## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（4/20）

Age (years): Min<= - <65
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 48 | 48 | 117 | 117 | 106 | 106 |
| Mean | 11.93 | 0.91 | 11.75 | 0.22 | 12.10 | 0.19 |
| SD | 4.783 | 4.673 | 4.993 | 4.010 | 4.272 | 4.399 |
| Minimum | 4.1 | -9.2 | 3.2 | -12.8 | 3.8 | -15.3 |
| Q1 | 7.70 | -2.05 | 8.30 | -1.80 | 9.20 | -2.00 |
| Median | 12.35 | -0.25 | 10.90 | 0.00 | 11.80 | -0.10 |
| Q3 | 14.55 | 3.90 | 13.90 | 2.20 | 14.60 | 2.30 |
| Maximum | 26.7 | 19.0 | 32.2 | 11.0 | 27.1 | 16.4 |
| Week 16 | | | | | | |
| N | 47 | 47 | 117 | 117 | 106 | 106 |
| Mean | 11.35 | 0.32 | 11.73 | 0.20 | 11.62 | -0.29 |
| SD | 4.394 | 3.873 | 5.326 | 5.101 | 4.617 | 4.632 |
| Minimum | 4.7 | -11.4 | 4.2 | -12.8 | 3.8 | -15.6 |
| Q1 | 7.90 | -2.40 | 8.80 | -2.20 | 8.40 | -2.70 |
| Median | 10.50 | 0.70 | 10.90 | 0.30 | 11.30 | -0.10 |
| Q3 | 14.60 | 2.30 | 13.80 | 2.20 | 14.10 | 2.10 |
| Maximum | 20.8 | 9.1 | 50.0 | 36.6 | 32.3 | 22.2 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（5/20）

Age (years): Min<= - <65
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 46 | 46 | 116 | 116 | 106 | 106 |
| Mean | 11.38 | 0.37 | 12.46 | 0.91 | 10.90 | -1.00 |
| SD | 5.122 | 4.863 | 5.444 | 4.901 | 3.990 | 4.493 |
| Minimum | 3.9 | -7.5 | 3.3 | -10.9 | 3.4 | -18.6 |
| Q1 | 7.50 | -2.60 | 8.65 | -1.95 | 7.90 | -3.30 |
| Median | 10.45 | -0.35 | 12.35 | 0.70 | 10.65 | -0.75 |
| Q3 | 13.70 | 1.80 | 14.90 | 3.45 | 13.20 | 1.10 |
| Maximum | 27.9 | 20.2 | 38.5 | 29.5 | 25.6 | 15.2 |
| Week 24 | | | | | | |
| N | 45 | 45 | 116 | 116 | 106 | 106 |
| Mean | 11.24 | 0.18 | 11.44 | -0.11 | 11.35 | -0.55 |
| SD | 5.575 | 4.670 | 4.635 | 3.861 | 4.109 | 4.400 |
| Minimum | 2.9 | -10.4 | 2.7 | -9.7 | 4.3 | -14.2 |
| Q1 | 6.20 | -2.90 | 8.10 | -2.65 | 7.70 | -3.00 |
| Median | 11.40 | -0.20 | 11.25 | 0.15 | 11.60 | -0.20 |
| Q3 | 14.60 | 2.20 | 14.10 | 1.95 | 14.50 | 2.20 |
| Maximum | 30.8 | 12.0 | 27.1 | 12.2 | 23.3 | 10.6 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（6/20）

Age (years): Min<= - <65
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 52 | | 119 | | 109 | |
| Mean | 0.532 | | 0.495 | | 0.490 | |
| SD | 0.2264 | | 0.1951 | | 0.1973 | |
| Minimum | 0.11 | | 0.20 | | 0.13 | |
| Q1 | 0.375 | | 0.350 | | 0.350 | |
| Median | 0.470 | | 0.480 | | 0.480 | |
| Q3 | 0.725 | | 0.600 | | 0.580 | |
| Maximum | 1.15 | | 1.09 | | 1.17 | |
| Week -4 | | | | | | |
| N | 52 | | 119 | | 109 | |
| Mean | 0.563 | | 0.549 | | 0.535 | |
| SD | 0.2435 | | 0.2312 | | 0.2582 | |
| Minimum | 0.18 | | 0.18 | | 0.00 | |
| Q1 | 0.380 | | 0.370 | | 0.390 | |
| Median | 0.500 | | 0.500 | | 0.520 | |
| Q3 | 0.705 | | 0.670 | | 0.650 | |
| Maximum | 1.29 | | 1.34 | | 1.88 | |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（7/20）

Age (years): Min<= - <65
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 52 | | 119 | | 109 | |
| Mean | 0.580 | | 0.557 | | 0.578 | |
| SD | 0.2782 | | 0.2675 | | 0.2331 | |
| Minimum | 0.11 | | 0.00 | | 0.20 | |
| Q1 | 0.410 | | 0.370 | | 0.400 | |
| Median | 0.525 | | 0.500 | | 0.550 | |
| Q3 | 0.710 | | 0.710 | | 0.720 | |
| Maximum | 1.50 | | 1.43 | | 1.22 | |
| Week 2 | | | | | | |
| N | 52 | 52 | 119 | 119 | 109 | 109 |
| Mean | 0.551 | -0.029 | 0.564 | 0.007 | 0.553 | -0.025 |
| SD | 0.3120 | 0.2087 | 0.2694 | 0.2199 | 0.2476 | 0.2225 |
| Minimum | 0.15 | -0.40 | 0.15 | -0.80 | 0.00 | -0.55 |
| Q1 | 0.320 | -0.155 | 0.380 | -0.110 | 0.400 | -0.180 |
| Median | 0.485 | -0.015 | 0.480 | -0.020 | 0.510 | -0.010 |
| Q3 | 0.710 | 0.105 | 0.700 | 0.110 | 0.660 | 0.090 |
| Maximum | 1.24 | 0.53 | 1.38 | 0.70 | 1.49 | 0.64 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（8/20）

Age (years): Min<= - <65
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 51 | 51 | 119 | 119 | 108 | 108 |
| Mean | 0.550 | -0.037 | 0.567 | 0.010 | 0.571 | -0.001 |
| SD | 0.2667 | 0.2176 | 0.2834 | 0.2263 | 0.2393 | 0.2227 |
| Minimum | 0.12 | -0.54 | 0.00 | -0.75 | 0.00 | -0.69 |
| Q1 | 0.360 | -0.180 | 0.370 | -0.120 | 0.395 | -0.140 |
| Median | 0.510 | 0.010 | 0.500 | -0.010 | 0.545 | -0.020 |
| Q3 | 0.670 | 0.080 | 0.710 | 0.160 | 0.715 | 0.155 |
| Maximum | 1.46 | 0.49 | 1.68 | 0.55 | 1.16 | 0.53 |
| Week 8 | | | | | | |
| N | 49 | 49 | 118 | 118 | 107 | 107 |
| Mean | 0.580 | -0.010 | 0.606 | 0.048 | 0.592 | 0.018 |
| SD | 0.2893 | 0.1958 | 0.3178 | 0.2581 | 0.2673 | 0.2472 |
| Minimum | 0.14 | -0.42 | 0.00 | -0.69 | 0.00 | -0.55 |
| Q1 | 0.390 | -0.170 | 0.370 | -0.090 | 0.410 | -0.130 |
| Median | 0.480 | 0.010 | 0.530 | 0.035 | 0.570 | 0.020 |
| Q3 | 0.750 | 0.140 | 0.800 | 0.170 | 0.750 | 0.140 |
| Maximum | 1.31 | 0.42 | 1.83 | 0.96 | 1.64 | 0.99 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（9/20）

Age (years): Min<= - <65
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 48 | 48 | 117 | 117 | 106 | 106 |
| Mean | 0.601 | 0.009 | 0.570 | 0.015 | 0.576 | -0.001 |
| SD | 0.3166 | 0.3159 | 0.2689 | 0.2287 | 0.3093 | 0.2546 |
| Minimum | 0.13 | -0.92 | 0.00 | -0.58 | 0.00 | -0.55 |
| Q1 | 0.365 | -0.135 | 0.380 | -0.100 | 0.350 | -0.160 |
| Median | 0.545 | 0.010 | 0.510 | 0.000 | 0.530 | -0.040 |
| Q3 | 0.780 | 0.185 | 0.720 | 0.140 | 0.760 | 0.160 |
| Maximum | 1.69 | 0.72 | 1.41 | 0.90 | 1.54 | 0.87 |
| Week 16 | | | | | | |
| N | 47 | 47 | 117 | 117 | 106 | 106 |
| Mean | 0.536 | -0.064 | 0.561 | 0.006 | 0.539 | -0.038 |
| SD | 0.2554 | 0.2181 | 0.2907 | 0.2602 | 0.2315 | 0.2243 |
| Minimum | 0.12 | -0.66 | 0.11 | -0.78 | 0.00 | -0.59 |
| Q1 | 0.370 | -0.190 | 0.350 | -0.100 | 0.350 | -0.200 |
| Median | 0.480 | -0.030 | 0.470 | -0.020 | 0.500 | -0.035 |
| Q3 | 0.690 | 0.080 | 0.740 | 0.150 | 0.700 | 0.130 |
| Maximum | 1.19 | 0.39 | 1.50 | 0.87 | 1.14 | 0.44 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（10/20）

