

TABLE OF CONTENTS

BY DOMAIN

12-LEAD ECG	16
BASELINE/DAY 1	16
BASELINE/DAY 1 RESCUE THERAPY	16
SCREENING	16
UNSCHEDULED	16
WEEK 1	16
WEEK 1 RESCUE THERAPY	16
WEEK 12	16
WEEK 12 RESCUE THERAPY	16
ADVERSE EVENT SUMMARY	17
ADVERSE EVENTS	17
ADVERSE EVENT	18
COMPLETE PHYSICAL EXAM PLUS RETINAL	21
EARLY TERMINATION (RESCUE THERAPY)	21
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	21
SCREENING	21
WEEK 12 RESCUE THERAPY	21
WEEK 24 RESCUE THERAPY	21
WEEK 48 RESCUE THERAPY	21
COMPLETE PHYSICAL EXAMINATION	22
BASELINE/DAY 1	22
BASELINE/DAY 1 RESCUE THERAPY	22
EARLY TERMINATION (INITIAL TREATMENT)	22
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	22
POST-TREATMENT FOLLOW-UP WEEK 4	22
POST-TREATMENT FOLLOW-UP WEEK 24	22
WEEK 12	22
WEEK 24	22
CONCOMITANT MEDICATION SUMMARY	23
CONCOMITANT MEDICATION	23
CONCOMITANT MEDICATION	24
CONCOMITANT MEDICATION	24
DEATH REPORT	25

DEATH	25
DEMOGRAPHICS	26
SCREENING	26
DOSE ADMINISTRATION (DAY 1)	27
BASELINE/DAY 1	27
DOSE ADMINISTRATION (SERIAL PK)	28
WEEK 2	28
DOSE ADMINISTRATION (SINGLE PK)	29
EARLY TERMINATION (INITIAL TREATMENT)	29
WEEK 1	29
WEEK 2	29
WEEK 4	29
WEEK 6	29
WEEK 8	29
WEEK 10	29
WEEK 12	29
WEEK 16	29
WEEK 20	29
WEEK 24	29
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	30
DAY 2	30
DAY 3	30
DAY 4	30
DAY 5	30
DAY 10	30
GENERAL COMMENTS	31
GENERAL COMMENTS	31
INCLUSION/EXCLUSION CRITERIA	36
SCREENING	36
INVESTIGATOR'S SIGNATURE	40
LIVER FIBROSIS ASSESSMENT	41
SCREENING	41
MEDICAL HISTORY	43
SCREENING	43
MISSED DOSE AND OVERDOSE LOG – INITIAL TREATMENT	44
MISSED DOSE OVERDOSE LOG	44
MISSED DOSE AND OVERDOSE LOG – RESCUE TREATMENT	45
MISSED DOSE OVERDOSE LOG	45

PK PLASMA (VIRAL DYNAMIC SUBSTUDY DAY 1)	46
BASELINE/DAY 1	46
PREGNANCY REPORT	47
PRIOR HCV TREATMENT HISTORY	48
SCREENING	48
PRIOR RESPONSE CLASSIFICATION	49
SCREENING	49
PRIOR RESPONSE HISTORY - BREAKTHROUGH	50
SCREENING	50
PRIOR RESPONSE HISTORY - NULL OR PARTIAL	51
PRIOR RESPONSE HISTORY - RELAPSER	52
SCREENING	52
RANDOMIZATION	53
BASELINE/DAY 1	53
REGISTRY SUBSTUDY	54
RESCUE THERAPY STATUS	55
RESCUE THERAPY SUBSTUDY TREATMENT VISITS	55
SERIAL PK PLASMA	56
WEEK 2	56
SINGLE PK PLASMA	57
DAY 2	57
DAY 3	57
DAY 4	57
DAY 5	57
DAY 10	57
EARLY TERMINATION (INITIAL TREATMENT)	57
WEEK 1	57
WEEK 2	57
WEEK 4	57
WEEK 6	57
WEEK 8	57
WEEK 10	57
WEEK 12	57
WEEK 16	57
WEEK 20	57
WEEK 24	57
STOP TREATMENT	58
WEEK 24 RESCUE THERAPY	58

STUDY COMPLETION	59
STUDY COMPLETION	59
STUDY DRUG ACCOUNTABILITY - GS-5885 RESCUE THERAPY	60
STUDY DRUG ACCOUNTABILITY	60
STUDY DRUG ACCOUNTABILITY - GS-5885	61
STUDY DRUG ACCOUNTABILITY	61
STUDY DRUG ACCOUNTABILITY - GS-9451 RESCUE THERAPY	62
STUDY DRUG ACCOUNTABILITY	62
STUDY DRUG ACCOUNTABILITY - GS-9451	63
STUDY DRUG ACCOUNTABILITY	63
STUDY DRUG ACCOUNTABILITY - PEG RESCUE THERAPY	64
STUDY DRUG ACCOUNTABILITY	64
STUDY DRUG ACCOUNTABILITY - RBV RESCUE THERAPY	66
STUDY DRUG ACCOUNTABILITY	66
STUDY DRUG ACCOUNTABILITY - RBV/PLACEBO	68
STUDY DRUG ACCOUNTABILITY	68
STUDY DRUG ACCOUNTABILITY - TEGOBUVIR/PLACEBO	69
STUDY DRUG ACCOUNTABILITY	69
STUDY DRUG ADMINISTRATION - INITIAL TREATMENT	70
STUDY DRUG ADMINISTRATION	70
STUDY DRUG ADMINISTRATION - RESCUE THERAPY	71
STUDY DRUG ADMINISTRATION	71
STUDY DRUG COMPLETION (INITIAL TREATMENT)	72
STUDY DRUG COMPLETION (INITIAL TREATMENT)	72
STUDY DRUG COMPLETION (RESCUE THERAPY)	73
STUDY DRUG COMPLETION (RESCUE THERAPY)	73
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 8	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 16	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 20	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	74
POST-TREATMENT FOLLOW-UP WEEK 4	74
POST-TREATMENT FOLLOW-UP WEEK 8	74
POST-TREATMENT FOLLOW-UP WEEK 12	74
POST-TREATMENT FOLLOW-UP WEEK 16	74
POST-TREATMENT FOLLOW-UP WEEK 20	74

POST-TREATMENT FOLLOW-UP WEEK 24	74
SUBJECT NUMBER	75
URINE PREGNANCY TEST (BASELINE)	76
BASELINE/DAY 1	76
URINE PREGNANCY TEST	77
BASELINE/DAY 1 RESCUE THERAPY	77
EARLY TERMINATION (INITIAL TREATMENT)	77
EARLY TERMINATION (RESCUE THERAPY)	77
POST-RESCUE THERAPY FOLLOW-UP MONTH 6	77
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	77
POST-RESCUE THERAPY FOLLOW-UP WEEK 8	77
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	77
POST-RESCUE THERAPY FOLLOW-UP WEEK 16	77
POST-RESCUE THERAPY FOLLOW-UP WEEK 20	77
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	77
POST-TREATMENT FOLLOW-UP MONTH 6	77
POST-TREATMENT FOLLOW-UP WEEK 4	77
POST-TREATMENT FOLLOW-UP WEEK 8	77
POST-TREATMENT FOLLOW-UP WEEK 12	77
POST-TREATMENT FOLLOW-UP WEEK 16	77
POST-TREATMENT FOLLOW-UP WEEK 20	77
POST-TREATMENT FOLLOW-UP WEEK 24	77
UNSCHEDULED	77
WEEK 4	77
WEEK 4 RESCUE THERAPY	77
WEEK 8	77
WEEK 8 RESCUE THERAPY	77
WEEK 12	77
WEEK 12 RESCUE THERAPY	77
WEEK 16	77
WEEK 16 RESCUE THERAPY	77
WEEK 20	77
WEEK 20 RESCUE THERAPY	77
WEEK 24	77
WEEK 24 RESCUE THERAPY	77
WEEK 28 RESCUE THERAPY	77
WEEK 32 RESCUE THERAPY	77
WEEK 36 RESCUE THERAPY	77

