 YES 15:18:06 NORMAL 73 138 87 368 393

7.95 11SEP2016 YES 15:19:09 NORMAL 69 137 86 372 390

11.92 11SEP2016 YES 19:16:01 NORMAL 80 139 83 357 393

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 6 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2003 1 2 M 1 11.93 11SEP2016 YES 19:17:07 NORMAL 79 139 83 358 392

11.95 11SEP2016 YES 19:19:10 NORMAL 73 140 83 365 390

2 23.92 12SEP2016 YES 7:17:14 NORMAL 78 145 90 369 403

23.93 12SEP2016 YES 7:18:16 NORMAL 76 146 90 373 404

23.95 12SEP2016 YES 7:19:18 NORMAL 74 147 89 369 396

36.17 12SEP2016 YES 19:31:01 NORMAL 82 146 86 354 393 EARLY REPOLARIZATION

36.18 12SEP2016 YES 19:31:41 NORMAL 82 146 88 356 395 EARLY REPOLARIZATION

36.20 12SEP2016 YES 19:32:31 NORMAL 82 148 84 354 393 EARLY REPOLARIZATION

3 48.17 13SEP2016 YES 7:52:10 NORMAL 75 156 86 370 399 EARLY REPOLARIZATION

48.18 13SEP2016 YES 7:52:54 NORMAL 72 154 88 374 397 EARLY REPOLARIZATION

48.20 13SEP2016 YES 7:53:40 NORMAL 76 154 86 374 405 EARLY REPOLARIZATION

2004 Screen 2 M 1 0.00 30AUG2016 NO 6:56:58 ANCS 44 156 108 458 413 PREMATURE

VENTRICULAR

COMPLEX; SINUS

BRADYCARDIA

0.02 30AUG2016 NO 6:58:14 ANCS 43 152 110 464 415 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC;

PREMATURE

VENTRICULAR

COMPLEX; SINUS

BRADYCARDIA

0.03 30AUG2016 NO 6:59:20 NORMAL 45 160 102 460 418 SINUS BRADYCARDIA

1 2 M -3 -73.00 08SEP2016 NO 6:13:12 NORMAL 46 154 108 444 406 SINUS BRADYCARDIA

-72.98 08SEP2016 NO 6:14:12 ANCS 49 154 122 c 438 409 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC; SINUS

BRADYCARDIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 7 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2004 1 2 M -3 -72.97 08SEP2016 NO 6:14:52 ANCS 49 154 110 442 413 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC; SINUS

BRADYCARDIA

1 -1.48 11SEP2016 NO 5:55:00 ANCS 47 159 110 456 420 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC; SINUS

BRADYCARDIA

-1.47 11SEP2016 NO 5:56:02 NORMAL 43 162 109 451 404 SINUS BRADYCARDIA

-1.45 11SEP2016 NO 5:57:02 NORMAL 44 166 108 459 414 SINUS BRADYCARDIA

-0.98 11SEP2016 NO 6:26:19 NORMAL 47 156 109 458 422 SINUS BRADYCARDIA

-0.97 11SEP2016 NO 6:27:24 ANCS 45 156 110 460 418 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC; SINUS

BRADYCARDIA

-0.95 11SEP2016 NO 6:28:45 NORMAL 45 158 108 459 417 SINUS BRADYCARDIA

-0.48 11SEP2016 YES 6:55:35 NORMAL 43 157 107 462 413 SINUS BRADYCARDIA

-0.47 11SEP2016 YES 6:56:17 NORMAL 43 157 99 458 410 SINUS BRADYCARDIA

-0.45 11SEP2016 YES 6:56:54 NORMAL 47 158 101 459 423 SINUS BRADYCARDIA

0.17 11SEP2016 YES 7:34:00 NORMAL 45 159 101 448 407 SINUS BRADYCARDIA

0.18 11SEP2016 YES 7:34:45 ANCS 43 161 114 459 411 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC;

PREMATURE

VENTRICULAR

COMPLEX; SINUS

BRADYCARDIA

0.20 11SEP2016 YES 7:35:32 NORMAL 43 167 108 451 404 SINUS BRADYCARDIA

0.42 11SEP2016 YES 7:49:01 NORMAL 44 163 107 456 411 SINUS BRADYCARDIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 8 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2004 1 2 M 1 0.43 11SEP2016 YES 7:50:03 NORMAL 44 160 107 448 404 SINUS BRADYCARDIA