Age (years): Min<= - <65
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=52) | | QD (N=119) | | BID (N=109) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 46 | 46 | 116 | 116 | 106 | 106 |
| Mean | 0.525 | -0.072 | 0.559 | 0.000 | 0.515 | -0.062 |
| SD | 0.2737 | 0.2549 | 0.3138 | 0.2593 | 0.2353 | 0.2381 |
| Minimum | 0.20 | -0.61 | 0.00 | -1.00 | 0.00 | -0.76 |
| Q1 | 0.320 | -0.220 | 0.345 | -0.170 | 0.320 | -0.240 |
| Median | 0.405 | -0.045 | 0.475 | -0.020 | 0.495 | -0.040 |
| Q3 | 0.720 | 0.060 | 0.695 | 0.135 | 0.680 | 0.100 |
| Maximum | 1.23 | 0.50 | 1.59 | 0.60 | 1.13 | 0.45 |
| Week 24 | | | | | | |
| N | 45 | 45 | 116 | 116 | 106 | 106 |
| Mean | 0.496 | -0.104 | 0.486 | -0.072 | 0.509 | -0.067 |
| SD | 0.3115 | 0.2894 | 0.2760 | 0.2302 | 0.2265 | 0.2227 |
| Minimum | 0.00 | -0.81 | 0.00 | -1.00 | 0.14 | -0.84 |
| Q1 | 0.270 | -0.220 | 0.305 | -0.190 | 0.340 | -0.200 |
| Median | 0.440 | -0.090 | 0.410 | -0.070 | 0.480 | -0.065 |
| Q3 | 0.610 | 0.000 | 0.590 | 0.050 | 0.630 | 0.090 |
| Maximum | 1.36 | 0.56 | 1.40 | 0.59 | 1.19 | 0.48 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（11/20）

Age (years): 65<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 19 | | 33 | | 42 | |
| Mean | 11.83 | | 9.86 | | 11.13 | |
| SD | 7.145 | | 3.761 | | 3.814 | |
| Minimum | 4.6 | | 4.9 | | 3.2 | |
| Q1 | 6.10 | | 6.70 | | 8.50 | |
| Median | 10.20 | | 10.10 | | 11.30 | |
| Q3 | 13.20 | | 13.20 | | 13.20 | |
| Maximum | 31.9 | | 16.8 | | 22.4 | |
| Week -4 | | | | | | |
| N | 19 | | 33 | | 42 | |
| Mean | 9.47 | | 10.29 | | 10.88 | |
| SD | 3.671 | | 3.608 | | 4.115 | |
| Minimum | 3.2 | | 4.7 | | 3.2 | |
| Q1 | 7.30 | | 7.10 | | 8.70 | |
| Median | 9.80 | | 9.90 | | 9.55 | |
| Q3 | 12.50 | | 12.90 | | 13.90 | |
| Maximum | 15.8 | | 17.4 | | 23.3 | |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（12/20）

Age (years): 65<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 19 | | 33 | | 42 | |
| Mean | 10.16 | | 10.19 | | 10.62 | |
| SD | 3.893 | | 3.569 | | 3.693 | |
| Minimum | 3.6 | | 4.3 | | 3.2 | |
| Q1 | 7.10 | | 6.90 | | 7.80 | |
| Median | 9.90 | | 11.20 | | 11.50 | |
| Q3 | 13.60 | | 12.60 | | 13.60 | |
| Maximum | 16.9 | | 17.3 | | 16.7 | |
| Week 2 | | | | | | |
| N | 19 | 19 | 33 | 33 | 42 | 42 |
| Mean | 10.99 | 0.83 | 10.38 | 0.19 | 10.71 | 0.09 |
| SD | 5.649 | 3.821 | 4.265 | 2.816 | 4.343 | 3.617 |
| Minimum | 2.6 | -6.4 | 5.1 | -6.9 | 3.6 | -8.1 |
| Q1 | 7.20 | -2.00 | 6.80 | -1.40 | 7.50 | -1.70 |
| Median | 10.00 | 0.30 | 8.70 | 0.40 | 9.55 | -0.05 |
| Q3 | 15.00 | 2.70 | 12.70 | 2.20 | 14.20 | 1.30 |
| Maximum | 27.0 | 10.1 | 19.6 | 5.5 | 21.1 | 7.6 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（13/20）

Age (years): 65<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 10.71 | 0.55 | 9.69 | -0.69 | 12.15 | 1.53 |
| SD | 4.802 | 3.121 | 3.685 | 3.368 | 4.984 | 3.744 |
| Minimum | 3.3 | -5.5 | 4.8 | -7.5 | 3.5 | -6.2 |
| Q1 | 7.80 | -1.70 | 6.70 | -3.60 | 9.10 | -1.20 |
| Median | 10.70 | 0.70 | 8.90 | -0.10 | 11.20 | 1.05 |
| Q3 | 13.30 | 2.50 | 12.10 | 1.40 | 16.40 | 2.90 |
| Maximum | 25.3 | 8.4 | 19.9 | 8.0 | 25.3 | 10.7 |
| Week 8 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 10.15 | -0.01 | 10.96 | 0.58 | 12.07 | 1.45 |
| SD | 4.024 | 3.249 | 4.582 | 3.794 | 4.604 | 4.272 |
| Minimum | 3.7 | -5.4 | 4.4 | -6.5 | 3.7 | -5.5 |
| Q1 | 8.00 | -1.90 | 7.70 | -1.60 | 8.40 | -1.60 |
| Median | 9.40 | 0.20 | 10.10 | 0.30 | 11.35 | 0.85 |
| Q3 | 12.30 | 1.90 | 13.90 | 1.60 | 14.90 | 3.50 |
| Maximum | 17.6 | 6.1 | 25.1 | 13.8 | 25.3 | 13.4 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（14/20）

Age (years): 65<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 11.57 | 1.41 | 10.06 | -0.32 | 11.60 | 0.97 |
| SD | 6.994 | 5.338 | 3.381 | 3.643 | 4.159 | 4.220 |
| Minimum | 3.6 | -8.8 | 4.0 | -8.8 | 3.3 | -6.7 |
| Q1 | 7.00 | -1.70 | 6.90 | -2.70 | 8.30 | -1.90 |
| Median | 10.50 | 0.50 | 10.60 | 0.20 | 11.00 | 0.00 |
| Q3 | 13.10 | 2.70 | 13.10 | 2.30 | 15.30 | 3.60 |
| Maximum | 34.8 | 17.9 | 16.0 | 6.6 | 21.1 | 11.7 |
| Week 16 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 11.32 | 1.16 | 10.89 | 0.51 | 10.76 | 0.14 |
| SD | 5.692 | 3.875 | 3.723 | 3.146 | 4.287 | 4.146 |
| Minimum | 3.7 | -6.7 | 5.3 | -6.3 | 3.8 | -8.7 |
| Q1 | 7.80 | -0.80 | 7.30 | -0.70 | 7.50 | -2.10 |
| Median | 9.80 | 0.80 | 11.20 | 0.60 | 10.55 | -0.05 |
| Q3 | 13.70 | 3.50 | 13.50 | 2.50 | 13.30 | 1.80 |
| Maximum | 29.0 | 12.1 | 19.6 | 6.9 | 20.4 | 12.6 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（15/20）

Age (years): 65<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 19 | 19 | 30 | 30 | 42 | 42 |
| Mean | 10.23 | 0.07 | 10.01 | -0.33 | 11.19 | 0.56 |
| SD | 5.025 | 3.477 | 3.392 | 2.886 | 4.258 | 3.592 |
| Minimum | 2.6 | -5.3 | 5.2 | -6.6 | 4.1 | -8.1 |
| Q1 | 6.30 | -3.90 | 6.90 | -2.60 | 8.10 | -1.40 |
| Median | 9.60 | 0.10 | 9.75 | 0.15 | 11.20 | 0.35 |
| Q3 | 13.30 | 3.20 | 12.30 | 2.00 | 13.80 | 1.50 |
| Maximum | 21.8 | 5.6 | 17.2 | 4.3 | 22.0 | 10.4 |
| Week 24 | | | | | | |
| N | 19 | 19 | 30 | 30 | 42 | 42 |
| Mean | 9.59 | -0.56 | 10.78 | 0.44 | 11.31 | 0.69 |
| SD | 4.854 | 3.383 | 4.200 | 3.822 | 4.865 | 4.568 |
| Minimum | 3.3 | -6.6 | 3.3 | -7.8 | 3.1 | -9.1 |
| Q1 | 6.60 | -2.80 | 7.50 | -2.00 | 7.90 | -1.70 |
| Median | 8.50 | -0.30 | 11.20 | 0.55 | 11.10 | -0.05 |
| Q3 | 11.10 | 2.00 | 14.00 | 3.20 | 13.90 | 1.70 |
| Maximum | 23.1 | 6.2 | 19.7 | 9.7 | 30.9 | 19.3 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（16/20）