WEEK 40 RESCUE THERAPY	77
WEEK 44 RESCUE THERAPY	77
WEEK 48 RESCUE THERAPY	77
VISIT DATE	78
BASELINE/DAY 1	78
BASELINE/DAY 1 RESCUE THERAPY	78
DAY 2	78
DAY 3	78
DAY 4	78
DAY 5	78
DAY 10	78
EARLY TERMINATION (INITIAL TREATMENT)	78
EARLY TERMINATION (RESCUE THERAPY)	78
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	78
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	78
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	78
POST-TREATMENT FOLLOW-UP WEEK 4	78
POST-TREATMENT FOLLOW-UP WEEK 12	78
POST-TREATMENT FOLLOW-UP WEEK 24	78
SCREENING	78
UNSCHEDULED	78
WEEK 1	78
WEEK 1 RESCUE THERAPY	78
WEEK 2	78
PK WEEK 2	78
WEEK 2 RESCUE THERAPY	78
WEEK 4	78
WEEK 4 RESCUE THERAPY	78
WEEK 6	78
WEEK 6 RESCUE THERAPY	78
WEEK 8	78
WEEK 8 RESCUE THERAPY	78
WEEK 10	78
WEEK 10 RESCUE THERAPY	78
WEEK 12	78
WEEK 12 RESCUE THERAPY	78
WEEK 16	78
WEEK 16 RESCUE THERAPY	78

WEEK 20	78
WEEK 20 RESCUE THERAPY	78
WEEK 24	78
WEEK 24 RESCUE THERAPY	78
WEEK 28 RESCUE THERAPY	78
WEEK 32 RESCUE THERAPY	78
WEEK 36 RESCUE THERAPY	78
WEEK 40 RESCUE THERAPY	78
WEEK 44 RESCUE THERAPY	78
WEEK 48 RESCUE THERAPY	78
VITAL SIGNS (SCREENING)	79
SCREENING	79
VITAL SIGNS WITH WEIGHT	80
BASELINE/DAY 1	80
BASELINE/DAY 1 RESCUE THERAPY	80
EARLY TERMINATION (INITIAL TREATMENT)	80
EARLY TERMINATION (RESCUE THERAPY)	80
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	80
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	80
POST-TREATMENT FOLLOW-UP WEEK 12	80
POST-TREATMENT FOLLOW-UP WEEK 24	80
WEEK 1 RESCUE THERAPY	80
WEEK 2 RESCUE THERAPY	80
WEEK 4 RESCUE THERAPY	80
WEEK 6 RESCUE THERAPY	80
WEEK 8 RESCUE THERAPY	80
WEEK 10 RESCUE THERAPY	80
WEEK 12	80
WEEK 12 RESCUE THERAPY	80
WEEK 16 RESCUE THERAPY	80
WEEK 20 RESCUE THERAPY	80
WEEK 24	80
WEEK 24 RESCUE THERAPY	80
WEEK 28 RESCUE THERAPY	80
WEEK 32 RESCUE THERAPY	80
WEEK 36 RESCUE THERAPY	80
WEEK 40 RESCUE THERAPY	80
WEEK 44 RESCUE THERAPY	80

WEEK 48 RESCUE THERAPY	80
VITAL SIGNS	81
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	81
POST-TREATMENT FOLLOW-UP WEEK 4	81
WEEK 1	81
WEEK 2	81
WEEK 4	81
WEEK 6	81
WEEK 8	81
WEEK 10	81
WEEK 16	81
WEEK 20	81

BY VISIT

SCREENING	51
PRIOR RESPONSE HISTORY - NULL OR PARTIAL	51
VISIT DATE	78
INCLUSION/EXCLUSION CRITERIA	36
DEMOGRAPHICS	26
VITAL SIGNS (SCREENING)	79
COMPLETE PHYSICAL EXAM PLUS RETINAL	21
MEDICAL HISTORY	43
LIVER FIBROSIS ASSESSMENT	41
PRIOR HCV TREATMENT HISTORY	48
PRIOR RESPONSE CLASSIFICATION	49
PRIOR RESPONSE HISTORY - BREAKTHROUGH	50
PRIOR RESPONSE HISTORY - RELAPSER	52
12-LEAD ECG	16
BASELINE/DAY 1	78
VISIT DATE	78
RANDOMIZATION	53
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST (BASELINE)	76
DOSE ADMINISTRATION (DAY 1)	27
PK PLASMA (VIRAL DYNAMIC SUBSTUDY DAY 1)	46
12-LEAD ECG	16
DAY 2	78
VISIT DATE	78

SINGLE PK PLASMA	57
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	30
DAY 3	78
VISIT DATE	78
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	30
DAY 4	78
VISIT DATE	78
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	30
DAY 5	78
VISIT DATE	78
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	30
WEEK 1	78
VISIT DATE	78
VITAL SIGNS	81
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
12-LEAD ECG	16
DAY 10	78
VISIT DATE	78
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (VIRAL DYNAMIC SUBSTUDY)	30
WEEK 2	78
VISIT DATE	78
VITAL SIGNS	81
SINGLE PK PLASMA	57
SERIAL PK PLASMA	56
DOSE ADMINISTRATION (SINGLE PK)	29
DOSE ADMINISTRATION (SERIAL PK)	28
WEEK 4	78
VISIT DATE	78
VITAL SIGNS	81
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
WEEK 6	78

VISIT DATE	78
VITAL SIGNS	81
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
WEEK 8	78
VISIT DATE	78
VITAL SIGNS	81
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
WEEK 10	78
VISIT DATE	78
VITAL SIGNS	81
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
WEEK 12	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
12-LEAD ECG	16
WEEK 16	78
VISIT DATE	78
VITAL SIGNS	81
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
WEEK 20	78
VISIT DATE	78
VITAL SIGNS	81
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
WEEK 24	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80

COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
EARLY TERMINATION (INITIAL TREATMENT)	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
SINGLE PK PLASMA	57
DOSE ADMINISTRATION (SINGLE PK)	29
STUDY DRUG COMPLETION (INITIAL TREATMENT)	72
STUDY DRUG COMPLETION (INITIAL TREATMENT)	72
PK WEEK 2	78
VISIT DATE	78
POST-TREATMENT FOLLOW-UP WEEK 4	78
VISIT DATE	78
VITAL SIGNS	81
COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-TREATMENT FOLLOW-UP WEEK 8	77
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-TREATMENT FOLLOW-UP WEEK 12	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-TREATMENT FOLLOW-UP WEEK 16	77
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-TREATMENT FOLLOW-UP WEEK 20	77
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-TREATMENT FOLLOW-UP WEEK 24	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80

COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-TREATMENT FOLLOW-UP MONTH 6	77
URINE PREGNANCY TEST	77
RESCUE THERAPY SUBSTUDY TREATMENT VISITS	55
RESCUE THERAPY STATUS	55
BASELINE/DAY 1 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
12-LEAD ECG	16
WEEK 1 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
12-LEAD ECG	16
WEEK 2 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
WEEK 4 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 6 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
WEEK 8 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 10 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
WEEK 12 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAM PLUS RETINAL	21

URINE PREGNANCY TEST	77
12-LEAD ECG	16
WEEK 16 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 20 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 24 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAM PLUS RETINAL	21
URINE PREGNANCY TEST	77
STOP TREATMENT	58
WEEK 28 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 32 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 36 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 40 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 44 RESCUE THERAPY	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
WEEK 48 RESCUE THERAPY	78
VISIT DATE	78

VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAM PLUS RETINAL	21
URINE PREGNANCY TEST	77
EARLY TERMINATION (RESCUE THERAPY)	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAM PLUS RETINAL	21
URINE PREGNANCY TEST	77
STUDY DRUG COMPLETION (RESCUE THERAPY)	73
STUDY DRUG COMPLETION (RESCUE THERAPY)	73
POST-RESCUE THERAPY FOLLOW-UP WEEK 4	78
VISIT DATE	78
VITAL SIGNS	81
COMPLETE PHYSICAL EXAM PLUS RETINAL	21
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 8	77
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 12	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 16	77
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 20	77
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP WEEK 24	78
VISIT DATE	78
VITAL SIGNS WITH WEIGHT	80
COMPLETE PHYSICAL EXAMINATION	22
URINE PREGNANCY TEST	77
SUBJECT FOLLOW-UP STATUS	74
POST-RESCUE THERAPY FOLLOW-UP MONTH 6	77
URINE PREGNANCY TEST	77

ADVERSE EVENTS	17
ADVERSE EVENT SUMMARY	17
CONCOMITANT MEDICATION	23
CONCOMITANT MEDICATION SUMMARY	23
CONCOMITANT MEDICATION	24
STUDY DRUG ADMINISTRATION	70
STUDY DRUG ADMINISTRATION - INITIAL TREATMENT	70
STUDY DRUG ADMINISTRATION - RESCUE THERAPY	71
MISSED DOSE OVERDOSE LOG	44
MISSED DOSE AND OVERDOSE LOG – INITIAL TREATMENT	44
MISSED DOSE AND OVERDOSE LOG – RESCUE TREATMENT	45
STUDY DRUG ACCOUNTABILITY	61
STUDY DRUG ACCOUNTABILITY - GS-5885	61
STUDY DRUG ACCOUNTABILITY - GS-9451	63
STUDY DRUG ACCOUNTABILITY - TEGOBUVIR/PLACEBO	69
STUDY DRUG ACCOUNTABILITY - RBV/PLACEBO	68
STUDY DRUG ACCOUNTABILITY - GS-5885 RESCUE THERAPY	60
STUDY DRUG ACCOUNTABILITY - GS-9451 RESCUE THERAPY	62
STUDY DRUG ACCOUNTABILITY - RBV RESCUE THERAPY	66
STUDY DRUG ACCOUNTABILITY - PEG RESCUE THERAPY	64
DEATH	25
DEATH REPORT	25
GENERAL COMMENTS	31
GENERAL COMMENTS	31
UNSCHEDULED	78
VISIT DATE	78
URINE PREGNANCY TEST	77
12-LEAD ECG	16
STUDY COMPLETION	59
STUDY COMPLETION	59
PREGNANCY REPORT	47
RESCUE THERAPY STATUS	55
INVESTIGATOR'S SIGNATURE	40
SUBJECT NUMBER	75

Project Name: GS-US-248-0131

Form: 12-Lead ECG [ECG12]

Generated On: 08-01-2013 09:32:54

Was an ECG performed?

☐ Yes

☐ No

If No, please comment why ECG was not done:

Date of ECG:

Time of ECG:

HR Rate (bpm):

PR Interval (msec):

QRS Interval (msec):

QT Interval (msec):

QTcF Interval (msec) (Calculated)

Overall Assessment of ECG:

☐ Normal

☐ Abnormal

If Abnormal, please describe the abnormality:

Significance of Abnormality:

☐ Not Clinically Significant

☐ Clinically Significant

Project Name: GS-US-248-0131

Form: Adverse Event Summary [AES]

Generated On: 08-01-2013 09:32:54

Did the subject experience any Adverse Events during the course of the study?

☐ Yes

☐ No

Project Name: GS-US-248-0131

Form: Adverse Event [AE]

Generated On: 08-01-2013 09:32:54

Adverse Event:

(List diagnosis or each symptom separately)

AE serious:

(If the Adverse Event is Serious, please click the [?] help text to open the SAE Report Form in another window. Print and fill in all the information for the first three pages on the SAE form and fax to the appropriate CRO contact)

☐ Yes

☐ No

Start Date: (DD-MMM-YYYY)

End Date: (DD-MMM-YYYY)

Please check if Ongoing:

☐

Related to any of the Study Drugs:

☐ Yes

(All study drugs are to be considered in assessment of relationship to study drugs: GS-5885, GS-9451, Tego buvir/Placebo , RBV/Placebo and PEG)

☐ No

Related to Study Procedures:

☐ Yes

☐ No

Study Drug Action Taken - GS-5885:

☐ No change

☐ Interrupted

☐ Discontinued

☐ Dose Reduced

Study Drug Action Taken - GS-9451:

☐ No change

☐ Interrupted

☐ Discontinued

☐ Dose Reduced

Study Drug Action Taken - Tego buvir/Placebo:

(Choose 'Not Applicable' if subject is participating in the Rescue Therapy substudy at the time of the AE)

☐ No change

☐ Interrupted

☐ Discontinued

☐ Dose Reduced

☐ Not Applicable

Project Name: GS-US-248-0131

Form: Adverse Event [AE]

Generated On: 08-01-2013 09:32:54

Study Drug Action Taken - RBV/Placebo:

- ☐ No change
☐ Interrupted
☐ Discontinued
☐ Dose Reduced

Study Drug Action Taken - PEG:

(Choose 'Not Applicable' if subject is not participating in the Rescue Therapy substudy at the time of the AE.)

- ☐ No change
☐ Interrupted
☐ Discontinued
☐ Dose Reduced
☐ Not Applicable

Severity:

- ☐ Mild
☐ Moderate
☐ Severe
☐ Life-Threatening

Other Action Taken: (Check all that apply)
None:

☐

Medication Required:

☐

Other Treatment Required:

☐

Hospitalized/Prolonged Hospitalization:

☐

Hidden field for AE_AESER_ALERT

Note: To add additional adverse events, please complete an additional form, by clicking on 'Add a new log line'.

If Adverse Event is Serious, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and E-mail or fax the SAE Report within 24 hours of the Reporter's knowledge of the event. Contact information for faxing and e-mailing this form is found in the study protocol in section 8.5.1.

Project Name: GS-US-248-0131

Form: Adverse Event [AE]

Generated On: 08-01-2013 09:32:54

A Serious Adverse Event is any adverse experience that results in any of the following outcomes:

- (1) Death,**
- (2) Is life-threatening (at immediate risk of death at time of the event),**
- (3) Requires subject hospitalization or prolonged hospitalization,**
- (4) Persistent or significant disability/incapacity,**
- (5) Congenital abnormality/birth defect or**
- (6) Any other important Medical Event based on clinician's judgment or may require medical or surgical intervention to prevent one of the other serious criteria.**

Refer to protocol for protocol-specific SAE definitions.

Project Name: GS-US-248-0131

Form: Complete Physical Exam plus Retinal [PE]

Generated On: 08-01-2013 09:32:54

Select a response for each body system. If a body system is not examined, select "Not Done."

Body System

- ☐ Head, Neck & Thyroid
- ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue
- ☐ Chest (Excluding breasts)
- ☐ Respiratory
- ☐ Cardiovascular
- ☐ Lymph Nodes
- ☐ Abdomen
- ☐ Skin, Nails & Hair
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Retinal Exam Results
- ☐ Other

If Body System is Other, please specify:

Result:

- ☐ Abnormal
- ☐ Normal
- ☐ Not Done

If "Abnormal", please describe abnormal physical findings:

If additional Body Systems are needed then click on 'Add New Log Line' at the bottom of the form.

Project Name: GS-US-248-0131
Form: Complete Physical Examination [PE1]
Generated On: 08-01-2013 09:32:54

Select a response for each body system. If a body system is not examined, select "Not Done."

Body System

- ☐ Head, Neck & Thyroid
- ☐ Eyes, Ears, Nose, Throat, Mouth & Tongue
- ☐ Chest (Excluding breasts)
- ☐ Respiratory
- ☐ Cardiovascular
- ☐ Lymph Nodes
- ☐ Abdomen
- ☐ Skin, Nails & Hair
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Retinal Exam Results
- ☐ Other

If Body System is Other, please specify:

Result:

- ☐ Abnormal
- ☐ Normal
- ☐ Not Done

If "Abnormal", please describe abnormal physical findings:

If additional Body Systems are needed then click on 'Add New Log Line' at the bottom of the form.