0.45 11SEP2016 YES 7:51:04 NORMAL 44 161 108 458 413 SINUS BRADYCARDIA

0.92 11SEP2016 YES 8:19:11 NORMAL 43 163 104 454 406 SINUS BRADYCARDIA

0.93 11SEP2016 YES 8:19:50 NORMAL 43 159 103 458 410 SINUS BRADYCARDIA

0.95 11SEP2016 YES 8:20:31 NORMAL 43 158 105 459 411 SINUS BRADYCARDIA

1.92 11SEP2016 YES 9:19:03 NORMAL 44 157 98 451 407 SINUS BRADYCARDIA

1.93 11SEP2016 YES 9:19:52 NORMAL 46 158 99 450 412 SINUS BRADYCARDIA

1.95 11SEP2016 YES 9:20:27 NORMAL 44 159 99 449 405 SINUS BRADYCARDIA

2.92 11SEP2016 YES 10:19:00 ANCS 47 154 111 442 407 INTRAVENTRICULAR

CONDUCTION DELAY,

NONSPECIFIC; SINUS

BRADYCARDIA

2.93 11SEP2016 YES 10:19:45 NORMAL 47 156 100 438 404 SINUS BRADYCARDIA

2.95 11SEP2016 YES 10:20:22 NORMAL 46 158 105 441 404 SINUS BRADYCARDIA

3.92 11SEP2016 YES 11:19:00 NORMAL 49 158 98 443 414 SINUS BRADYCARDIA

3.93 11SEP2016 YES 11:19:48 NORMAL 48 158 97 437 406 SINUS BRADYCARDIA

3.95 11SEP2016 YES 11:20:28 NORMAL 46 157 97 438 401 SINUS BRADYCARDIA

5.92 11SEP2016 YES 13:19:01 NORMAL 60 160 90 406 406

5.93 11SEP2016 YES 13:19:57 NORMAL 59 158 96 404 402

5.95 11SEP2016 YES 13:20:47 NORMAL 56 160 96 409 400

7.92 11SEP2016 YES 15:19:04 NORMAL 55 157 91 414 402

7.93 11SEP2016 YES 15:19:53 NORMAL 54 158 94 420 406

7.95 11SEP2016 YES 15:20:40 NORMAL 55 152 99 417 405

11.92 11SEP2016 YES 19:19:04 NORMAL 54 151 104 416 402

11.93 11SEP2016 YES 19:19:44 NORMAL 55 152 103 420 408

11.95 11SEP2016 YES 19:22:01 NORMAL 54 150 95 421 406

2 23.92 12SEP2016 YES 7:19:42 NORMAL 47 161 100 448 413 SINUS BRADYCARDIA

23.93 12SEP2016 YES 7:20:16 NORMAL 47 162 96 444 409 SINUS BRADYCARDIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 9 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2004 1 2 M 2 23.95 12SEP2016 YES 7:20:48 ANCS 47 156 98 453 418 PREMATURE

VENTRICULAR

COMPLEX; SINUS

BRADYCARDIA

36.17 12SEP2016 YES 19:37:24 NORMAL 51 158 96 426 404

36.18 12SEP2016 YES 19:38:01 NORMAL 51 158 92 430 407

36.20 12SEP2016 YES 19:38:28 NORMAL 53 160 98 426 409

3 48.17 13SEP2016 YES 7:35:02 NORMAL 51 160 106 440 417

48.18 13SEP2016 YES 7:36:39 NORMAL 53 162 108 438 420

48.20 13SEP2016 YES 7:37:40 NORMAL 52 162 104 440 420

2006 Screen 2 M 1 0.00 30AUG2016 NO 7:02:06 NORMAL 51 162 104 428 405

0.02 30AUG2016 NO 7:03:10 NORMAL 57 164 104 426 419 SINUS ARRHYTHMIA

0.03 30AUG2016 NO 7:04:21 NORMAL 57 166 104 422 415

1 2 M -3 -73.00 08SEP2016 NO 6:21:37 NORMAL 65 160 108 402 413

-72.98 08SEP2016 NO 6:22:24 NORMAL 67 160 104 400 415

-72.97 08SEP2016 NO 6:23:04 NORMAL 65 164 102 398 409

1 -1.48 11SEP2016 NO 6:01:44 NORMAL 57 159 107 430 423

-1.47 11SEP2016 NO 6:02:49 NORMAL 48 158 108 438 407 SINUS BRADYCARDIA

-1.45 11SEP2016 NO 6:03:50 NORMAL 48 155 109 439 408 SINUS BRADYCARDIA

-0.98 11SEP2016 NO 6:31:28 NORMAL 47 157 107 440 406 SINUS BRADYCARDIA

-0.97 11SEP2016 NO 6:32:27 NORMAL 47 156 106 444 409 SINUS BRADYCARDIA

-0.95 11SEP2016 NO 6:33:04 NORMAL 52 158 104 442 421

-0.48 11SEP2016 YES 7:01:01 NORMAL 51 160 105 441 418

-0.47 11SEP2016 YES 7:01:35 NORMAL 50 158 104 447 421

-0.45 11SEP2016 YES 7:02:11 ANCS 48 156 106 449 417 INDETERMINATE QRS

AXIS

0.17 11SEP2016 YES 7:40:02 ANCS 50 154 106 440 414 LEFT AXIS DEVIATION

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 10 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2006 1 2 M 1 0.18 11SEP2016 YES 7:40:49 ANCS 48 154 105 443 411 LEFT AXIS

DEVIATION; SINUS

BRADYCARDIA

0.20 11SEP2016 YES 7:41:30 ANCS 48 153 108 448 416 LEFT AXIS

DEVIATION; SINUS

BRADYCARDIA

0.42 11SEP2016 YES 7:55:25 ANCS 49 154 108 431 403 LEFT AXIS

DEVIATION; SINUS

BRADYCARDIA

0.43 11SEP2016 YES 7:56:14 NORMAL 49 151 107 438 409 SINUS BRADYCARDIA

0.45 11SEP2016 YES 7:57:00 ANCS 51 154 106 430 407 LEFT AXIS DEVIATION

0.92 11SEP2016 YES 8:25:02 NORMAL 48 153 106 436 405 SINUS BRADYCARDIA

0.93 11SEP2016 YES 8:25:43 NORMAL 49 151 107 440 411 SINUS BRADYCARDIA

0.95 11SEP2016 YES 8:26:13 NORMAL 51 151 106 442 419

1.92 11SEP2016 YES 9:25:01 ANCS 47 156 104 428 395 INDETERMINATE QRS

AXIS; SINUS

BRADYCARDIA

1.93 11SEP2016 YES 9:25:35 ANCS 45 156 104 427 388 INDETERMINATE QRS

AXIS

1.95 11SEP2016 YES 9:26:06 NORMAL 49 154 102 435 407 SINUS BRADYCARDIA

2.92 11SEP2016 YES 10:25:07 ANCS 50 152 104 431 406 LEFT AXIS DEVIATION

2.93 11SEP2016 YES 10:26:06 ANCS 49 153 105 424 396 LEFT AXIS

DEVIATION; SINUS

BRADYCARDIA

2.95 11SEP2016 YES 10:27:04 NORMAL 50 152 105 438 412

3.92 11SEP2016 YES 11:25:04 NORMAL 48 157 102 426 395 SINUS BRADYCARDIA

3.93 11SEP2016 YES 11:26:56 ANCS 56 153 105 428 403 INDETERMINATE QRS

AXIS

3.95 11SEP2016 YES 11:27:59 NORMAL 52 154 102 427 407

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 11 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2006 1 2 M 1 5.92 11SEP2016 YES 13:25:04 ANCS 63 151 108 388 394 LEFT AXIS DEVIATION