Age (years): 65<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 19 | | 33 | | 42 | |
| Mean | 0.563 | | 0.400 | | 0.472 | |
| SD | 0.4258 | | 0.1862 | | 0.1578 | |
| Minimum | 0.27 | | 0.13 | | 0.16 | |
| Q1 | 0.330 | | 0.280 | | 0.370 | |
| Median | 0.360 | | 0.370 | | 0.465 | |
| Q3 | 0.640 | | 0.450 | | 0.590 | |
| Maximum | 1.97 | | 1.04 | | 0.78 | |
| Week -4 | | | | | | |
| N | 19 | | 33 | | 42 | |
| Mean | 0.446 | | 0.417 | | 0.468 | |
| SD | 0.2579 | | 0.1462 | | 0.2442 | |
| Minimum | 0.16 | | 0.00 | | 0.00 | |
| Q1 | 0.220 | | 0.310 | | 0.330 | |
| Median | 0.340 | | 0.430 | | 0.440 | |
| Q3 | 0.640 | | 0.490 | | 0.560 | |
| Maximum | 1.07 | | 0.76 | | 1.45 | |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（17/20）

Age (years): 65<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 19 | | 33 | | 42 | |
| Mean | 0.506 | | 0.445 | | 0.505 | |
| SD | 0.2595 | | 0.2063 | | 0.2000 | |
| Minimum | 0.23 | | 0.16 | | 0.00 | |
| Q1 | 0.340 | | 0.290 | | 0.380 | |
| Median | 0.430 | | 0.400 | | 0.480 | |
| Q3 | 0.590 | | 0.560 | | 0.570 | |
| Maximum | 1.23 | | 0.95 | | 1.07 | |
| Week 2 | | | | | | |
| N | 19 | 19 | 33 | 33 | 42 | 42 |
| Mean | 0.479 | -0.027 | 0.435 | -0.010 | 0.465 | -0.040 |
| SD | 0.3210 | 0.1876 | 0.2435 | 0.2100 | 0.1548 | 0.1648 |
| Minimum | 0.26 | -0.30 | 0.00 | -0.56 | 0.19 | -0.42 |
| Q1 | 0.290 | -0.160 | 0.270 | -0.110 | 0.350 | -0.120 |
| Median | 0.330 | -0.060 | 0.420 | -0.030 | 0.450 | -0.040 |
| Q3 | 0.580 | 0.100 | 0.550 | 0.100 | 0.570 | 0.050 |
| Maximum | 1.50 | 0.42 | 1.23 | 0.38 | 0.81 | 0.38 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（18/20）

Age (years): 65<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 0.485 | -0.021 | 0.417 | -0.023 | 0.530 | 0.025 |
| SD | 0.2115 | 0.1793 | 0.2197 | 0.2155 | 0.1854 | 0.1887 |
| Minimum | 0.24 | -0.46 | 0.00 | -0.76 | 0.20 | -0.52 |
| Q1 | 0.330 | -0.100 | 0.300 | -0.100 | 0.380 | -0.070 |
| Median | 0.430 | 0.040 | 0.370 | -0.020 | 0.535 | 0.025 |
| Q3 | 0.610 | 0.100 | 0.540 | 0.090 | 0.670 | 0.170 |
| Maximum | 1.06 | 0.27 | 1.23 | 0.38 | 1.01 | 0.36 |
| Week 8 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 0.472 | -0.034 | 0.438 | -0.002 | 0.555 | 0.050 |
| SD | 0.2507 | 0.1193 | 0.1749 | 0.2163 | 0.2570 | 0.2195 |
| Minimum | 0.19 | -0.28 | 0.17 | -0.59 | 0.00 | -0.38 |
| Q1 | 0.280 | -0.090 | 0.290 | -0.070 | 0.350 | -0.110 |
| Median | 0.430 | -0.040 | 0.450 | 0.000 | 0.545 | 0.025 |
| Q3 | 0.580 | 0.060 | 0.550 | 0.120 | 0.740 | 0.210 |
| Maximum | 1.07 | 0.15 | 0.81 | 0.40 | 1.22 | 0.55 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（19/20）

Age (years): 65<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 0.522 | 0.016 | 0.408 | -0.032 | 0.505 | 0.000 |
| SD | 0.3315 | 0.1653 | 0.2250 | 0.2466 | 0.1973 | 0.2045 |
| Minimum | 0.13 | -0.33 | 0.00 | -0.76 | 0.17 | -0.41 |
| Q1 | 0.320 | -0.060 | 0.280 | -0.140 | 0.360 | -0.130 |
| Median | 0.390 | 0.020 | 0.370 | 0.030 | 0.480 | -0.020 |
| Q3 | 0.630 | 0.170 | 0.480 | 0.110 | 0.690 | 0.110 |
| Maximum | 1.42 | 0.27 | 1.04 | 0.48 | 0.84 | 0.53 |
| Week 16 | | | | | | |
| N | 19 | 19 | 31 | 31 | 42 | 42 |
| Mean | 0.507 | 0.002 | 0.424 | -0.016 | 0.473 | -0.032 |
| SD | 0.2720 | 0.1681 | 0.2468 | 0.2423 | 0.1930 | 0.2310 |
| Minimum | 0.19 | -0.35 | 0.00 | -0.76 | 0.00 | -0.75 |
| Q1 | 0.340 | -0.070 | 0.250 | -0.140 | 0.360 | -0.130 |
| Median | 0.420 | -0.030 | 0.410 | -0.020 | 0.445 | -0.015 |
| Q3 | 0.580 | 0.050 | 0.510 | 0.080 | 0.590 | 0.100 |
| Maximum | 1.12 | 0.37 | 1.02 | 0.62 | 0.90 | 0.41 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-18　年齢別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（20/20）

Age (years): 65<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=19) | | QD (N=33) | | BID (N=42) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 19 | 19 | 30 | 30 | 42 | 42 |
| Mean | 0.441 | -0.065 | 0.381 | -0.067 | 0.440 | -0.065 |
| SD | 0.2266 | 0.1213 | 0.1935 | 0.2273 | 0.2043 | 0.2155 |
| Minimum | 0.19 | -0.24 | 0.00 | -0.76 | 0.11 | -0.61 |
| Q1 | 0.310 | -0.160 | 0.280 | -0.160 | 0.290 | -0.160 |
| Median | 0.350 | -0.080 | 0.330 | -0.035 | 0.410 | -0.095 |
| Q3 | 0.540 | 0.050 | 0.450 | 0.060 | 0.550 | 0.100 |
| Maximum | 1.07 | 0.14 | 0.97 | 0.38 | 1.08 | 0.44 |
| Week 24 | | | | | | |
| N | 19 | 19 | 30 | 30 | 42 | 42 |
| Mean | 0.383 | -0.123 | 0.389 | -0.058 | 0.418 | -0.087 |
| SD | 0.1535 | 0.1831 | 0.2205 | 0.2311 | 0.2013 | 0.2131 |
| Minimum | 0.17 | -0.60 | 0.00 | -0.76 | 0.00 | -0.64 |
| Q1 | 0.290 | -0.280 | 0.270 | -0.150 | 0.310 | -0.190 |
| Median | 0.320 | -0.100 | 0.305 | -0.015 | 0.390 | -0.085 |
| Q3 | 0.500 | -0.010 | 0.510 | 0.080 | 0.530 | 0.010 |
| Maximum | 0.77 | 0.16 | 0.97 | 0.38 | 1.04 | 0.49 |