Project Name: GS-US-248-0131

Form: Concomitant Medication Summary [CMS]

Generated On: 08-01-2013 09:32:54

Did the subject take any Medications from time of informed consent signing through study completion?

☐ Yes

☐ No

Project Name: GS-US-248-0131

Form: Concomitant Medication [CM]

Generated On: 08-01-2013 09:32:54

Drug Name:

Indication: (Use Medical Terminology)

Route:

- ☐ Inhalation
- ☐ Intradermal
- ☐ Intralesional
- ☐ Intramuscular
- ☐ Intranasal
- ☐ Intravenous
- ☐ Intraocular
- ☐ Intraperitoneal
- ☐ Oral
- ☐ Rectal
- ☐ Subcutaneous
- ☐ Sublingual
- ☐ Topical
- ☐ Vaginal
- ☐ Other

If "Other", please specify:

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Please check if Ongoing:

☐

Note: To add additional concomitant medications, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0131
Form: Death Report [DEATH]
Generated On: 08-01-2013 09:32:54

In addition to this eCRF, please refer to the regulatory binder for an SAE Report form. Complete an SAE Report and E-mail or fax the SAE Report within 24 hours of the Reporter's knowledge of the event. Please also send a copy of the discharge/death summary and autopsy report, if available.

Contact information for faxing and e-mailing these forms is found in the study protocol in section 8.5.1 (Click the [?] help text to open the SAE Report Form in another window. Please fill in all appropriate information on the first three pages before faxing the forms to the appropriate CRO contact.)

Please update the Adverse Event eCRF, as needed.

Date of Death: (DD-MMM-YYYY)

Immediate Cause of Death:

Project Name: GS-US-248-0131

Form: Demographics [DM]

Generated On: 08-01-2013 09:32:54

Date of Birth: (DD-MMM-YYYY)

Age:

Sex:

☐

Male

☐

Female

Ethnicity:

☐

Hispanic or Latino

☐

Not Hispanic or Latino

☐

Not Permitted

Race:

☐

American Indian or Alaska Native

☐

Asian

☐

Black or African Heritage

☐

Native Hawaiian or Pacific Islander

☐

White

☐

Not Permitted

☐

Other

If "Other", please specify:

Year of Birth (yyyy)

Project Name: GS-US-248-0131

Form: Dose Administration (Day 1) [PKEX]

Generated On: 08-01-2013 09:32:54

Name of Actual Treatment:

☐

GS-5885

☐

GS-9451

☐

Tegobuvir/Placebo

☐

RBV/Placebo

Date of First Dose: (DD-MMM-YYYY)

Time of First Dose: (00:00-23:59)

Dose:

Dose Units:

☐

mg

☐

ug

☐

tablets

☐

capsules

Dose Taken With Food

☐

Yes

☐

No

Project Name: GS-US-248-0131

Form: Dose Administration (Serial PK) [PKEX2]

Generated On: 08-01-2013 09:32:55

Dose Timepoint:

- ☐ Pre-PK Day Dose
- ☐ PK Day AM Dose
- ☐ PK Day PM Dose
- ☐ Post-PK Day AM Dose

Name of Actual Treatment:

- ☐ GS-5885
- ☐ GS-9451
- ☐ Tego buvir/Placebo
- ☐ RBV/Placebo

Date of Dose: (DD-MMM-YYYY)

Time of Dose: (00:00-23:59)

Dose:

Dose Units:

- ☐ mg
- ☐ ug
- ☐ tablets
- ☐ capsules

Dose Taken With Food:

- ☐ Yes
- ☐ No

Project Name: GS-US-248-0131

Form: Dose Administration (Single PK) [PKEX1]

Generated On: 08-01-2013 09:32:55

Check 'Not Applicable' box if Subject is participating in Serial PK Substudy at this visit:

☐

Name of Actual Treatment:

☐

GS-5885

☐

GS-9451

☐

Tegobuvir/Placebo

☐

RBV/Placebo

Date of Dose prior to Sample Draw: (DD-MMM-YYYY)

Time of Dose prior to Sample Draw: (00:00-23:59)

Dose:

Dose Units:

☐

mg

☐

ug

☐

tablets

☐

capsules

Dose Taken With Food

☐

Yes

☐

No

Project Name: GS-US-248-0131

Form: Dose Administration (Viral Dynamic Substudy) [PKEX3]

Generated On: 08-01-2013 09:32:55

Name of Actual Treatment:

- ☐ GS-5885
- ☐ GS-9451
- ☐ Tegobuvir/Placebo
- ☐ RBV/Placebo

Date of Dose prior to Sample Draw: (DD-MMM-YYYY)

Time of Dose prior to Sample Draw: (00:00-23:59)

Dose:

Dose Units:

- ☐ mg
- ☐ ug
- ☐ tablets
- ☐ capsules

Dose Taken With Food:

- ☐ Yes
- ☐ No

Project Name: GS-US-248-0131
Form: General Comments [CO]
Generated On: 08-01-2013 09:32:55

Visit:

- ☐ Screening
 - ☐ Initial Treatment Visits
 - ☐ Baseline/Day 1
 - ☐ Day 1
 - ☐ Day 2
 - ☐ Day 3
 - ☐ Day 4
 - ☐ Day 5
 - ☐ Week 1
 - ☐ Day 10
 - ☐ Week 2
 - ☐ Week 4
 - ☐ Week 6
 - ☐ Week 8
 - ☐ Week 10
 - ☐ Week 12
 - ☐ Week 16
 - ☐ Week 20
 - ☐ Week 24
 - ☐ Early Termination (Initial Treatment)
 - ☐ Study Drug Completion (Initial Treatment)
 - ☐ PK and/or Viral Dynamic Substudies
 - ☐ PK Week 2
 - ☐ Post-Treatment Follow-Up Visits
 - ☐ Post-Treatment Follow-Up Week 4
 - ☐ Post-Treatment Follow-Up Week 8
 - ☐ Post-Treatment Follow-Up Week 12
 - ☐ Post-Treatment Follow-Up Week 16
 - ☐ Post-Treatment Follow-Up Week 20
-

- ☐ Post-Treatment Follow-Up Week 24
 - ☐ Post-Treatment Follow-Up Month 6
 - ☐ Rescue Therapy Substudy Follow-Up Visits
 - ☐ Baseline/Day 1 Rescue Therapy
 - ☐ Week 1 Rescue Therapy
 - ☐ Week 2 Rescue Therapy
 - ☐ Week 4 Rescue Therapy
 - ☐ Week 6 Rescue Therapy
 - ☐ Week 8 Rescue Therapy
 - ☐ Week 10 Rescue Therapy
 - ☐ Week 12 Rescue Therapy
 - ☐ Week 16 Rescue Therapy
 - ☐ Week 20 Rescue Therapy
 - ☐ Week 24 Rescue Therapy
 - ☐ Week 28 Rescue Therapy
 - ☐ Week 32 Rescue Therapy
 - ☐ Week 36 Rescue Therapy
 - ☐ Week 40 Rescue Therapy
 - ☐ Week 44 Rescue Therapy
 - ☐ Week 48 Rescue Therapy
 - ☐ Early Termination (Rescue Therapy)
 - ☐ Study Drug Completion (Rescue Therapy)
 - ☐ Post-Rescue Therapy Follow-Up Week 4
 - ☐ Post-Rescue Therapy Follow-Up Week 8
 - ☐ Post-Rescue Therapy Follow-Up Week 12
 - ☐ Post-Rescue Therapy Follow-Up Week 16
 - ☐ Post-Rescue Therapy Follow-Up Week 20
 - ☐ Post-Rescue Therapy Follow-Up Week 24
 - ☐ Post-Rescue Therapy Follow-Up Week 28
-

Project Name: GS-US-248-0131
Form: General Comments [CO]
Generated On: 08-01-2013 09:32:55