5.93 11SEP2016 YES 13:25:45 ANCS 76 152 108 384 415 LEFT AXIS DEVIATION

5.95 11SEP2016 YES 13:26:17 ANCS 70 151 107 385 405 LEFT AXIS DEVIATION

7.92 11SEP2016 YES 15:25:01 ANCS 67 149 105 392 407 LEFT AXIS DEVIATION

7.93 11SEP2016 YES 15:26:01 ANCS 61 149 105 396 398 LEFT AXIS DEVIATION

7.95 11SEP2016 YES 15:27:03 ANCS 63 148 106 397 404 LEFT AXIS DEVIATION

11.92 11SEP2016 YES 19:25:01 ANCS 62 147 104 398 402 LEFT AXIS DEVIATION

11.93 11SEP2016 YES 19:26:09 ANCS 66 148 105 398 411 LEFT AXIS DEVIATION

11.95 11SEP2016 YES 19:27:07 ANCS 64 149 104 392 401 LEFT AXIS DEVIATION

2 23.92 12SEP2016 YES 7:25:01 NORMAL 55 154 105 419 407

23.93 12SEP2016 YES 7:26:02 NORMAL 53 158 104 422 405

23.95 12SEP2016 YES 7:27:04 ANCS 57 154 103 425 418 INDETERMINATE QRS

AXIS

36.17 12SEP2016 YES 19:40:01 ANCS 60 162 102 414 414 LEFT AXIS DEVIATION

36.18 12SEP2016 YES 19:40:40 ANCS 59 158 104 410 408 LEFT AXIS DEVIATION

36.20 12SEP2016 YES 19:41:17 ANCS 61 156 102 410 412 LEFT AXIS DEVIATION

3 48.17 13SEP2016 YES 7:40:01 NORMAL 51 170 106 442 419

48.18 13SEP2016 YES 7:40:57 NORMAL 51 170 104 438 415

48.20 13SEP2016 YES 7:41:50 NORMAL 58 166 104 436 431 d

2007 Screen 2 F 1 0.00 06SEP2016 NO 8:36:05 NORMAL 67 196 86 426 442

0.02 06SEP2016 NO 8:37:29 NORMAL 66 192 84 428 442

0.03 06SEP2016 NO 8:38:36 NORMAL 63 184 88 424 431

1 2 F -3 -73.00 08SEP2016 NO 6:12:09 NORMAL 65 198 98 428 440

-72.98 08SEP2016 NO 6:13:14 NORMAL 63 198 102 428 435

-72.97 08SEP2016 NO 6:13:46 NORMAL 65 198 96 426 438

1 -1.48 11SEP2016 NO 6:20:19 NORMAL 74 188 102 413 443 ECG LATE DUE TO

SYSTEM ERROR

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 12 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2007 1 2 F 1 -1.47 11SEP2016 NO 6:21:19 NORMAL 71 194 101 419 443 ECG LATE DUE TO

SYSTEM ERROR

-1.45 11SEP2016 NO 6:23:04 NORMAL 75 188 102 418 450 ECG LATE DUE TO

SYSTEM ERROR

-0.98 11SEP2016 NO 6:40:03 NORMAL 68 184 102 428 446

-0.97 11SEP2016 NO 6:40:43 NORMAL 65 189 99 428 440

-0.95 11SEP2016 NO 6:41:21 NORMAL 70 185 100 426 448

-0.48 11SEP2016 YES 7:04:34 NORMAL 65 187 102 429 441

-0.47 11SEP2016 YES 7:05:26 NORMAL 64 184 102 434 443

-0.45 11SEP2016 YES 7:06:02 NORMAL 67 185 92 432 448

0.17 11SEP2016 YES 7:43:00 NORMAL 69 179 101 427 447

0.18 11SEP2016 YES 7:43:37 NORMAL 64 186 100 427 436

0.20 11SEP2016 YES 7:44:19 NORMAL 67 182 88 433 449

0.42 11SEP2016 YES 7:58:02 NORMAL 67 184 90 426 442

0.43 11SEP2016 YES 7:59:04 NORMAL 64 190 89 424 433

0.45 11SEP2016 YES 8:00:06 NORMAL 64 194 101 427 436

0.92 11SEP2016 YES 8:28:01 NORMAL 66 187 88 424 438

0.93 11SEP2016 YES 8:28:40 NORMAL 63 187 101 436 443

0.95 11SEP2016 YES 8:29:32 NORMAL 61 187 101 429 431

1.92 11SEP2016 YES 9:28:00 NORMAL 67 191 101 419 435

1.93 11SEP2016 YES 9:28:50 NORMAL 67 190 89 429 445

1.95 11SEP2016 YES 9:29:27 NORMAL 67 188 89 429 445

2.92 11SEP2016 YES 10:28:00 NORMAL 61 186 88 428 430

2.93 11SEP2016 YES 10:28:42 NORMAL 65 187 100 430 442

2.95 11SEP2016 YES 10:29:25 NORMAL 65 188 87 427 439

3.92 11SEP2016 YES 11:28:02 NORMAL 69 180 88 424 444

3.93 11SEP2016 YES 11:28:40 NORMAL 65 186 97 421 432

3.95 11SEP2016 YES 11:29:11 NORMAL 67 186 101 421 437

5.92 11SEP2016 YES 13:27:59 NORMAL 85 168 88 377 423

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 13 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