添付資料（5.3.5.3-3）Table 2.3.1.1

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（1/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 41 | | 72 | | 88 | |
| Mean | 11.36 | | 10.70 | | 11.56 | |
| SD | 5.338 | | 3.738 | | 4.382 | |
| Minimum | 4.6 | | 4.4 | | 3.2 | |
| Q1 | 7.40 | | 7.75 | | 8.40 | |
| Median | 10.20 | | 10.25 | | 10.95 | |
| Q3 | 13.70 | | 13.30 | | 14.50 | |
| Maximum | 31.9 | | 19.8 | | 22.4 | |
| Week -4 | | | | | | |
| N | 41 | | 72 | | 88 | |
| Mean | 10.45 | | 11.45 | | 11.03 | |
| SD | 3.732 | | 4.498 | | 4.054 | |
| Minimum | 3.2 | | 4.4 | | 3.2 | |
| Q1 | 8.30 | | 8.10 | | 8.35 | |
| Median | 10.20 | | 11.05 | | 10.40 | |
| Q3 | 12.40 | | 13.90 | | 13.30 | |
| Maximum | 20.3 | | 24.6 | | 24.0 | |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（2/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 41 | | 72 | | 88 | |
| Mean | 10.64 | | 11.08 | | 11.53 | |
| SD | 3.706 | | 4.168 | | 4.259 | |
| Minimum | 3.6 | | 5.1 | | 3.2 | |
| Q1 | 7.70 | | 7.65 | | 8.30 | |
| Median | 10.60 | | 10.90 | | 11.65 | |
| Q3 | 13.30 | | 12.70 | | 14.40 | |
| Maximum | 18.7 | | 22.0 | | 23.3 | |
| Week 2 | | | | | | |
| N | 41 | 41 | 72 | 72 | 88 | 88 |
| Mean | 10.15 | -0.49 | 11.60 | 0.52 | 11.25 | -0.29 |
| SD | 4.746 | 3.154 | 5.084 | 3.521 | 4.470 | 3.114 |
| Minimum | 2.6 | -6.4 | 3.0 | -9.6 | 3.6 | -8.1 |
| Q1 | 7.20 | -2.30 | 7.55 | -1.45 | 8.00 | -1.95 |
| Median | 9.30 | -0.60 | 10.60 | 0.45 | 10.35 | -0.15 |
| Q3 | 12.20 | 0.30 | 13.80 | 2.50 | 14.35 | 1.65 |
| Maximum | 27.0 | 10.1 | 25.8 | 12.1 | 26.7 | 7.6 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（3/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 40 | 40 | 72 | 72 | 88 | 88 |
| Mean | 10.74 | 0.09 | 10.82 | -0.27 | 12.02 | 0.49 |
| SD | 4.251 | 3.528 | 4.607 | 3.414 | 4.530 | 3.315 |
| Minimum | 3.3 | -7.0 | 3.2 | -8.5 | 3.5 | -6.5 |
| Q1 | 8.10 | -2.20 | 7.30 | -2.60 | 8.60 | -1.55 |
| Median | 10.65 | 0.25 | 9.65 | -0.20 | 11.40 | 0.40 |
| Q3 | 12.90 | 1.50 | 14.30 | 1.75 | 15.60 | 2.00 |
| Maximum | 25.3 | 9.1 | 27.3 | 8.4 | 25.3 | 10.7 |
| Week 8 | | | | | | |
| N | 39 | 39 | 72 | 72 | 88 | 88 |
| Mean | 11.04 | 0.49 | 11.33 | 0.25 | 11.78 | 0.25 |
| SD | 4.213 | 2.646 | 4.786 | 3.293 | 4.286 | 3.420 |
| Minimum | 3.7 | -5.4 | 4.0 | -8.0 | 3.7 | -10.2 |
| Q1 | 8.00 | -0.90 | 8.05 | -1.70 | 8.40 | -1.25 |
| Median | 10.80 | 0.30 | 10.65 | 0.00 | 11.35 | 0.30 |
| Q3 | 14.80 | 2.90 | 13.55 | 1.90 | 14.00 | 2.05 |
| Maximum | 19.1 | 5.2 | 29.8 | 14.0 | 27.2 | 9.8 |

添付資料（5.3.5.3-3）Table 2.3.1.2

表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（4/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 39 | 39 | 71 | 71 | 88 | 88 |
| Mean | 11.49 | 0.94 | 10.63 | -0.30 | 11.99 | 0.45 |
| SD | 5.514 | 4.539 | 4.456 | 3.282 | 4.173 | 4.010 |
| Minimum | 3.6 | -9.2 | 4.0 | -6.5 | 3.3 | -11.1 |
| Q1 | 7.20 | -1.20 | 8.00 | -2.70 | 9.05 | -1.85 |
| Median | 11.30 | 1.10 | 10.00 | 0.00 | 11.65 | -0.25 |
| Q3 | 13.90 | 3.80 | 13.40 | 1.30 | 14.90 | 2.65 |
| Maximum | 34.8 | 17.9 | 32.2 | 10.5 | 21.1 | 11.7 |
| Week 16 | | | | | | |
| N | 39 | 39 | 71 | 71 | 88 | 88 |
| Mean | 10.91 | 0.36 | 10.70 | -0.23 | 11.29 | -0.24 |
| SD | 5.043 | 3.816 | 3.528 | 3.066 | 4.302 | 3.849 |
| Minimum | 3.7 | -6.7 | 4.2 | -8.7 | 3.8 | -8.7 |
| Q1 | 7.80 | -2.40 | 8.10 | -2.10 | 8.00 | -2.60 |
| Median | 9.10 | 0.80 | 10.10 | 0.00 | 11.05 | 0.05 |
| Q3 | 14.10 | 2.30 | 12.80 | 1.60 | 13.75 | 1.70 |
| Maximum | 29.0 | 12.1 | 21.6 | 7.2 | 21.4 | 12.6 |