- ☐ Post-Rescue Therapy Follow-Up
Month 6
 - ☐ Adverse Events
 - ☐ Concomitant Medication
 - ☐ Study Drug Administration
 - ☐ Missed Dose Overdose Log
 - ☐ Study Drug Accountability
 - ☐ Pregnancy Report
 - ☐ Death
 - ☐ General Comments
 - ☐ Unscheduled
 - ☐ Study Completion
 - ☐ Rescue Therapy Status
-

Project Name: GS-US-248-0131
Form: General Comments [CO]
Generated On: 08-01-2013 09:32:55

Form:

- ☐ Adverse Event
 - ☐ Adverse Event Summary
 - ☐ Complete Physical Examination
 - ☐ Concomitant Medication
 - ☐ Concomitant Medication Summary
 - ☐ Death Report
 - ☐ Demographics
 - ☐ Dose Administration (Day 1)
 - ☐ Dose Administration (Single PK)
 - ☐ Dose Administration (Serial PK)
 - ☐ Dose Administration (Viral Dynamic Substudy)
 - ☐ General Comments
 - ☐ Inclusion/Exclusion Criteria
 - ☐ Investigator's Signature
 - ☐ Liver Fibrosis Assessment
 - ☐ Medical History
 - ☐ Missed Dose and Overdose Log – Initial Treatment
 - ☐ Missed Dose and Overdose Log – Rescue Treatment
 - ☐ Pregnancy Report
 - ☐ PK Plasma (Viral Dynamic Substudy Day 1)
 - ☐ Prior HCV Treatment History
 - ☐ Prior Response Classification
 - ☐ Prior Response History - Breakthrough
 - ☐ Prior Response History - Null or Partial
 - ☐ Prior Response History - Relapser
 - ☐ Randomization
 - ☐ Rescue Therapy Status
 - ☐ Single PK Plasma
 - ☐ Serial PK Plasma
-

Project Name: GS-US-248-0131
Form: General Comments [CO]
Generated On: 08-01-2013 09:32:55

- ☐ Stop Treatment
- ☐ Study Completion
- ☐ Study Drug Accountability - GS-5885
- ☐ Study Drug Accountability - GS-5885 Rescue Therapy
- ☐ Study Drug Accountability - GS-9451
- ☐ Study Drug Accountability - GS-9451 Rescue Therapy
- ☐ Study Drug Accountability - Tego buvir/Placebo
- ☐ Study Drug Accountability - PEG Rescue Therapy
- ☐ Study Drug Accountability - RBV
- ☐ Study Drug Accountability - RBV Rescue Therapy
- ☐ Study Drug Administration - Initial Treatment
- ☐ Study Drug Administration - Rescue Therapy
- ☐ Study Drug Completion (Initial Treatment)
- ☐ Study Drug Completion (Rescue Therapy)
- ☐ Subject Follow-Up Status
- ☐ Urine Pregnancy Test
- ☐ Urine Pregnancy Test (Baseline)
- ☐ Visit Date
- ☐ Vital Signs
- ☐ Vital Signs (Screening)
- ☐ Vital Signs with Weight
- ☐ 12-Lead ECG

General Comments:

General Comments (Continued)

Note: To add additional comments, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0131
Form: Inclusion/Exclusion Criteria [IE]
Generated On: 08-01-2013 09:32:55

Date informed Consent Signed: (DD-MMM-YYYY)

Under which protocol version was the subject enrolled?

- ☐ Amendment 1
☐ Amendment 2

Was subject a Screen Failure?

- ☐ Yes
☐ No

Did the subject meet all eligibility criteria?

- ☐ Yes
☐ No

If “No”, Please complete the following (Please tick all Inclusion criteria not met or Exclusion criteria met):

Inclusion/Exclusion criteria:

- ☐ Inclusion 1
 - ☐ Inclusion 2
 - ☐ Inclusion 3
 - ☐ Inclusion 4
 - ☐ Inclusion 5
 - ☐ Inclusion 6
 - ☐ Inclusion 7
 - ☐ Inclusion 8
 - ☐ Inclusion 9
 - ☐ Inclusion 10
 - ☐ Inclusion 11
 - ☐ Inclusion 12
 - ☐ Inclusion 13
 - ☐ Inclusion 14
 - ☐ Inclusion 15
 - ☐ Inclusion 16
 - ☐ Inclusion 17
 - ☐ Exclusion 1
 - ☐ Exclusion 2
 - ☐ Exclusion 3
 - ☐ Exclusion 4
 - ☐ Exclusion 5
 - ☐ Exclusion 6
 - ☐ Exclusion 7
 - ☐ Exclusion 8
 - ☐ Exclusion 9
 - ☐ Exclusion 10
 - ☐ Exclusion 11
 - ☐ Exclusion 12
-

Project Name: GS-US-248-0131
Form: Inclusion/Exclusion Criteria [IE]
Generated On: 08-01-2013 09:32:55

- ☐ Exclusion 13
- ☐ Exclusion 14
- ☐ Exclusion 15
- ☐ Exclusion 16
- ☐ Exclusion 17
- ☐ Exclusion 18
- ☐ Exclusion 19
- ☐ Exclusion 20
- ☐ Exclusion 21
- ☐ Exclusion 22
- ☐ Exclusion 23
- ☐ Exclusion 24
- ☐ Exclusion 25
- ☐ Exclusion 26
- ☐ Exclusion 27
- ☐ Exclusion 28
- ☐ Exclusion 29

Inclusion criteria not met/Exclusion criteria met?

☐

If subject that did not meet inclusion/exclusion criteria was enrolled, please provide an explanation.

For subjects who are screen failures but meet eligibility criteria - ONLY:
Provide the most significant reason why the subject was not randomized in the IWRS.

- ☐ Adverse Event
 - ☐ Investigator Decision
 - ☐ Subject Withdrew Consent
 - ☐ Lost to Follow-Up
 - ☐ Outside of Visit Window
 - ☐ Study Enrollment Closed
 - ☐ Other
-

Project Name: GS-US-248-0131

Form: Inclusion/Exclusion Criteria *[IE]*

Generated On: 08-01-2013 09:32:55

If "Other", specify:

Project Name: GS-US-248-0131

Form: Investigator's Signature *[INVSIG]*

Generated On: 08-01-2013 09:32:55

By entering my Medidata password, I affirm that I have reviewed and evaluated the case report forms and verify that they accurately reflect the information in the source documents for this subject. I understand source documentation can include (but is not limited to) medical records, laboratory results, x-rays, electronic communications, etc.

Project Name: GS-US-248-0131
Form: Liver Fibrosis Assessment [BIOPSY]
Generated On: 08-01-2013 09:32:55

LIVER BIOPSY

Check if Biopsy not done:

☐

Date of Liver Biopsy: (DD-MMM-YYYY)

Fibrosis Staging Method:

☐

Metavir

☐

Ishak

☐

Knodell

☐

Batts-Ludwig

☐

Scheuer

Fibrosis Staging Result:

☐

F0

☐

F0-F1

☐

F1

☐

F1-F2

☐

F2

☐

F2-F3

☐

F3

☐

F3-F4

☐

F4

☐

F5

☐

F6

Cirrhosis:

☐

Yes

☐

No

NON-INVASIVE ALTERNATIVE TO LIVER BIOPSY

Check if not done:

☐

Date of Procedure: (DD-MMM-YYYY)

Project Name: GS-US-248-0131
Form: Liver Fibrosis Assessment [BIOPSY]
Generated On: 08-01-2013 09:32:55

Method:	<input type="checkbox"/> FibroTest
	<input type="checkbox"/> FibroScan
	<input type="checkbox"/> Acoustic Radiation Force Impulse Imaging
	<input type="checkbox"/> Other
If Method is Other, please specify:	<input type="text"/>
Result:	<input type="text"/>
Cirrhosis	<input type="checkbox"/> Yes
	<input type="checkbox"/> No

Project Name: GS-US-248-0131
Form: Medical History [MH]
Generated On: 08-01-2013 09:32:55

Please record date of diagnosis for Hepatitis C on row 1 and indicate if ongoing by checking the ‘Ongoing’ box.

In addition, click on the 'Add a new Log line' link below and add any relevant medical history.