-------------------------------------------------------------------------------------------------------------------------------------------

2007 1 2 F 1 5.93 11SEP2016 YES 13:28:46 NORMAL 83 171 101 377 420

5.95 11SEP2016 YES 13:29:26 NORMAL 80 165 102 385 424

7.92 11SEP2016 YES 15:28:02 NORMAL 82 165 102 388 431

7.93 11SEP2016 YES 15:28:54 NORMAL 73 165 99 392 418

7.95 11SEP2016 YES 15:29:41 NORMAL 79 164 100 394 432

11.92 11SEP2016 YES 19:28:29 NORMAL 71 182 101 410 434

11.93 11SEP2016 YES 19:29:19 NORMAL 71 180 89 407 430

11.95 11SEP2016 YES 19:30:06 NORMAL 74 183 89 410 440

2 23.92 12SEP2016 YES 7:28:03 NORMAL 67 191 90 431 447

23.93 12SEP2016 YES 7:28:37 NORMAL 67 188 89 429 445

23.95 12SEP2016 YES 7:29:15 NORMAL 71 177 101 426 451 e

36.17 12SEP2016 YES 19:43:28 NORMAL 67 194 90 426 442

36.18 12SEP2016 YES 19:44:04 NORMAL 69 186 88 430 451 e

36.20 12SEP2016 YES 19:44:36 NORMAL 67 188 104 428 444

3 48.17 13SEP2016 YES 7:43:00 NORMAL 63 196 92 438 445

48.18 13SEP2016 YES 7:44:00 NORMAL 67 190 88 432 448

48.20 13SEP2016 YES 7:45:00 NORMAL 65 192 84 436 448

2008 Screen 2 M 1 0.00 07SEP2016 NO 10:34:37 NORMAL 51 188 92 424 402

0.02 07SEP2016 NO 10:35:42 NORMAL 50 186 82 422 397

0.03 07SEP2016 NO 10:36:45 NORMAL 50 186 88 426 401

1 2 M -3 -73.00 08SEP2016 NO 6:37:07 NORMAL 45 196 94 442 402 NORMAL U WAVE

PRESENT; SINUS

BRADYCARDIA

-72.98 08SEP2016 NO 6:37:48 NORMAL 45 196 90 438 398 NORMAL U WAVE

PRESENT; SINUS

BRADYCARDIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 14 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2008 1 2 M -3 -72.97 08SEP2016 NO 6:38:35 NORMAL 47 190 92 436 402 NORMAL U WAVE

PRESENT; SINUS

BRADYCARDIA

1 -1.48 11SEP2016 NO 6:07:04 NORMAL 49 178 78 428 400 SINUS BRADYCARDIA

-1.47 11SEP2016 NO 6:08:07 NORMAL 50 177 82 431 406

-1.45 11SEP2016 NO 6:09:49 NORMAL 46 180 81 436 399 SINUS BRADYCARDIA

-0.98 11SEP2016 NO 6:53:29 NORMAL 46 165 97 440 403 SINUS BRADYCARDIA

-0.97 11SEP2016 NO 6:54:13 NORMAL 45 164 84 443 402 SINUS BRADYCARDIA

-0.95 11SEP2016 NO 6:54:47 NORMAL 46 165 97 445 407 SINUS BRADYCARDIA

-0.48 11SEP2016 YES 7:07:02 NORMAL 47 166 97 440 406 SINUS BRADYCARDIA

-0.47 11SEP2016 YES 7:07:36 NORMAL 47 185 81 436 402 SINUS BRADYCARDIA

-0.45 11SEP2016 YES 7:08:18 NORMAL 48 182 83 438 407 SINUS BRAYDCARDIA

0.17 11SEP2016 YES 7:46:02 NORMAL 50 186 80 423 398

0.18 11SEP2016 YES 7:46:41 NORMAL 49 170 80 424 396 SINUS BRADYCARDIA

0.20 11SEP2016 YES 7:47:08 NORMAL 49 168 80 427 399 SINUS BRADYCARDIA

0.42 11SEP2016 YES 8:01:07 NORMAL 50 165 80 425 400

0.43 11SEP2016 YES 8:02:01 NORMAL 50 162 80 430 405

0.45 11SEP2016 YES 8:02:57 NORMAL 57 189 80 422 415

0.92 11SEP2016 YES 8:31:02 NORMAL 49 163 80 427 399 SINUS BRADYCARDIA

0.93 11SEP2016 YES 8:31:38 NORMAL 50 164 80 427 402

0.95 11SEP2016 YES 8:32:12 NORMAL 50 166 80 424 399

1.92 11SEP2016 YES 9:31:02 NORMAL 50 174 77 418 393

1.93 11SEP2016 YES 9:31:38 NORMAL 60 176 76 411 411

1.95 11SEP2016 YES 9:32:11 NORMAL 51 154 78 416 394

2.92 11SEP2016 YES 10:31:03 NORMAL 55 163 76 405 393

2.93 11SEP2016 YES 10:32:22 NORMAL 57 175 76 405 398

2.95 11SEP2016 YES 10:33:16 NORMAL 61 177 76 402 404

3.92 11SEP2016 YES 11:31:05 NORMAL 66 177 75 394 407

3.93 11SEP2016 YES 11:32:04 NORMAL 65 176 73 390 401

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 15 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2008 1 2 M 1 3.95 11SEP2016 YES 11:33:05 NORMAL 55 173 74 406 394