添付資料（5.3.5.3-3）Table 2.3.1.2

表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（5/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 38 | 38 | 71 | 71 | 88 | 88 |
| Mean | 9.82 | -0.69 | 11.53 | 0.60 | 10.88 | -0.65 |
| SD | 4.159 | 3.452 | 5.440 | 5.053 | 3.692 | 3.598 |
| Minimum | 2.6 | -7.5 | 3.7 | -8.1 | 3.4 | -11.7 |
| Q1 | 6.70 | -3.40 | 7.70 | -2.20 | 8.00 | -2.70 |
| Median | 9.55 | -0.80 | 11.20 | 0.30 | 11.40 | -0.40 |
| Q3 | 13.30 | 1.30 | 14.10 | 2.80 | 13.35 | 1.40 |
| Maximum | 21.8 | 7.0 | 38.5 | 29.5 | 19.5 | 10.1 |
| Week 24 | | | | | | |
| N | 38 | 38 | 71 | 71 | 88 | 88 |
| Mean | 9.98 | -0.52 | 10.88 | -0.05 | 11.00 | -0.53 |
| SD | 5.033 | 4.072 | 4.316 | 3.758 | 4.102 | 4.049 |
| Minimum | 2.9 | -9.8 | 2.7 | -9.7 | 3.1 | -14.2 |
| Q1 | 6.10 | -3.10 | 7.60 | -2.60 | 7.40 | -2.25 |
| Median | 8.50 | -0.45 | 10.70 | 0.20 | 11.30 | -0.20 |
| Q3 | 13.80 | 2.20 | 13.90 | 1.90 | 14.75 | 1.45 |
| Maximum | 23.1 | 8.5 | 27.1 | 12.2 | 19.4 | 10.6 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（6/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 41 | | 72 | | 88 | |
| Mean | 0.501 | | 0.460 | | 0.481 | |
| SD | 0.2388 | | 0.1974 | | 0.1827 | |
| Minimum | 0.15 | | 0.15 | | 0.13 | |
| Q1 | 0.350 | | 0.305 | | 0.350 | |
| Median | 0.440 | | 0.430 | | 0.485 | |
| Q3 | 0.630 | | 0.525 | | 0.580 | |
| Maximum | 1.35 | | 1.04 | | 1.09 | |
| Week -4 | | | | | | |
| N | 41 | | 72 | | 88 | |
| Mean | 0.475 | | 0.516 | | 0.499 | |
| SD | 0.2506 | | 0.2395 | | 0.2436 | |
| Minimum | 0.16 | | 0.00 | | 0.00 | |
| Q1 | 0.280 | | 0.360 | | 0.370 | |
| Median | 0.420 | | 0.460 | | 0.490 | |
| Q3 | 0.580 | | 0.635 | | 0.570 | |
| Maximum | 1.19 | | 1.31 | | 1.88 | |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（7/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 41 | | 72 | | 88 | |
| Mean | 0.521 | | 0.527 | | 0.538 | |
| SD | 0.2683 | | 0.2502 | | 0.2097 | |
| Minimum | 0.11 | | 0.17 | | 0.00 | |
| Q1 | 0.330 | | 0.380 | | 0.395 | |
| Median | 0.470 | | 0.475 | | 0.510 | |
| Q3 | 0.620 | | 0.590 | | 0.620 | |
| Maximum | 1.50 | | 1.43 | | 1.14 | |
| Week 2 | | | | | | |
| N | 41 | 41 | 72 | 72 | 88 | 88 |
| Mean | 0.463 | -0.059 | 0.520 | -0.007 | 0.500 | -0.038 |
| SD | 0.2774 | 0.1812 | 0.2873 | 0.1921 | 0.2024 | 0.1911 |
| Minimum | 0.17 | -0.38 | 0.00 | -0.53 | 0.00 | -0.51 |
| Q1 | 0.290 | -0.180 | 0.325 | -0.120 | 0.345 | -0.165 |
| Median | 0.370 | -0.060 | 0.450 | -0.035 | 0.500 | -0.040 |
| Q3 | 0.560 | 0.040 | 0.685 | 0.100 | 0.605 | 0.080 |
| Maximum | 1.50 | 0.38 | 1.38 | 0.46 | 1.09 | 0.44 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（8/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 40 | 40 | 72 | 72 | 88 | 88 |
| Mean | 0.485 | -0.044 | 0.529 | 0.002 | 0.532 | -0.006 |
| SD | 0.2459 | 0.2292 | 0.2859 | 0.2296 | 0.2096 | 0.1938 |
| Minimum | 0.18 | -0.54 | 0.13 | -0.75 | 0.00 | -0.40 |
| Q1 | 0.325 | -0.205 | 0.340 | -0.110 | 0.380 | -0.140 |
| Median | 0.420 | 0.005 | 0.460 | -0.005 | 0.525 | -0.020 |
| Q3 | 0.590 | 0.080 | 0.645 | 0.130 | 0.670 | 0.150 |
| Maximum | 1.46 | 0.49 | 1.49 | 0.55 | 1.16 | 0.44 |
| Week 8 | | | | | | |
| N | 39 | 39 | 72 | 72 | 88 | 88 |
| Mean | 0.492 | -0.039 | 0.573 | 0.047 | 0.541 | 0.003 |
| SD | 0.2695 | 0.1626 | 0.2763 | 0.2099 | 0.2597 | 0.2224 |
| Minimum | 0.14 | -0.42 | 0.22 | -0.48 | 0.00 | -0.55 |
| Q1 | 0.290 | -0.160 | 0.365 | -0.070 | 0.350 | -0.150 |
| Median | 0.430 | -0.020 | 0.500 | 0.030 | 0.520 | 0.010 |
| Q3 | 0.660 | 0.040 | 0.685 | 0.120 | 0.745 | 0.100 |
| Maximum | 1.28 | 0.21 | 1.49 | 0.79 | 1.22 | 0.55 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（9/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 39 | 39 | 71 | 71 | 88 | 88 |
| Mean | 0.546 | 0.014 | 0.501 | -0.021 | 0.518 | -0.020 |
| SD | 0.3069 | 0.2769 | 0.2214 | 0.2030 | 0.2462 | 0.2135 |
| Minimum | 0.21 | -0.92 | 0.15 | -0.58 | 0.00 | -0.55 |
| Q1 | 0.340 | -0.090 | 0.350 | -0.140 | 0.355 | -0.160 |
| Median | 0.480 | 0.050 | 0.450 | -0.020 | 0.490 | -0.050 |
| Q3 | 0.630 | 0.170 | 0.630 | 0.090 | 0.695 | 0.100 |
| Maximum | 1.69 | 0.72 | 1.13 | 0.48 | 1.54 | 0.53 |
| Week 16 | | | | | | |
| N | 39 | 39 | 71 | 71 | 88 | 88 |
| Mean | 0.474 | -0.058 | 0.504 | -0.018 | 0.489 | -0.049 |
| SD | 0.2368 | 0.2050 | 0.2455 | 0.2031 | 0.2148 | 0.2218 |
| Minimum | 0.12 | -0.66 | 0.11 | -0.59 | 0.00 | -0.75 |
| Q1 | 0.310 | -0.130 | 0.310 | -0.110 | 0.335 | -0.195 |
| Median | 0.420 | -0.040 | 0.470 | -0.040 | 0.460 | -0.045 |
| Q3 | 0.620 | 0.060 | 0.630 | 0.090 | 0.625 | 0.120 |
| Maximum | 1.14 | 0.37 | 1.38 | 0.62 | 1.14 | 0.42 |

添付資料（5.3.5.3-3）Table 2.3.1.2

表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（10/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=41) | | QD (N=72) | | BID (N=88) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 38 | 38 | 71 | 71 | 88 | 88 |
| Mean | 0.416 | -0.111 | 0.499 | -0.022 | 0.468 | -0.070 |
| SD | 0.2078 | 0.1792 | 0.3062 | 0.2242 | 0.2256 | 0.2136 |
| Minimum | 0.19 | -0.61 | 0.13 | -0.61 | 0.00 | -0.61 |
| Q1 | 0.260 | -0.220 | 0.310 | -0.160 | 0.295 | -0.240 |
| Median | 0.345 | -0.085 | 0.410 | -0.050 | 0.455 | -0.055 |
| Q3 | 0.510 | 0.000 | 0.580 | 0.090 | 0.600 | 0.070 |
| Maximum | 1.07 | 0.21 | 1.59 | 0.59 | 1.08 | 0.44 |
| Week 24 | | | | | | |
| N | 38 | 38 | 71 | 71 | 88 | 88 |
| Mean | 0.385 | -0.142 | 0.471 | -0.050 | 0.452 | -0.085 |
| SD | 0.2138 | 0.1955 | 0.2561 | 0.1910 | 0.2041 | 0.2136 |
| Minimum | 0.00 | -0.62 | 0.00 | -0.66 | 0.00 | -0.84 |
| Q1 | 0.270 | -0.240 | 0.300 | -0.170 | 0.320 | -0.200 |
| Median | 0.340 | -0.100 | 0.430 | -0.050 | 0.425 | -0.100 |
| Q3 | 0.470 | -0.040 | 0.600 | 0.030 | 0.540 | 0.050 |
| Maximum | 1.15 | 0.29 | 1.30 | 0.38 | 1.19 | 0.39 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（11/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 30 | | 80 | | 63 | |
| Mean | 11.93 | | 10.71 | | 10.74 | |
| SD | 6.023 | | 4.104 | | 4.590 | |
| Minimum | 3.6 | | 2.8 | | 4.0 | |
| Q1 | 7.80 | | 7.35 | | 7.20 | |
| Median | 11.70 | | 10.95 | | 9.70 | |
| Q3 | 15.70 | | 13.40 | | 13.20 | |
| Maximum | 28.0 | | 22.9 | | 24.0 | |
| Week -4 | | | | | | |
| N | 30 | | 80 | | 63 | |
| Mean | 12.20 | | 11.57 | | 11.25 | |
| SD | 5.122 | | 4.274 | | 4.555 | |
| Minimum | 3.4 | | 3.4 | | 4.4 | |
| Q1 | 9.90 | | 8.40 | | 8.00 | |
| Median | 11.50 | | 11.05 | | 10.40 | |
| Q3 | 14.20 | | 15.00 | | 14.50 | |
| Maximum | 29.4 | | 23.7 | | 27.4 | |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（12/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 30 | | 80 | | 63 | |
| Mean | 11.28 | | 11.44 | | 11.58 | |
| SD | 4.583 | | 4.245 | | 4.312 | |
| Minimum | 5.2 | | 1.9 | | 4.2 | |
| Q1 | 7.70 | | 8.40 | | 9.20 | |
| Median | 10.15 | | 11.45 | | 10.60 | |
| Q3 | 13.90 | | 13.80 | | 13.40 | |
| Maximum | 26.0 | | 22.8 | | 26.9 | |
| Week 2 | | | | | | |
| N | 30 | 30 | 80 | 80 | 63 | 63 |
| Mean | 12.31 | 1.02 | 11.35 | -0.10 | 11.12 | -0.46 |
| SD | 6.263 | 4.461 | 4.396 | 2.960 | 3.723 | 4.262 |
| Minimum | 5.0 | -8.4 | 4.1 | -7.3 | 4.0 | -13.1 |
| Q1 | 8.20 | -2.00 | 7.80 | -2.05 | 8.40 | -2.30 |
| Median | 11.20 | 1.15 | 11.05 | 0.35 | 10.80 | -0.50 |
| Q3 | 14.40 | 3.90 | 14.45 | 2.00 | 13.50 | 1.90 |
| Maximum | 36.4 | 10.4 | 21.2 | 5.5 | 19.4 | 10.1 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（13/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 30 | 30 | 78 | 78 | 62 | 62 |
| Mean | 11.81 | 0.52 | 11.11 | -0.44 | 11.37 | -0.19 |
| SD | 5.031 | 4.157 | 3.913 | 3.805 | 3.732 | 4.571 |
| Minimum | 4.8 | -8.9 | 2.5 | -11.0 | 5.3 | -17.2 |
| Q1 | 7.80 | -2.00 | 8.70 | -3.00 | 8.80 | -1.60 |
| Median | 11.95 | 0.90 | 10.85 | -0.10 | 10.95 | 0.15 |
| Q3 | 15.60 | 3.20 | 13.60 | 1.70 | 13.90 | 2.20 |
| Maximum | 26.3 | 7.9 | 22.2 | 8.0 | 20.0 | 8.4 |
| Week 8 | | | | | | |
| N | 29 | 29 | 77 | 77 | 61 | 61 |
| Mean | 12.22 | 1.03 | 12.29 | 0.65 | 12.36 | 0.81 |
| SD | 4.053 | 3.001 | 4.648 | 3.969 | 4.403 | 4.751 |
| Minimum | 6.1 | -4.4 | 3.5 | -9.0 | 4.3 | -13.4 |
| Q1 | 9.80 | -1.70 | 9.20 | -1.40 | 9.20 | -1.80 |
| Median | 11.40 | 0.50 | 12.30 | 0.80 | 11.80 | 1.00 |
| Q3 | 14.50 | 3.60 | 14.70 | 2.30 | 15.00 | 2.70 |
| Maximum | 24.2 | 6.8 | 25.1 | 13.8 | 25.3 | 13.4 |

