14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| PR Interval (msec) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | -12.8 (15.7) |
| Median | -12.5 |
| Q1 ; Q3 | -22.0 ; -4.0 |
| Min ; Max | -36 ; 10 |
|  | | | |
|  | V6 (OLE Month 1) | n | 5 |
| Mean (SD) | -14.0 (16.2) |
| Median | -8.0 |
| Q1 ; Q3 | -26.0 ; 0.0 |
| Min ; Max | -36 ; 0 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | -9.3 (20.0) |
| Median | -8.0 |
| Q1 ; Q3 | -30.0 ; 10.0 |
| Min ; Max | -30 ; 10 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | -7.3 (12.1) |
| Median | -6.0 |
| Q1 ; Q3 | -20.0 ; 4.0 |
| Min ; Max | -20 ; 4 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 1 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| PR Interval (msec) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | -15.0 (7.1) |
| Median | -15.0 |
| Q1 ; Q3 | -20.0 ; -10.0 |
| Min ; Max | -20 ; -10 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 22.0 |
| Median | 22.0 |
| Q1 ; Q3 | 22.0 ; 22.0 |
| Min ; Max | 22 ; 22 |
|  | | | |
| QRS duration (msec) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | -2.3 (7.9) |
| Median | -3.0 |
| Q1 ; Q3 | -6.0 ; 4.0 |
| Min ; Max | -14 ; 8 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | -5.7 (6.5) |
| Median | -6.0 |
| Q1 ; Q3 | -8.0 ; -6.0 |
| Min ; Max | -14 ; 6 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 2 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| QRS duration (msec) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 4.7 (6.4) |
| Median | 2.0 |
| Q1 ; Q3 | 0.0 ; 12.0 |
| Min ; Max | 0 ; 12 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 0.0 (6.0) |
| Median | 0.0 |
| Q1 ; Q3 | -6.0 ; 6.0 |
| Min ; Max | -6 ; 6 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | -7.0 (1.4) |
| Median | -7.0 |
| Q1 ; Q3 | -8.0 ; -6.0 |
| Min ; Max | -8 ; -6 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | -8.0 |
| Median | -8.0 |
| Q1 ; Q3 | -8.0 ; -8.0 |
| Min ; Max | -8 ; -8 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 3 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| QT Interval (msec) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | -12.3 (13.9) |
| Median | -10.0 |
| Q1 ; Q3 | -24.0 ; 0.0 |
| Min ; Max | -32 ; 2 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | -1.3 (23.3) |
| Median | 7.0 |
| Q1 ; Q3 | -14.0 ; 10.0 |
| Min ; Max | -42 ; 24 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 2.7 (33.5) |
| Median | 20.0 |
| Q1 ; Q3 | -36.0 ; 24.0 |
| Min ; Max | -36 ; 24 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | -4.0 (40.1) |
| Median | -8.0 |
| Q1 ; Q3 | -42.0 ; 38.0 |
| Min ; Max | -42 ; 38 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 4 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| QT Interval (msec) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | -16.0 (5.7) |
| Median | -16.0 |
| Q1 ; Q3 | -20.0 ; -12.0 |
| Min ; Max | -20 ; -12 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | -38.0 |
| Median | -38.0 |
| Q1 ; Q3 | -38.0 ; -38.0 |
| Min ; Max | -38 ; -38 |
|  | | | |
| QTcB (msec) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 2.5 (9.3) |
| Median | 2.5 |
| Q1 ; Q3 | 2.0 ; 8.0 |
| Min ; Max | -14 ; 14 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | -1.0 (10.5) |
| Median | 2.5 |
| Q1 ; Q3 | -13.0 ; 7.0 |
| Min ; Max | -15 ; 10 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 5 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| QTcB (msec) | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | 1.0 (12.5) |
| Median | 5.0 |
| Q1 ; Q3 | -13.0 ; 11.0 |
| Min ; Max | -13 ; 11 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 1.3 (5.8) |
| Median | -2.0 |
| Q1 ; Q3 | -2.0 ; 8.0 |
| Min ; Max | -2 ; 8 |
|  | | | |
|  | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | -7.5 (21.9) |
| Median | -7.5 |
| Q1 ; Q3 | -23.0 ; 8.0 |
| Min ; Max | -23 ; 8 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | -9.0 |
| Median | -9.0 |
| Q1 ; Q3 | -9.0 ; -9.0 |
| Min ; Max | -9 ; -9 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 6 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Ventricular Rate (bpm) | V5 (OLE Week 2) | n | 6 |
| Mean (SD) | 6.0 (8.2) |
| Median | 6.0 |
| Q1 ; Q3 | 1.0 ; 10.0 |
| Min ; Max | -5 ; 18 |
|  | | | |
|  | V6 (OLE Month 1) | n | 6 |
| Mean (SD) | -0.5 (9.8) |
| Median | -2.0 |
| Q1 ; Q3 | -8.0 ; 0.0 |
| Min ; Max | -9 ; 18 |
|  | | | |
|  | V7 (OLE Month 2) | n | 3 |
| Mean (SD) | -1.0 (16.1) |
| Median | -6.0 |
| Q1 ; Q3 | -14.0 ; 17.0 |
| Min ; Max | -14 ; 17 |
|  | | | |
|  | V8 (OLE Month 3) | n | 3 |
| Mean (SD) | 2.0 (15.5) |
| Median | 3.0 |
| Q1 ; Q3 | -14.0 ; 17.0 |
| Min ; Max | -14 ; 17 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 7 of 8 | | | |

14. Vital Signs, Other Physical Findings and Other Observations Related to Safety

14.2. ECG

14.2.2 Change from Baseline by Visit

OLE Population

|  |  |  |  |
| --- | --- | --- | --- |
| Parameter (Unit) | Visit | Statistics | Overall  (N=6) |
|  | | | |
| Ventricular Rate (bpm) | V11 (OLE Month 12) | n | 2 |
| Mean (SD) | 4.5 (12.0) |
| Median | 4.5 |
| Q1 ; Q3 | -4.0 ; 13.0 |
| Min ; Max | -4 ; 13 |
|  | | | |
|  | V12 (End of Taper after OLE period) | n | 1 |
| Mean (SD) | 11.0 |
| Median | 11.0 |
| Q1 ; Q3 | 11.0 ; 11.0 |
| Min ; Max | 11 ; 11 |
| Source: Listing 14.2 Baseline is defined as the last available measurements obtained during the screening period, prior to first IMP dose administration during DB period. Output ID: T-ECGCHG 02AUG17 Z:\GWPHARMA\GWEP1447\OLE\_INTERIM\BIOSTATISTICS\PRODUCTION\TABLES\PGM\T-ECGCHG.sas                                                                                 Page 8 of 8 | | | |