5.92 11SEP2016 YES 13:31:02 NORMAL 58 166 79 383 379

5.93 11SEP2016 YES 13:32:14 NORMAL 57 169 77 386 379

5.95 11SEP2016 YES 13:32:54 NORMAL 58 170 80 390 386

7.92 11SEP2016 YES 15:31:02 NORMAL 57 165 75 397 390

7.93 11SEP2016 YES 15:32:02 NORMAL 58 164 73 402 397

7.95 11SEP2016 YES 15:33:03 NORMAL 57 167 73 403 396

11.92 11SEP2016 YES 19:31:01 NORMAL 65 163 76 387 397

11.93 11SEP2016 YES 19:32:01 NORMAL 57 161 74 398 391

11.95 11SEP2016 YES 19:33:02 NORMAL 64 166 75 386 394

2 23.92 12SEP2016 YES 7:31:00 NORMAL 52 162 77 411 392

23.93 12SEP2016 YES 7:32:02 NORMAL 58 165 76 413 408

23.95 12SEP2016 YES 7:33:07 NORMAL 50 166 78 425 400

36.17 12SEP2016 YES 19:46:01 NORMAL 57 174 76 396 389 EARLY REPOLARIZATION

36.18 12SEP2016 YES 19:46:42 NORMAL 57 162 76 400 393 EARLY REPOLARIZATION

36.20 12SEP2016 YES 19:47:26 NORMAL 58 174 76 396 392 EARLY REPOLARIZATION

3 48.17 13SEP2016 YES 7:46:06 NORMAL 52 178 92 408 389 EARLY REPOLARIZATION

48.18 13SEP2016 YES 7:46:50 NORMAL 53 180 74 410 393 EARLY REPOLARIZATION

48.20 13SEP2016 YES 7:47:31 NORMAL 53 180 92 412 395 EARLY REPOLARIZATION

2009 Screen 2 M 1 0.00 07SEP2016 NO 7:02:30 NORMAL 47 152 100 424 391 SINUS BRADYCARDIA

0.02 07SEP2016 NO 7:03:32 NORMAL 48 150 102 426 395 SINUS BRADYCARDIA

0.03 07SEP2016 NO 7:04:42 NORMAL 48 150 100 428 397 SINUS BRADYCARDIA

1 2 M -3 -73.00 08SEP2016 NO 6:05:01 NORMAL 54 150 98 408 394

-72.98 08SEP2016 NO 6:05:35 NORMAL 52 148 100 408 389

-72.97 08SEP2016 NO 6:06:13 NORMAL 51 152 100 408 386

1 -1.48 11SEP2016 NO 6:10:00 NORMAL 47 156 97 429 395 SINUS BRADYCARDIA

-1.47 11SEP2016 NO 6:11:03 NORMAL 47 156 97 428 395 SINUS BRADYCARDIA

-1.45 11SEP2016 NO 6:12:04 NORMAL 48 156 97 431 400 SINUS BRADYCARDIA

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 16 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2009 1 2 M 1 -0.98 11SEP2016 NO 6:40:02 NORMAL 47 155 97 428 395 SINUS BRADYCARDIA

-0.97 11SEP2016 NO 6:40:53 NORMAL 50 158 96 427 402

-0.95 11SEP2016 NO 6:41:42 NORMAL 50 155 96 425 400

-0.48 11SEP2016 YES 7:10:00 NORMAL 52 158 96 418 399

-0.47 11SEP2016 YES 7:11:29 NORMAL 49 159 96 416 389 SINUS BRADYCARDIA

-0.45 11SEP2016 YES 7:12:03 NORMAL 51 157 97 420 398

0.17 11SEP2016 YES 7:49:00 NORMAL 50 157 98 424 399

0.18 11SEP2016 YES 7:50:36 NORMAL 53 154 98 420 403

0.20 11SEP2016 YES 7:51:11 NORMAL 53 155 97 421 404

0.42 11SEP2016 YES 8:04:01 NORMAL 51 156 96 412 390

0.43 11SEP2016 YES 8:05:03 NORMAL 49 155 96 417 390 SINUS BRADYCARDIA

0.45 11SEP2016 YES 8:06:05 NORMAL 53 154 96 419 402

0.92 11SEP2016 YES 8:38:09 NORMAL 56 160 96 418 408

0.93 11SEP2016 YES 8:38:41 NORMAL 52 154 97 417 398

0.95 11SEP2016 YES 8:39:09 NORMAL 53 153 96 412 395

1.92 11SEP2016 YES 9:34:00 NORMAL 54 153 96 414 400

1.93 11SEP2016 YES 9:34:42 NORMAL 50 154 96 414 390

1.95 11SEP2016 YES 9:35:15 NORMAL 51 153 96 416 394

2.92 11SEP2016 YES 10:35:12 NORMAL 50 151 96 409 385

2.93 11SEP2016 YES 10:35:59 NORMAL 55 148 97 404 392

2.95 11SEP2016 YES 10:37:00 NORMAL 53 149 95 405 389

3.92 11SEP2016 YES 11:34:04 NORMAL 51 151 95 407 386

3.93 11SEP2016 YES 11:35:02 NORMAL 50 152 95 412 388

3.95 11SEP2016 YES 11:36:03 NORMAL 49 152 96 414 387 SINUS BRADYCARDIA

5.92 11SEP2016 YES 13:34:00 NORMAL 59 150 97 373 371

5.93 11SEP2016 YES 13:34:55 NORMAL 59 151 97 383 381

5.95 11SEP2016 YES 13:35:39 NORMAL 70 153 97 380 400

7.92 11SEP2016 YES 15:36:13 NORMAL 67 154 93 378 392

7.93 11SEP2016 YES 15:36:43 NORMAL 65 154 94 379 389

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 17 of 17

Table 2.7.1 Electrocardiogram Triplicates

Heart

Subject Study Used in Rate PR QRS QT QTcF\*

Number Period Cohort Gender Day Hour Date Triplicate? Time Result (bpm) (msec) (msec) (msec) (msec) Comments