添付資料（5.3.5.3-3）Table 2.3.1.2

表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（14/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 28 | 28 | 77 | 77 | 60 | 60 |
| Mean | 12.29 | 1.21 | 12.10 | 0.47 | 11.91 | 0.36 |
| SD | 5.416 | 5.301 | 4.914 | 4.435 | 4.354 | 4.838 |
| Minimum | 4.1 | -5.2 | 3.2 | -12.8 | 3.8 | -15.3 |
| Q1 | 8.05 | -2.05 | 8.60 | -1.80 | 8.85 | -2.05 |
| Median | 12.00 | -0.70 | 12.00 | 0.30 | 11.60 | 0.35 |
| Q3 | 15.15 | 4.00 | 14.40 | 3.10 | 14.50 | 2.90 |
| Maximum | 26.7 | 19.0 | 24.3 | 11.0 | 27.1 | 16.4 |
| Week 16 | | | | | | |
| N | 27 | 27 | 77 | 77 | 60 | 60 |
| Mean | 11.97 | 0.86 | 12.34 | 0.71 | 11.51 | -0.05 |
| SD | 4.328 | 3.983 | 6.018 | 5.880 | 4.875 | 5.324 |
| Minimum | 4.7 | -11.4 | 5.3 | -12.8 | 4.7 | -15.6 |
| Q1 | 9.30 | -1.50 | 9.00 | -1.60 | 7.85 | -2.80 |
| Median | 12.80 | 0.70 | 11.40 | 0.60 | 11.00 | -0.20 |
| Q3 | 15.40 | 3.50 | 14.30 | 3.00 | 13.80 | 2.55 |
| Maximum | 20.1 | 9.1 | 50.0 | 36.6 | 32.3 | 22.2 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（15/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 27 | 27 | 75 | 75 | 60 | 60 |
| Mean | 12.76 | 1.65 | 12.35 | 0.71 | 11.14 | -0.42 |
| SD | 5.805 | 5.393 | 4.916 | 4.115 | 4.564 | 5.199 |
| Minimum | 4.4 | -5.2 | 3.3 | -10.9 | 4.0 | -18.6 |
| Q1 | 8.40 | -2.20 | 8.80 | -2.10 | 7.90 | -2.90 |
| Median | 12.30 | 0.70 | 12.00 | 0.90 | 10.00 | -0.20 |
| Q3 | 15.10 | 4.00 | 14.90 | 3.50 | 14.20 | 1.25 |
| Maximum | 27.9 | 20.2 | 30.1 | 9.5 | 25.6 | 15.2 |
| Week 24 | | | | | | |
| N | 26 | 26 | 75 | 75 | 60 | 60 |
| Mean | 11.87 | 0.67 | 11.71 | 0.06 | 11.85 | 0.29 |
| SD | 5.780 | 4.637 | 4.742 | 3.952 | 4.610 | 5.015 |
| Minimum | 3.4 | -10.4 | 3.2 | -7.8 | 5.0 | -12.1 |
| Q1 | 8.20 | -1.90 | 9.10 | -2.90 | 8.55 | -2.55 |
| Median | 10.60 | -0.05 | 11.40 | 0.20 | 11.65 | -0.20 |
| Q3 | 15.20 | 2.10 | 14.20 | 2.40 | 14.25 | 3.70 |
| Maximum | 30.8 | 12.0 | 25.3 | 12.2 | 30.9 | 19.3 |

添付資料（5.3.5.3-3）Table 2.3.1.2

表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（16/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) Observed Value at Visit | Placebo (N=30) Change from Baseline | QD (N=80) Observed Value at Visit | QD (N=80) Change from Baseline | BID (N=63) Observed Value at Visit | BID (N=63) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 30 | | 80 | | 63 | |
| Mean | 0.594 | | 0.488 | | 0.490 | |
| SD | 0.3453 | | 0.1962 | | 0.1937 | |
| Minimum | 0.11 | | 0.13 | | 0.20 | |
| Q1 | 0.360 | | 0.350 | | 0.350 | |
| Median | 0.515 | | 0.460 | | 0.460 | |
| Q3 | 0.760 | | 0.580 | | 0.640 | |
| Maximum | 1.97 | | 1.09 | | 1.17 | |
| Week -4 | | | | | | |
| N | 30 | | 80 | | 63 | |
| Mean | 0.608 | | 0.525 | | 0.540 | |
| SD | 0.2344 | | 0.2065 | | 0.2710 | |
| Minimum | 0.22 | | 0.20 | | 0.00 | |
| Q1 | 0.460 | | 0.370 | | 0.360 | |
| Median | 0.615 | | 0.485 | | 0.530 | |
| Q3 | 0.770 | | 0.660 | | 0.700 | |
| Maximum | 1.29 | | 1.34 | | 1.45 | |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（17/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 30 | | 80 | | 63 | |
| Mean | 0.613 | | 0.538 | | 0.586 | |
| SD | 0.2761 | | 0.2681 | | 0.2462 | |
| Minimum | 0.23 | | 0.00 | | 0.21 | |
| Q1 | 0.420 | | 0.340 | | 0.380 | |
| Median | 0.530 | | 0.500 | | 0.520 | |
| Q3 | 0.750 | | 0.720 | | 0.760 | |
| Maximum | 1.28 | | 1.42 | | 1.22 | |
| Week 2 | | | | | | |
| N | 30 | 30 | 80 | 80 | 63 | 63 |
| Mean | 0.626 | 0.013 | 0.551 | 0.013 | 0.568 | -0.017 |
| SD | 0.3400 | 0.2237 | 0.2516 | 0.2384 | 0.2571 | 0.2298 |
| Minimum | 0.15 | -0.40 | 0.18 | -0.80 | 0.16 | -0.55 |
| Q1 | 0.310 | -0.090 | 0.375 | -0.105 | 0.410 | -0.150 |
| Median | 0.560 | 0.005 | 0.480 | 0.010 | 0.510 | -0.010 |
| Q3 | 0.800 | 0.150 | 0.695 | 0.130 | 0.710 | 0.060 |
| Maximum | 1.24 | 0.53 | 1.23 | 0.70 | 1.49 | 0.64 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（18/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 30 | 30 | 78 | 78 | 62 | 62 |
| Mean | 0.595 | -0.017 | 0.543 | 0.005 | 0.599 | 0.024 |
| SD | 0.2529 | 0.1750 | 0.2712 | 0.2198 | 0.2430 | 0.2391 |
| Minimum | 0.12 | -0.40 | 0.00 | -0.76 | 0.23 | -0.69 |
| Q1 | 0.440 | -0.100 | 0.360 | -0.140 | 0.400 | -0.060 |
| Median | 0.540 | 0.010 | 0.505 | -0.010 | 0.550 | 0.020 |
| Q3 | 0.780 | 0.100 | 0.690 | 0.160 | 0.770 | 0.170 |
| Maximum | 1.09 | 0.29 | 1.68 | 0.51 | 1.16 | 0.53 |
| Week 8 | | | | | | |
| N | 29 | 29 | 77 | 77 | 61 | 61 |
| Mean | 0.628 | 0.013 | 0.569 | 0.029 | 0.641 | 0.061 |
| SD | 0.2832 | 0.1940 | 0.3244 | 0.2837 | 0.2612 | 0.2600 |
| Minimum | 0.28 | -0.42 | 0.00 | -0.69 | 0.00 | -0.45 |
| Q1 | 0.420 | -0.090 | 0.320 | -0.120 | 0.470 | -0.090 |
| Median | 0.580 | 0.050 | 0.510 | 0.010 | 0.640 | 0.070 |
| Q3 | 0.810 | 0.130 | 0.760 | 0.170 | 0.760 | 0.220 |
| Maximum | 1.31 | 0.42 | 1.83 | 0.96 | 1.64 | 0.99 |