Condition:	<input type="text"/>
------------	----------------------

Start Date: (DD-MMM-YYYY)	<input type="text" value="/ /"/>
---------------------------	----------------------------------

Stop Date: (DD-MMM-YYYY)	<input type="text" value="/ /"/>
--------------------------	----------------------------------

Check if Condition is Ongoing:	<input type="checkbox"/>
--------------------------------	--------------------------

Note: To add additional Medical History entries, please complete an additional form, by clicking on 'Add a new log line'.

Project Name: GS-US-248-0131

Form: Missed Dose and Overdose Log – Initial Treatment [EXMSOV]

Generated On: 08-01-2013 09:32:55

Only enter a record for days on which the dairy indicates a missed dose or overdose of a study drug. Enter all dosing information for that day.

If a subject mistook an evening dose for the QD drugs GS-9451 or GS-5885 and this was indicated in the dairy, please enter them in the last two columns. If an evening dose of GS-9451 or GS-5885 were not taken, please leave the column blank.

Date (dd-mmm-yyyy)

Morning Dosing:

Please record number of tablets taken: **Ribavirin**

Morning Dosing:

Please record number of capsules taken: **Tegobuvir**

Morning Dosing:

Please record number of tablets taken: **GS-9451**

Morning Dosing:

Please record number of tablets taken: **GS-5885**

Evening Dosing:

Please record number of tablets taken: **Ribavirin**

Evening Dosing:

Please record number of capsules taken: **Tegobuvir**

Evening Dosing:

Please record number of tablets taken: **GS-9451**

Evening Dosing:

Please record number of tablets taken: **GS-5885**

If and overdose of study drug has been reported, please click on the [?] help text to open the Oversdose Form in another window. Fax or email the completed form to the appropriate CRO contact.

Project Name: GS-US-248-0131

Form: Missed Dose and Overdose Log – Rescue Treatment [EXMSOV_RESCUE]

Generated On: 08-01-2013 09:32:55

Only enter a record for days on which the dairy indicates a missed dose or overdose of a study drug. Enter all dosing information for that day.

If a subject mistook an evening dose for the QD drugs GS-9451 or GS-5885 and this was indicated in the dairy, please enter them in the last two columns. If an evening dose of GS-9451 or GS-5885 were not taken, please leave the column blank.

Date (dd-mmm-yyyy)	<input type="text" value="/ /"/>
--------------------	----------------------------------

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **Ribavirin**

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-9451**

Morning Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-5885**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **Ribavirin**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-9451**

Evening Dosing:	<input type="text"/>
------------------------	----------------------

Please record number of tablets taken: **GS-5885**

If and overdose of study drug has been reported, please click on the [?] help text to open the Oversdose Form in another window. Fax or email the completed form to the appropriate CRO contact.

Project Name: GS-US-248-0131

Form: PK Plasma (Viral Dynamic Substudy Day 1) [PKS1]

Generated On: 08-01-2013 09:32:55

Will a serial PK profile be collected for this subject?

☐ Yes

☐ No

IF YES, COMPLETE THE REMAINDER OF THIS FORM

Date of PK Collection: (DD-MMM-YYYY)

Dose Time Point:

☐ Collection Time 4.0 Hours Post-dose

☐ Collection Time 6.0 Hours Post-dose

☐ Collection Time 8.0 Hours Post-dose

Time of PK Collection: (00:00-23:59)

Not Collected

☐

Please specify why this timepoint was not collected:

Project Name: GS-US-248-0131
Form: Pregnancy Report [PREGREP]
Generated On: 08-01-2013 09:32:55

If a pregnancy occurs, please complete as much information as possible on this form.

In addition to this eCRF, refer to the regulatory binder and complete the ‘Pregnancy Report’ and email or fax the report within 24 hours of the Reporter’s knowledge of the event. When the outcome of the pregnancy is known, complete the ‘Pregnancy Outcome Report’.(Click the [?] help text to open the Pregnancy Report Form in another window. Please fill in all information before faxing the forms to the appropriate CRO contact.)

Contact information for faxing and e-mailing these forms to the CRO during the conduct of the study is found in the study protocol in section 8.5.1. Additional reporting details may be found in protocol section 8.7.

Please also report the pregnancy to the Ribavirin Pregnancy Registry at ribavirinpregnancyregistry.com

Last Menstrual Period: (DD-MMM-YYYY)

Pregnancy Confirmed: (DD-MMM-YYYY)

Estimated Date of Delivery: (DD-MMM-YYYY)

(Click the [?] help text to open the Pregnancy Outcome Report Form in another window. Please fill in all information on the first 3 pages before faxing the forms to the appropriate CRO contact.)

Project Name: GS-US-248-0131
Form: Prior HCV Treatment History [PRHCV]
Generated On: 08-01-2013 09:32:55

Treatment:

- ☐ Pegylated Interferon-alfa
☐ Ribavirin

Specify Peg:

- ☐ Peginterferon Alfa-2a (PEGASYs)
☐ Peginterferon Alfa-2b (PEG-INTRON)

Starting Dose:

Dose Unit:

- ☐ ug/kg/week
☐ ug/week
☐ mg/day

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Start Year (yyyy)

Stop Year (yyyy)

Project Name: GS-US-248-0131

Form: Prior Response Classification [PRC]

Generated On: 08-01-2013 09:32:55

Does subject meet protocol criteria for Breakthrough, Relapser, Null, or Partial Responder?

- ☐ Responder: Breakthrough
 - ☐ Responder: Relapser
 - ☐ Non-Responder: Null
 - ☐ Non-Responder: Partial
 - ☐ Protocol Criteria Not Met
-

Project Name: GS-US-248-0131
Form: Prior Response History - Breakthrough [PRHX1]
Generated On: 08-01-2013 09:32:55

Timepoint:

- ☐ Pretreatment HCV RNA
- ☐ Week 12 HCV RNA
- ☐ On Treatment HCV RNA Nadir
(lowest HCV RNA value while
on treatment)
- ☐ Breakthrough HCV RNA
- ☐ End of Treatment HCV RNA
- ☐ Post Treatment HCV RNA

Date of Collection:

Result:

Units:

- ☐ IU/ml
- ☐ Copies/ml
- ☐ Other

If "Other", please specify:

Detectable/Undetectable:

- ☐ Detectable
- ☐ Undetectable

Assay:

- ☐ Rt-PCR
- ☐ TMA
- ☐ bDNA
- ☐ Other

If "Other", please specify:

Breakthrough Year of Collection (yyyy)

Project Name: GS-US-248-0131

Form: Prior Response History - Null or Partial [PRHX3]

Generated On: 08-01-2013 09:32:55

Timepoint:

- ☐ Pretreatment HCV RNA
- ☐ Week 12 HCV RNA
- ☐ On Treatment HCV RNA Nadir
(lowest HCV RNA value while
on treatment)
- ☐ Breakthrough HCV RNA
- ☐ End of Treatment HCV RNA
- ☐ Post Treatment HCV RNA

Date of Collection:

Result:

Units:

- ☐ IU/ml
- ☐ Copies/ml
- ☐ Other

If "Other", please specify:

Detectable/Undetectable:

- ☐ Detectable
- ☐ Undetectable

Assay:

- ☐ Rt-PCR
- ☐ TMA
- ☐ bDNA
- ☐ Other

If "Other", please specify:

Null or Partial Year of Collection (yyyy)

Project Name: GS-US-248-0131

Form: Prior Response History - Relapser [PRHX2]

Generated On: 08-01-2013 09:32:55

Timepoint:

- ☐ Pretreatment HCV RNA
- ☐ Week 12 HCV RNA
- ☐ On Treatment HCV RNA Nadir
(lowest HCV RNA value while
on treatment)
- ☐ Breakthrough HCV RNA
- ☐ End of Treatment HCV RNA
- ☐ Post Treatment HCV RNA

Date of Collection:

Result:

Units:

- ☐ IU/ml
- ☐ Copies/ml
- ☐ Other

If "Other", please specify:

Detectable/Undetectable:

- ☐ Detectable
- ☐ Undetectable

Assay:

- ☐ Rt-PCR
- ☐ TMA
- ☐ bDNA
- ☐ Other

If "Other", please specify:

Relapser Year of Collection (yyyy)

Project Name: GS-US-248-0131

Form: Randomization [RAND]

Generated On: 08-01-2013 09:32:55

Note: All baseline tests and procedures, including ECGs, must be completed prior to randomization and dosing/dispensing of GS-5885, GS-9451, Tegobuvir/Placebo or RBV/Placebo.