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2009 1 2 M 1 7.95 11SEP2016 YES 15:37:29 NORMAL 63 151 96 378 384

11.92 11SEP2016 YES 19:34:03 NORMAL 61 147 95 378 380

11.93 11SEP2016 YES 19:34:45 NORMAL 66 147 95 371 383

11.95 11SEP2016 YES 19:35:33 NORMAL 63 148 94 378 384

2 23.92 12SEP2016 YES 7:34:02 NORMAL 55 148 95 402 391

23.93 12SEP2016 YES 7:34:36 NORMAL 59 152 95 400 398

23.95 12SEP2016 YES 7:35:13 NORMAL 53 149 94 403 387

36.17 12SEP2016 NO 19:48:01 NORMAL 65 152 96 380 390 ECG TAKEN EARLY IN

ERROR

12SEP2016 YES 19:49:01 NORMAL 65 152 96 380 390

36.18 12SEP2016 YES 19:49:29 NORMAL 62 152 94 380 384

36.20 12SEP2016 YES 19:49:58 NORMAL 71 152 96 378 400

3 48.17 13SEP2016 YES 7:49:10 NORMAL 54 150 106 412 398

48.18 13SEP2016 YES 7:50:12 NORMAL 59 150 102 404 402

48.20 13SEP2016 YES 7:51:13 NORMAL 57 150 104 408 401

Note: ANCS = Abnormal, Not Clinically Significant

QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg.sas 15SEP2016 18:57

Page 1 of 4

Table 2.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

2001 1 2 F 1 Baseline 63.3 141.3 93.3 420.3 428.0

0.25 hr 66.3 143.3 92.3 415.0 429.0 3.0 2.0 -1.0 -5.3 1.0

0.5 hr 73.7 145.0 92.7 402.3 430.3 10.3 3.7 -0.7 -18.0 2.3

1 hr 65.7 146.7 93.0 413.3 425.7 2.3 5.3 -0.3 -7.0 -2.3

2 hr 64.0 145.3 92.7 420.0 429.0 0.7 4.0 -0.7 -0.3 1.0

3 hr 68.0 146.7 92.3 410.7 428.0 4.7 5.3 -1.0 -9.7 0.0

4 hr 66.7 144.7 92.0 418.7 434.0 3.3 3.3 -1.3 -1.7 6.0

6 hr 67.3 150.0 93.0 398.3 414.0 4.0 8.7 -0.3 -22.0 -14.0

8 hr 79.0 141.0 91.3 394.0 432.0 15.7 -0.3 -2.0 -26.3 4.0

12 hr 73.7 139.3 91.0 403.0 431.3 10.3 -2.0 -2.3 -17.3 3.3

2 24 hr 66.7 144.3 93.0 412.7 427.0 3.3 3.0 -0.3 -7.7 -1.0

36 hr 75.0 138.7 94.0 402.0 433.0 11.7 -2.7 0.7 -18.3 5.0

3 48 hr 63.7 146.7 104.7 423.3 431.7 0.3 5.3 11.3 3.0 3.7

2002 1 2 F 1 Baseline 61.3 169.0 103.7 409.0 412.0

0.25 hr 62.3 165.3 95.3 402.7 408.0 1.0 -3.7 -8.3 -6.3 -4.0

0.5 hr 63.0 166.0 91.0 402.0 408.3 1.7 -3.0 -12.7 -7.0 -3.7

1 hr 67.7 168.3 94.7 397.0 413.3 6.3 -0.7 -9.0 -12.0 1.3

2 hr 62.3 165.7 94.0 408.0 413.3 1.0 -3.3 -9.7 -1.0 1.3

3 hr 65.3 162.7 89.0 393.7 405.0 4.0 -6.3 -14.7 -15.3 -7.0

4 hr 69.3 167.7 93.3 393.0 412.3 8.0 -1.3 -10.3 -16.0 0.3

6 hr 76.0 163.3 99.0 376.0 407.0 14.7 -5.7 -4.7 -33.0 -5.0

8 hr 75.7 163.3 88.0 377.3 407.7 14.3 -5.7 -15.7 -31.7 -4.3

12 hr 69.3 162.0 86.3 385.7 404.7 8.0 -7.0 -17.3 -23.3 -7.3

2 24 hr 71.7 167.0 88.7 381.3 404.7 10.3 -2.0 -15.0 -27.7 -7.3

36 hr 70.7 166.0 102.0 388.0 409.7 9.3 -3.0 -1.7 -21.0 -2.3

3 48 hr 67.7 173.3 101.3 392.7 409.0 6.3 4.3 -2.3 -16.3 -3.0

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 2 of 4

Table 2.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

2003 1 2 M 1 Baseline 72.0 149.3 90.0 383.7 407.7

0.25 hr 69.3 153.7 89.3 381.7 400.3 -2.7 4.3 -0.7 -2.0 -7.3

0.5 hr 72.7 153.3 89.7 380.3 405.3 0.7 4.0 -0.3 -3.3 -2.3

1 hr 71.7 145.3 89.0 374.3 397.3 -0.3 -4.0 -1.0 -9.3 -10.3

2 hr 75.7 143.7 89.3 372.3 402.0 3.7 -5.7 -0.7 -11.3 -5.7

3 hr 72.3 145.0 86.0 371.7 395.0 0.3 -4.3 -4.0 -12.0 -12.7

4 hr 71.3 143.3 85.0 377.0 399.3 -0.7 -6.0 -5.0 -6.7 -8.3

6 hr 92.0 134.3 75.7 334.7 385.7 20.0 -15.0 -14.3 -49.0 -22.0