添付資料（5.3.5.3-3）Table 2.3.1.2

表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（19/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 28 | 28 | 77 | 77 | 60 | 60 |
| Mean | 0.624 | 0.006 | 0.569 | 0.029 | 0.612 | 0.028 |
| SD | 0.3386 | 0.2898 | 0.3023 | 0.2558 | 0.3244 | 0.2754 |
| Minimum | 0.13 | -0.45 | 0.00 | -0.76 | 0.00 | -0.41 |
| Q1 | 0.360 | -0.175 | 0.360 | -0.060 | 0.360 | -0.150 |
| Median | 0.560 | -0.010 | 0.500 | 0.060 | 0.555 | -0.020 |
| Q3 | 0.835 | 0.170 | 0.760 | 0.160 | 0.800 | 0.165 |
| Maximum | 1.45 | 0.65 | 1.41 | 0.90 | 1.50 | 0.87 |
| Week 16 | | | | | | |
| N | 27 | 27 | 77 | 77 | 60 | 60 |
| Mean | 0.606 | -0.027 | 0.559 | 0.020 | 0.566 | -0.018 |
| SD | 0.2730 | 0.2097 | 0.3195 | 0.2966 | 0.2276 | 0.2313 |
| Minimum | 0.26 | -0.52 | 0.00 | -0.78 | 0.25 | -0.62 |
| Q1 | 0.380 | -0.120 | 0.320 | -0.100 | 0.405 | -0.145 |
| Median | 0.500 | -0.030 | 0.460 | 0.000 | 0.510 | -0.015 |
| Q3 | 0.830 | 0.080 | 0.780 | 0.160 | 0.720 | 0.125 |
| Maximum | 1.19 | 0.39 | 1.50 | 0.87 | 1.12 | 0.44 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-19　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（20/20）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=30) | | QD (N=80) | | BID (N=63) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 27 | 27 | 75 | 75 | 60 | 60 |
| Mean | 0.620 | -0.012 | 0.544 | -0.005 | 0.532 | -0.052 |
| SD | 0.2864 | 0.2664 | 0.2970 | 0.2802 | 0.2299 | 0.2564 |
| Minimum | 0.20 | -0.59 | 0.00 | -1.00 | 0.14 | -0.76 |
| Q1 | 0.350 | -0.180 | 0.330 | -0.170 | 0.340 | -0.165 |
| Median | 0.670 | 0.010 | 0.480 | 0.000 | 0.530 | -0.020 |
| Q3 | 0.870 | 0.180 | 0.700 | 0.140 | 0.720 | 0.115 |
| Maximum | 1.23 | 0.50 | 1.48 | 0.60 | 1.13 | 0.45 |
| Week 24 | | | | | | |
| N | 26 | 26 | 75 | 75 | 60 | 60 |
| Mean | 0.576 | -0.062 | 0.462 | -0.087 | 0.529 | -0.055 |
| SD | 0.3231 | 0.3335 | 0.2799 | 0.2610 | 0.2424 | 0.2285 |
| Minimum | 0.12 | -0.81 | 0.00 | -1.00 | 0.15 | -0.61 |
| Q1 | 0.320 | -0.220 | 0.290 | -0.230 | 0.335 | -0.190 |
| Median | 0.485 | -0.060 | 0.390 | -0.050 | 0.495 | -0.060 |
| Q3 | 0.770 | 0.160 | 0.560 | 0.070 | 0.665 | 0.090 |
| Maximum | 1.36 | 0.56 | 1.40 | 0.59 | 1.14 | 0.49 |