Was the Subject Randomized?

☐ Yes
☐ No

4-Digit Subject Number as assigned by IWR system

Will the subject participate in the PK Substudy?

☐ Yes
☐ No

Date of PK Substudy Consent (DD-MMM-YYYY)

Will the subject participate in the Viral Dynamic Substudy?

☐ Yes
☐ No

Date of Viral Dynamic Substudy Consent: (DD-MMM-YYYY)

Will the subject participate in Pharmacogenomic Testing?

☐ Yes
☐ No

Date of Pharmacogenomic Testing Consent: (DD-MMM-YYYY)

RANDNUM+Z_SUBID

Project Name: GS-US-248-0131

Form: Registry Substudy [REGISTRY]

Generated On: 08-01-2013 09:32:55

Which Registry study is the subject eligible to enroll in?

☐

None

☐

SVR Registry (248-0122)

☐

Sequence Registry (248-0123)

☐

NA, Site Not Participating

Will the subject enroll in the registry study?

☐

Yes

☐

No

If No, state the primary reason why the subject will not enroll?

☐

Subject is not interested in participating

☐

Subject will receive other HCV treatment

☐

Lost to follow-up

☐

Other

Other, specify

Project Name: GS-US-248-0131

Form: Rescue Therapy Status [RTS]

Generated On: 08-01-2013 09:32:55

Will subject enroll into Rescue Therapy substudy?

☐ Yes

☐ No

Was subject enrolled due to study unblinding? *if "Yes" check box*

☐

Project Name: GS-US-248-0131

Form: Serial PK Plasma [PKS]

Generated On: 08-01-2013 09:32:55

Will a serial PK profile be collected for this subject?

☐ Yes

☐ No

IF YES, COMPLETE THE REMAINDER OF THIS FORM

Date of PK Collection: (DD-MMM-YYYY)

PK Time Point:

- ☐ Collection Time Pre-dose
- ☐ Collection Time 1.0 Hour Post-dose
- ☐ Collection Time 2.0 Hours Post-dose
- ☐ Collection Time 3.0 Hours Post-dose
- ☐ Collection Time 4.0 Hours Post-dose
- ☐ Collection Time 6.0 Hours Post-dose
- ☐ Collection Time 8.0 Hours Post-dose
- ☐ Collection Time 10.0 Hours Post-dose
- ☐ Collection Time 12.0 Hours Post-dose
- ☐ Collection Time 24.0 Post-dose

Time of PK Collection: (00:00-23:59)

Not Collected

☐

Please specify why this timepoint was not collected:

Collection Time 24.0 Hours Post-Dose: Not Collected

☐

Collection Time 24.0 Hours Post-Dose: Date of PK Collection: (DD-MMM-YYYY)

Collection Time 24.0 Hours Post-Dose: Time of PK Collection: (00:00-23:59)

Collection Time 24.0 Hours Post-Dose: Please specify why this timepoint was not collected:

Project Name: GS-US-248-0131
Form: Single PK Plasma [PK]
Generated On: 08-01-2013 09:32:55

Was Single PK Plasma Sample collected?

☐ Yes

☐ No

Date of PK Collection: (DD-MMM-YYYY)

/ /

Time of PK Collection: (00:00-23:59)

:

Project Name: GS-US-248-0131

Form: Stop Treatment [SPTREAT]

Generated On: 08-01-2013 09:32:55

Has the subject been instructed to stop treatment by the IWR system?

☐ Yes

☐ No

Did subject stop ALL study drug treatment including PEG/RBV at Week 24 based on response based treatment criteria using investigator's discretion?

☐ Yes

☐ No

Project Name: GS-US-248-0131

Form: Study Completion [STUDCOMP]

Generated On: 08-01-2013 09:32:55

Did the subject complete the protocol-planned duration of the study?

☐ Yes

☐ No

If "No", please specify reason for study discontinuation.

☐ Adverse Event

☐ Death

☐ Pregnancy

☐ Efficacy Failure

☐ Protocol Violation

☐ Subject Withdrew Consent

☐ Lost to Follow-Up

☐ Investigator Decision

☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0131

Form: Study Drug Accountability - GS-5885 Rescue Therapy [DAI_RS]

Generated On: 08-01-2013 09:32:55

Visit Dispensed:

- ☐ Baseline Rescue Therapy
- ☐ Week 4 Rescue Therapy
- ☐ Week 8 Rescue Therapy
- ☐ Week 12 Rescue Therapy
- ☐ Week 16 Rescue Therapy
- ☐ Week 20 Rescue Therapy
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☐ Tego buvir/Placebo
- ☒ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tego buvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - GS-5885 [DA1]

Generated On: 08-01-2013 09:32:55

Visit Dispensed:

- ☐ Baseline
☐ Week 4
☐ Week 8
☐ Week 12
☐ Week 16
☐ Week 20
☐ Unscheduled

Drug Name:

- ☒ GS-5885
☐ GS-9451
☐ RBV/Placebo
☐ Tenofovir/Placebo
☐ GS-5885 Rescue Therapy
☐ GS-9451 Rescue Therapy
☐ RBV Rescue Therapy
☐ Tenofovir/Placebo Rescue Therapy
☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - GS-9451 Rescue Therapy [DA2_RS]

Generated On: 08-01-2013 09:32:56

Visit Dispensed:

- ☐ Baseline Rescue Therapy
- ☐ Week 4 Rescue Therapy
- ☐ Week 8 Rescue Therapy
- ☐ Week 12 Rescue Therapy
- ☐ Week 16 Rescue Therapy
- ☐ Week 20 Rescue Therapy
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☐ Tegobuvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☒ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tegobuvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - GS-9451 [DA2]

Generated On: 08-01-2013 09:32:56

Visit Dispensed:

- ☐ Baseline
☐ Week 4
☐ Week 8
☐ Week 12
☐ Week 16
☐ Week 20
☐ Unscheduled

Drug Name:

- ☐ GS-5885
☒ GS-9451
☐ RBV/Placebo
☐ Tenofovir/Placebo
☐ GS-5885 Rescue Therapy
☐ GS-9451 Rescue Therapy
☐ RBV Rescue Therapy
☐ Tenofovir/Placebo Rescue Therapy
☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - PEG Rescue Therapy [DA5_RS]

Generated On: 08-01-2013 09:32:56

Visit Dispensed:

- ☐ Baseline Rescue Therapy
- ☐ Week 4 Rescue Therapy
- ☐ Week 8 Rescue Therapy
- ☐ Week 12 Rescue Therapy
- ☐ Week 16 Rescue Therapy
- ☐ Week 20 Rescue Therapy
- ☐ Week 24 Rescue Therapy
- ☐ Week 28 Rescue Therapy
- ☐ Week 32 Rescue Therapy
- ☐ Week 36 Rescue Therapy
- ☐ Week 40 Rescue Therapy
- ☐ Week 44 Rescue Therapy
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☐ Tego buvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tego buvir/Placebo Rescue Therapy
- ☒ PEG Rescue Therapy

Date Dispensed:

5-Digit Lot Number

Number of Syringes Dispensed:

Project Name: GS-US-248-0131
Form: Study Drug Accountability - PEG Rescue Therapy [DA5_RS]
Generated On: 08-01-2013 09:32:56

Date Returned:

Number of Unused Syringes Returned:

Study Drug Not Returned: ☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - RBV Rescue Therapy [DA4_RS]

Generated On: 08-01-2013 09:32:56

Visit Dispensed:

- ☐ Baseline Rescue Therapy
- ☐ Week 4 Rescue Therapy
- ☐ Week 8 Rescue Therapy
- ☐ Week 12 Rescue Therapy
- ☐ Week 16 Rescue Therapy
- ☐ Week 20 Rescue Therapy
- ☐ Week 24 Rescue Therapy
- ☐ Week 28 Rescue Therapy
- ☐ Week 32 Rescue Therapy
- ☐ Week 36 Rescue Therapy
- ☐ Week 40 Rescue Therapy
- ☐ Week 44 Rescue Therapy
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☐ Tegobuvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☒ RBV Rescue Therapy
- ☐ Tegobuvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Project Name: GS-US-248-0131

Form: Study Drug Accountability - RBV Rescue Therapy [DA4_RS]

Generated On: 08-01-2013 09:32:56

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - RBV/Placebo [DA4]

Generated On: 08-01-2013 09:32:56

Visit Dispensed:

- ☐ Baseline
- ☐ Week 4
- ☐ Week 8
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☒ RBV/Placebo
- ☐ Tegobuvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tegobuvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Tablets Dispensed:

Date Returned:

Number of Tablets Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Accountability - Tegobuvir/Placebo [DA3]

Generated On: 08-01-2013 09:32:56

Visit Dispensed:

- ☐ Baseline
- ☐ Week 4
- ☐ Week 8
- ☐ Week 12
- ☐ Week 16
- ☐ Week 20
- ☐ Unscheduled

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ RBV/Placebo
- ☒ Tegobuvir/Placebo
- ☐ GS-5885 Rescue Therapy
- ☐ GS-9451 Rescue Therapy
- ☐ RBV Rescue Therapy
- ☐ Tegobuvir/Placebo Rescue Therapy
- ☐ PEG Rescue Therapy

Date Dispensed:

5-Digit Bottle Number:

Number of Capsules Dispensed:

Date Returned:

Number of Capsules Returned:

Study Drug Not Returned:

☐

Project Name: GS-US-248-0131

Form: Study Drug Administration - Initial Treatment [EX]

Generated On: 08-01-2013 09:32:56

Drug Name:

- ☐ GS-5885
- ☐ GS-9451
- ☐ Tegobuvir/Placebo
- ☐ RBV/Placebo

Dose:

Dose Units / Frequency:

- ☐ capsules/day
- ☐ tablets/day
- ☐ Other

If "Other", please specify:

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Ongoing:

☐

Check box if study drug was permanently discontinued:

☐

Project Name: GS-US-248-0131

Form: Study Drug Administration - Rescue Therapy [EX_RESCUE]

Generated On: 08-01-2013 09:32:56

Drug Name:

☐

GS-5885 Rescue Therapy

☐

GS-9451 Rescue Therapy

☐

RBV Rescue Therapy

☐

PEG Rescue Therapy

Dose:

Dose Units / Frequency:

☐

capsules/day

☐

tablets/day

☐

ug/week

☐

Other

If "Other", please specify:

Start Date: (DD-MMM-YYYY)

Stop Date: (DD-MMM-YYYY)

Ongoing:

☐

Check box if study drug was permanently discontinued:

☐

Project Name: GS-US-248-0131

Form: Study Drug Completion (Initial Treatment) [SDRGCOMP]

Generated On: 08-01-2013 09:32:56

Did subject complete study drug treatment through Week 24?

☐ Yes

☐ No

If "No", please specify reason for study drug discontinuation:

☐ Adverse Event

☐ Death

☐ Pregnancy

☐ Efficacy Failure

☐ Protocol Violation

☐ Subject Withdrew Consent

☐ Lost to Follow-Up

☐ Investigator Decision

☐ Randomized but Subject Never
Dosed with Study Drug

☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0131

Form: Study Drug Completion (Rescue Therapy) [SDRGCOMP2]

Generated On: 08-01-2013 09:32:56

Did subject complete the rescue therapy study drug through Week 24 or Week 48 as described in the protocol?

☐ Yes

☐ No

If "No", please specify reason for study drug discontinuation

☐ Adverse Event

☐ Death

☐ Pregnancy

☐ Efficacy Failure

☐ Protocol Violation

☐ Subject Withdrew Consent

☐ Lost to Follow-Up

☐ Investigator Decision

☐ Study Discontinued by Sponsor

Project Name: GS-US-248-0131

Form: Subject Follow-Up Status *[DS]*

Generated On: 08-01-2013 09:32:56

Provide the subject status:

If subject has discontinued, please complete the Study Completion form. For female subjects of childbearing potential, please also continue to complete the follow-up Urine Pregnancy Tests until Month 6

Project Name: GS-US-248-0131
Form: Subject Number [SUBID]
Generated On: 08-01-2013 09:32:56

Screening Number (XXX):

Subject Initials (XXX):

SCRNID + SUBJINIT

Project Name: GS-US-248-0131

Form: Urine Pregnancy Test (Baseline) [PREGTEST1]

Generated On: 08-01-2013 09:32:56

Is female subject of childbearing potential?

☐ Yes

☐ No

Date Test Performed: (DD-MMM-YYYY)

Test Result:

☐ Negative

☐ Positive

☐ Not Done

Note: A positive urine pregnancy test must be immediately confirmed with a serum pregnancy test, and the subject must not be enrolled.

Project Name: GS-US-248-0131
Form: Urine Pregnancy Test [PREGTEST]
Generated On: 08-01-2013 09:32:56

Is female subject of childbearing potential?

☐ Yes

☐ No

Date Test Performed: (DD-MMM-YYYY)

Test Result:

☐ Negative

☐ Positive

☐ Not Done

Note: A positive urine pregnancy test must be immediately confirmed with a serum pregnancy test.

Project Name: GS-US-248-0131

Form: Visit Date [VISDT]

Generated On: 08-01-2013 09:32:56

Was Post-Treatment Follow-Up Week 4 visit performed?

☐ Yes

☐ No

Was Post-Rescue Therapy Follow-Up Week 4 visit performed?

☐ Yes

☐ No

Visit Date: (DD-MMM-YYYY)

Was visit performed on the same day as Week 1

☐ Yes

☐ No

Reason for Unscheduled Visit: (Check all that apply)

Evaluation of AE and/or Concomitant Medications:

☐

Vital Signs:

☐

Physical Exam:

☐

ECG:

☐

PK:

☐

Lab Evaluations:

☐

Study Drug Adjustment or Dispensation:

☐

Other:

☐

Other, Specify:

Project Name: GS-US-248-0131
Form: Vital Signs (Screening) [VS1]
Generated On: 08-01-2013 09:32:56

Weight:	<input type="text"/>	kg/ lb
---------	----------------------	--------

Height:	<input type="text"/>	cm/ in
---------	----------------------	--------

Blood Pressure Systolic: (mmHg)	<input type="text"/>
---------------------------------	----------------------

Blood Pressure Diastolic: (mmHg)	<input type="text"/>
----------------------------------	----------------------

Pulse (beats/minute):	<input type="text"/>
-----------------------	----------------------

Respiration: (breaths/minute)	<input type="text"/>
-------------------------------	----------------------

Temperature:	<input type="text"/>	Celsius/ Fahrenheit
--------------	----------------------	------------------------

Project Name: GS-US-248-0131

Form: Vital Signs with Weight [VS2]

Generated On: 08-01-2013 09:32:56

Weight:

kg/ lb

Height:

cm/ in

Blood Pressure Systolic: (mmHg)

Blood Pressure Diastolic: (mmHg)

Pulse (beats/minute):

Respiration: (breaths/minute)

Temperature:

Celsius/
Fahrenheit

Project Name: GS-US-248-0131

Form: Vital Signs [VS]

Generated On: 08-01-2013 09:32:56

Weight:

kg/ lb

Height:

cm/ in

Blood Pressure Systolic: (mmHg)

Blood Pressure Diastolic: (mmHg)

Pulse (beats/minute):

Respiration: (breaths/minute)

Temperature:

Celsius/
Fahrenheit