8 hr 72.0 137.7 84.3 369.3 392.7 0.0 -11.7 -5.7 -14.3 -15.0

12 hr 77.3 139.3 83.0 360.0 391.7 5.3 -10.0 -7.0 -23.7 -16.0

2 24 hr 76.0 146.0 89.7 370.3 401.0 4.0 -3.3 -0.3 -13.3 -6.7

36 hr 82.0 146.7 86.0 354.7 393.7 10.0 -2.7 -4.0 -29.0 -14.0

3 48 hr 74.3 154.7 86.7 372.7 400.3 2.3 5.3 -3.3 -11.0 -7.3

2004 1 2 M 1 Baseline 44.3 157.3 102.3 459.7 415.3

0.25 hr 43.7 162.3 107.7 452.7 407.3 -0.7 5.0 5.3 -7.0 -8.0

0.5 hr 44.0 161.3 107.3 454.0 409.3 -0.3 4.0 5.0 -5.7 -6.0

1 hr 43.0 160.0 104.0 457.0 409.0 -1.3 2.7 1.7 -2.7 -6.3

2 hr 44.7 158.0 98.7 450.0 408.0 0.3 0.7 -3.7 -9.7 -7.3

3 hr 46.7 156.0 105.3 440.3 405.0 2.3 -1.3 3.0 -19.3 -10.3

4 hr 47.7 157.7 97.3 439.3 407.0 3.3 0.3 -5.0 -20.3 -8.3

6 hr 58.3 159.3 94.0 406.3 402.7 14.0 2.0 -8.3 -53.3 -12.7

8 hr 54.7 155.7 94.7 417.0 404.3 10.3 -1.7 -7.7 -42.7 -11.0

12 hr 54.3 151.0 100.7 419.0 405.3 10.0 -6.3 -1.7 -40.7 -10.0

2 24 hr 47.0 159.7 98.0 448.3 413.3 2.7 2.3 -4.3 -11.3 -2.0

36 hr 51.7 158.7 95.3 427.3 406.7 7.3 1.3 -7.0 -32.3 -8.7

3 48 hr 52.0 161.3 106.0 439.3 419.0 7.7 4.0 3.7 -20.3 3.7

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 3 of 4

Table 2.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

2006 1 2 M 1 Baseline 49.7 158.0 105.0 445.7 418.7

0.25 hr 48.7 153.7 106.3 443.7 413.7 -1.0 -4.3 1.3 -2.0 -5.0

0.5 hr 49.7 153.0 107.0 433.0 406.3 0.0 -5.0 2.0 -12.7 -12.3

1 hr 49.3 151.7 106.3 439.3 411.7 -0.3 -6.3 1.3 -6.3 -7.0

2 hr 47.0 155.3 103.3 430.0 396.7 -2.7 -2.7 -1.7 -15.7 -22.0

3 hr 49.7 152.3 104.7 431.0 404.7 0.0 -5.7 -0.3 -14.7 -14.0

4 hr 52.0 154.7 103.0 427.0 401.7 2.3 -3.3 -2.0 -18.7 -17.0

6 hr 69.7 151.3 107.7 385.7 404.7 20.0 i -6.7 2.7 -60.0 -14.0

8 hr 63.7 148.7 105.3 395.0 403.0 14.0 -9.3 0.3 -50.7 -15.7

12 hr 64.0 148.0 104.3 396.0 404.7 14.3 -10.0 -0.7 -49.7 -14.0

2 24 hr 55.0 155.3 104.0 422.0 410.0 5.3 -2.7 -1.0 -23.7 -8.7

36 hr 60.0 158.7 102.7 411.3 411.3 10.3 0.7 -2.3 -34.3 -7.3

3 48 hr 53.3 168.7 104.7 438.7 421.7 3.7 10.7 -0.3 -7.0 3.0

2007 1 2 F 1 Baseline 65.3 185.3 98.7 431.7 444.0

0.25 hr 66.7 182.3 96.3 429.0 444.0 1.3 -3.0 -2.3 -2.7 0.0

0.5 hr 65.0 189.3 93.3 425.7 437.0 -0.3 4.0 -5.3 -6.0 -7.0

1 hr 63.3 187.0 96.7 429.7 437.3 -2.0 1.7 -2.0 -2.0 -6.7

2 hr 67.0 189.7 93.0 425.7 441.7 1.7 4.3 -5.7 -6.0 -2.3

3 hr 63.7 187.0 91.7 428.3 437.0 -1.7 1.7 -7.0 -3.3 -7.0

4 hr 67.0 184.0 95.3 422.0 437.7 1.7 -1.3 -3.3 -9.7 -6.3

6 hr 82.7 168.0 97.0 379.7 422.3 17.3 -17.3 -1.7 -52.0 -21.7

8 hr 78.0 164.7 100.3 391.3 427.0 12.7 -20.7 1.7 -40.3 -17.0

12 hr 72.0 181.7 93.0 409.0 434.7 6.7 -3.7 -5.7 -22.7 -9.3

2 24 hr 68.3 185.3 93.3 428.7 447.7 3.0 0.0 -5.3 -3.0 3.7

36 hr 67.7 189.3 94.0 428.0 445.7 2.3 4.0 -4.7 -3.7 1.7

3 48 hr 65.0 192.7 88.0 435.3 447.0 -0.3 7.3 -10.7 3.7 3.0

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 4 of 4

Table 2.7.2 Electrocardiogram Triplicate Averages

Average of ECG Change From Baseline

Subject Study ------------------------------------------ ----------------------------------------

Number Period Cohort Gender Day Hour HR PR QRS QT QTcF\* HR PR QRS QT QTcF\*

----------------------------------------------------------------------------------------------------------------------------------------

2008 1 2 M 1 Baseline 47.3 177.7 87.0 438.0 405.0

0.25 hr 49.3 174.7 80.0 424.7 397.7 2.0 -3.0 -7.0 -13.3 -7.3

0.5 hr 52.3 172.0 80.0 425.7 406.7 5.0 -5.7 -7.0 -12.3 1.7

1 hr 49.7 164.3 80.0 426.0 400.0 2.3 -13.3 -7.0 -12.0 -5.0

2 hr 53.7 168.0 77.0 415.0 399.3 6.3 -9.7 -10.0 -23.0 -5.7

3 hr 57.7 171.7 76.0 404.0 398.3 10.3 -6.0 -11.0 -34.0 -6.7

4 hr 62.0 175.3 74.0 396.7 400.7 14.7 -2.3 -13.0 -41.3 -4.3

6 hr 57.7 168.3 78.7 386.3 381.3 10.3 -9.3 -8.3 -51.7 -23.7

8 hr 57.3 165.3 73.7 400.7 394.3 10.0 -12.3 -13.3 -37.3 -10.7

12 hr 62.0 163.3 75.0 390.3 394.0 14.7 -14.3 -12.0 -47.7 -11.0

2 24 hr 53.3 164.3 77.0 416.3 400.0 6.0 -13.3 -10.0 -21.7 -5.0

36 hr 57.3 170.0 76.0 397.3 391.3 10.0 -7.7 -11.0 -40.7 -13.7

3 48 hr 52.7 179.3 86.0 410.0 392.3 5.3 1.7 -1.0 -28.0 -12.7

2009 1 2 M 1 Baseline 50.7 158.0 96.3 418.0 395.3

0.25 hr 52.0 155.3 97.7 421.7 402.0 1.3 -2.7 1.3 3.7 6.7

0.5 hr 51.0 155.0 96.0 416.0 394.0 0.3 -3.0 -0.3 -2.0 -1.3

1 hr 53.7 155.7 96.3 415.7 400.3 3.0 -2.3 0.0 -2.3 5.0

2 hr 51.7 153.3 96.0 414.7 394.7 1.0 -4.7 -0.3 -3.3 -0.7

3 hr 52.7 149.3 96.0 406.0 388.7 2.0 -8.7 -0.3 -12.0 -6.7

4 hr 50.0 151.7 95.3 411.0 387.0 -0.7 -6.3 -1.0 -7.0 -8.3

6 hr 62.7 151.3 97.0 378.7 384.0 12.0 -6.7 0.7 -39.3 -11.3

8 hr 65.0 153.0 94.3 378.3 388.3 14.3 -5.0 -2.0 -39.7 -7.0

12 hr 63.3 147.3 94.7 375.7 382.3 12.7 -10.7 -1.7 -42.3 -13.0

2 24 hr 55.7 149.7 94.7 401.7 392.0 5.0 -8.3 -1.7 -16.3 -3.3

36 hr 66.0 152.0 95.3 379.3 391.3 15.3 -6.0 -1.0 -38.7 -4.0

3 48 hr 56.7 150.0 104.0 408.0 400.3 6.0 -8.0 7.7 -10.0 5.0

Note: QTcF\* = QTc corrected for Fridericia equation

Cohort 2 = 100 mg TD-1439 or placebo

a: Heart Rate is greater than 120 bpm, b: PR is greater than 200 msec, c: QRS Interval is greater than 120 msec,

d: 430 < QTcF (Male Only) <= 450 msec, e: 450 < QTcF <= 470 msec, f: 470 < QTcF <= 480 msec,

g: 480 < QTcF <= 500 msec, h: QTcF > 500 msec,

i: Heart Rate change from baseline is greater than 20 bpm,

j: PR %change from baseline is greater than 15 msec,

k: QTcF change from baseline is greater than 30.

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_ecg\_trip\_ave.sas 15SEP2016 18:57

Page 1 of 1

Table 2.8 Prior and Concomitant Medications

Prior

Subject Any Start Start Stop Stop to

Number Med? Medication Dosage Route Date Time Date Time Frequency Indication Continuing? Study?

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2001 YES AZURETTE 1 TABLET(S) BY MOUTH JAN2016 UNK EVERY DAY BIRTH YES

CONTROL

AZURETTE 1 TABLET(S) BY MOUTH JAN2016 UNK EVERY DAY BIRTH YES

CONTROL

2002 NO None

2003 NO None

2004 NO None

2005 NO None

2006 NO None

2007 NO None

2008 NO None

2009 NO None

2010 NO None

Note: UNK = Unknown

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_con.sas 15SEP2016 18:57

Page 1 of 1

Table 2.9 Demographics

Body Mass

Subject Date Of Age\* Height Weight Index

Number Birth (yrs) Gender Race Ethnicity (cm) (kg) (kg/m²)

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2001 30SEP1987 28 Female Black or African American Not Hispanic or Latino 172 92.4 31.17

2002 02MAY1992 24 Female White, Black or African American Not Hispanic or Latino 173 75.2 25.12

2003 18APR1983 33 Male Black or African American Not Hispanic or Latino 178 72.9 22.99

2004 27FEB1961 55 Male White Not Hispanic or Latino 175 92.6 30.14

2006 19NOV1964 51 Male White Not Hispanic or Latino 179 89.3 28.00

2007 30JUL1976 40 Female White Not Hispanic or Latino 167 66.1 23.73

2008 08APR1996 20 Male Black or African American Not Hispanic or Latino 173 73.7 24.62

2009 30JAN1982 34 Male White Not Hispanic or Latino 171 70.5 24.21

Note: \* Age is calculated from the date of first dosing.

BMI (body mass index) and weight are based on the CRF data collected at admission (Day -3).

Program: /CA19379/sas\_prg/stsas/Interim2/cdash\_lis\_dem.sas 15SEP2016 18:57