添付資料（5.3.5.3-3）Table 2.3.1.2

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（1/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 66 | | 124 | | 126 | |
| Mean | 11.63 | | 10.22 | | 10.89 | |
| SD | 5.731 | | 3.734 | | 4.342 | |
| Minimum | 3.6 | | 2.8 | | 3.2 | |
| Q1 | 7.60 | | 7.05 | | 7.70 | |
| Median | 10.85 | | 10.15 | | 10.30 | |
| Q3 | 13.70 | | 13.15 | | 13.50 | |
| Maximum | 31.9 | | 19.9 | | 22.5 | |
| Week -4 | | | | | | |
| N | 66 | | 124 | | 126 | |
| Mean | 11.10 | | 11.32 | | 10.98 | |
| SD | 4.502 | | 4.457 | | 4.280 | |
| Minimum | 3.2 | | 3.4 | | 3.2 | |
| Q1 | 8.40 | | 8.10 | | 8.00 | |
| Median | 10.60 | | 10.80 | | 10.35 | |
| Q3 | 13.30 | | 14.50 | | 13.80 | |
| Maximum | 29.4 | | 24.6 | | 27.4 | |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（2/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 66 | | 124 | | 126 | |
| Mean | 10.79 | | 10.75 | | 11.20 | |
| SD | 4.092 | | 4.113 | | 4.130 | |
| Minimum | 3.6 | | 1.9 | | 3.2 | |
| Q1 | 7.70 | | 7.65 | | 8.20 | |
| Median | 10.30 | | 10.60 | | 10.65 | |
| Q3 | 13.30 | | 13.00 | | 13.60 | |
| Maximum | 26.0 | | 22.8 | | 23.9 | |
| Week 2 | | | | | | |
| N | 66 | 66 | 124 | 124 | 126 | 126 |
| Mean | 11.14 | 0.35 | 10.96 | 0.20 | 10.96 | -0.24 |
| SD | 5.672 | 3.840 | 4.690 | 3.338 | 4.114 | 3.549 |
| Minimum | 2.6 | -8.4 | 3.0 | -9.6 | 3.6 | -10.4 |
| Q1 | 7.20 | -2.00 | 7.20 | -1.80 | 8.00 | -2.00 |
| Median | 10.00 | 0.15 | 10.20 | 0.45 | 10.35 | -0.55 |
| Q3 | 13.30 | 2.90 | 13.30 | 2.40 | 13.50 | 1.80 |
| Maximum | 36.4 | 10.4 | 25.8 | 12.1 | 26.7 | 10.1 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（3/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 65 | 65 | 123 | 123 | 125 | 125 |
| Mean | 11.23 | 0.43 | 10.52 | -0.24 | 11.56 | 0.37 |
| SD | 4.724 | 3.684 | 4.034 | 3.470 | 4.279 | 3.793 |
| Minimum | 3.3 | -8.9 | 2.5 | -9.0 | 3.5 | -15.0 |
| Q1 | 7.80 | -1.50 | 7.40 | -2.60 | 8.50 | -1.60 |
| Median | 10.80 | 0.50 | 10.20 | 0.10 | 11.00 | 0.40 |
| Q3 | 14.00 | 2.50 | 13.60 | 1.80 | 13.90 | 2.20 |
| Maximum | 26.3 | 9.1 | 22.2 | 8.4 | 25.3 | 10.7 |
| Week 8 | | | | | | |
| N | 63 | 63 | 122 | 122 | 124 | 124 |
| Mean | 11.51 | 0.82 | 11.48 | 0.67 | 11.78 | 0.60 |
| SD | 4.227 | 2.793 | 4.804 | 3.590 | 4.453 | 3.998 |
| Minimum | 3.7 | -5.4 | 3.5 | -8.0 | 3.7 | -13.4 |
| Q1 | 8.30 | -0.90 | 8.00 | -1.30 | 8.45 | -1.40 |
| Median | 10.90 | 0.50 | 11.00 | 0.40 | 11.40 | 0.50 |
| Q3 | 14.80 | 3.10 | 13.80 | 2.30 | 14.00 | 2.20 |
| Maximum | 24.2 | 6.8 | 29.8 | 14.0 | 27.2 | 13.4 |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（4/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 62 | 62 | 121 | 121 | 123 | 123 |
| Mean | 12.00 | 1.37 | 10.83 | 0.11 | 11.71 | 0.53 |
| SD | 5.561 | 4.787 | 4.295 | 3.692 | 4.275 | 4.396 |
| Minimum | 3.6 | -8.8 | 3.2 | -9.2 | 3.3 | -12.0 |
| Q1 | 8.00 | -1.40 | 7.90 | -2.30 | 8.30 | -2.00 |
| Median | 11.95 | 0.20 | 10.50 | 0.20 | 11.20 | 0.10 |
| Q3 | 14.50 | 4.00 | 13.50 | 2.20 | 14.60 | 2.90 |
| Maximum | 34.8 | 19.0 | 24.1 | 11.0 | 27.1 | 16.4 |
| Week 16 | | | | | | |
| N | 61 | 61 | 121 | 121 | 123 | 123 |
| Mean | 11.46 | 0.82 | 11.31 | 0.59 | 11.23 | 0.05 |
| SD | 4.917 | 3.802 | 5.200 | 4.772 | 4.658 | 4.507 |
| Minimum | 3.7 | -11.4 | 4.2 | -12.4 | 3.8 | -11.1 |
| Q1 | 7.80 | -1.80 | 8.20 | -1.50 | 7.80 | -2.70 |
| Median | 10.90 | 0.80 | 10.90 | 0.60 | 10.80 | 0.00 |
| Q3 | 14.60 | 2.90 | 13.40 | 2.40 | 13.60 | 2.20 |
| Maximum | 29.0 | 12.1 | 50.0 | 36.6 | 32.3 | 22.2 |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（5/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 60 | 60 | 119 | 119 | 123 | 123 |
| Mean | 11.18 | 0.56 | 11.57 | 0.86 | 10.70 | -0.48 |
| SD | 5.235 | 4.448 | 5.360 | 4.546 | 4.206 | 4.253 |
| Minimum | 2.6 | -5.6 | 3.3 | -6.6 | 3.4 | -11.7 |
| Q1 | 7.10 | -2.45 | 7.70 | -2.10 | 7.80 | -2.70 |
| Median | 10.70 | -0.10 | 11.20 | 0.90 | 10.40 | -0.40 |
| Q3 | 13.75 | 2.85 | 14.50 | 3.00 | 13.00 | 1.30 |
| Maximum | 27.9 | 20.2 | 38.5 | 29.5 | 25.6 | 15.2 |
| Week 24 | | | | | | |
| N | 60 | 60 | 119 | 119 | 123 | 123 |
| Mean | 10.80 | 0.19 | 10.86 | 0.15 | 10.92 | -0.26 |
| SD | 5.468 | 4.235 | 4.464 | 3.775 | 4.335 | 4.656 |
| Minimum | 2.9 | -10.4 | 2.7 | -7.8 | 3.1 | -14.2 |
| Q1 | 6.50 | -2.80 | 7.60 | -2.00 | 7.40 | -2.50 |
| Median | 9.60 | -0.15 | 11.00 | 0.50 | 11.20 | -0.20 |
| Q3 | 14.45 | 2.35 | 13.80 | 2.40 | 14.00 | 2.20 |
| Maximum | 30.8 | 12.0 | 27.1 | 12.2 | 30.9 | 19.3 |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（6/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) Observed Value at Visit | Placebo (N=66) Change from Baseline | QD (N=124) Observed Value at Visit | QD (N=124) Change from Baseline | BID (N=126) Observed Value at Visit | BID (N=126) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 66 | | 124 | | 126 | |
| Mean | 0.535 | | 0.452 | | 0.474 | |
| SD | 0.2897 | | 0.1901 | | 0.1904 | |
| Minimum | 0.11 | | 0.13 | | 0.13 | |
| Q1 | 0.340 | | 0.310 | | 0.340 | |
| Median | 0.460 | | 0.430 | | 0.460 | |
| Q3 | 0.690 | | 0.530 | | 0.580 | |
| Maximum | 1.97 | | 1.09 | | 1.17 | |
| Week -4 | | | | | | |
| N | 66 | | 124 | | 126 | |
| Mean | 0.519 | | 0.507 | | 0.498 | |
| SD | 0.2454 | | 0.2083 | | 0.2401 | |
| Minimum | 0.16 | | 0.00 | | 0.00 | |
| Q1 | 0.340 | | 0.360 | | 0.340 | |
| Median | 0.470 | | 0.460 | | 0.480 | |
| Q3 | 0.670 | | 0.630 | | 0.640 | |
| Maximum | 1.29 | | 1.34 | | 1.45 | |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（7/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 66 | | 124 | | 126 | |
| Mean | 0.540 | | 0.502 | | 0.543 | |
| SD | 0.2544 | | 0.2435 | | 0.2225 | |
| Minimum | 0.11 | | 0.00 | | 0.00 | |
| Q1 | 0.360 | | 0.340 | | 0.380 | |
| Median | 0.490 | | 0.440 | | 0.490 | |
| Q3 | 0.650 | | 0.610 | | 0.650 | |
| Maximum | 1.28 | | 1.43 | | 1.22 | |
| Week 2 | | | | | | |
| N | 66 | 66 | 124 | 124 | 126 | 126 |
| Mean | 0.525 | -0.015 | 0.507 | 0.006 | 0.514 | -0.029 |
| SD | 0.3119 | 0.1970 | 0.2708 | 0.2134 | 0.2326 | 0.2048 |
| Minimum | 0.15 | -0.40 | 0.00 | -0.56 | 0.00 | -0.54 |
| Q1 | 0.310 | -0.150 | 0.325 | -0.100 | 0.360 | -0.150 |
| Median | 0.425 | -0.015 | 0.440 | -0.025 | 0.490 | -0.035 |
| Q3 | 0.670 | 0.100 | 0.615 | 0.100 | 0.600 | 0.060 |
| Maximum | 1.50 | 0.53 | 1.38 | 0.70 | 1.49 | 0.64 |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（8/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 65 | 65 | 123 | 123 | 125 | 125 |
| Mean | 0.526 | -0.018 | 0.511 | 0.011 | 0.539 | 0.001 |
| SD | 0.2513 | 0.1959 | 0.2747 | 0.2246 | 0.2185 | 0.2141 |
| Minimum | 0.12 | -0.46 | 0.00 | -0.76 | 0.00 | -0.53 |
| Q1 | 0.360 | -0.140 | 0.340 | -0.110 | 0.380 | -0.140 |
| Median | 0.480 | 0.010 | 0.430 | 0.000 | 0.520 | -0.010 |
| Q3 | 0.620 | 0.100 | 0.620 | 0.150 | 0.660 | 0.160 |
| Maximum | 1.46 | 0.49 | 1.68 | 0.55 | 1.16 | 0.53 |
| Week 8 | | | | | | |
| N | 63 | 63 | 122 | 122 | 124 | 124 |
| Mean | 0.544 | -0.002 | 0.543 | 0.042 | 0.554 | 0.015 |
| SD | 0.2764 | 0.1715 | 0.2837 | 0.2367 | 0.2547 | 0.2257 |
| Minimum | 0.14 | -0.42 | 0.00 | -0.59 | 0.00 | -0.55 |
| Q1 | 0.310 | -0.120 | 0.320 | -0.080 | 0.380 | -0.125 |
| Median | 0.470 | 0.010 | 0.480 | 0.020 | 0.530 | 0.015 |
| Q3 | 0.740 | 0.130 | 0.670 | 0.170 | 0.730 | 0.140 |
| Maximum | 1.31 | 0.42 | 1.49 | 0.79 | 1.22 | 0.74 |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（9/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 62 | 62 | 121 | 121 | 123 | 123 |
| Mean | 0.580 | 0.033 | 0.516 | 0.018 | 0.526 | -0.016 |
| SD | 0.3267 | 0.2525 | 0.2659 | 0.2240 | 0.2752 | 0.2343 |
| Minimum | 0.13 | -0.45 | 0.00 | -0.76 | 0.00 | -0.55 |
| Q1 | 0.360 | -0.130 | 0.350 | -0.080 | 0.330 | -0.160 |
| Median | 0.510 | 0.020 | 0.460 | 0.010 | 0.480 | -0.050 |
| Q3 | 0.730 | 0.170 | 0.650 | 0.130 | 0.690 | 0.100 |
| Maximum | 1.69 | 0.72 | 1.41 | 0.90 | 1.54 | 0.87 |
| Week 16 | | | | | | |
| N | 61 | 61 | 121 | 121 | 123 | 123 |
| Mean | 0.527 | -0.025 | 0.506 | 0.009 | 0.501 | -0.041 |
| SD | 0.2618 | 0.1806 | 0.2844 | 0.2585 | 0.2213 | 0.2165 |
| Minimum | 0.12 | -0.52 | 0.00 | -0.78 | 0.00 | -0.75 |
| Q1 | 0.370 | -0.120 | 0.300 | -0.100 | 0.340 | -0.180 |
| Median | 0.440 | -0.030 | 0.430 | 0.000 | 0.460 | -0.030 |
| Q3 | 0.670 | 0.060 | 0.640 | 0.120 | 0.620 | 0.110 |
| Maximum | 1.19 | 0.39 | 1.50 | 0.87 | 1.14 | 0.44 |

添付資料（5.3.5.3-3）Table 2.3.1.3

表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（10/40）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=66) | | QD (N=124) | | BID (N=126) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 60 | 60 | 119 | 119 | 123 | 123 |
| Mean | 0.501 | -0.048 | 0.504 | 0.002 | 0.469 | -0.072 |
| SD | 0.2635 | 0.2061 | 0.3000 | 0.2503 | 0.2234 | 0.2238 |
| Minimum | 0.19 | -0.59 | 0.00 | -1.00 | 0.00 | -0.76 |
| Q1 | 0.315 | -0.170 | 0.300 | -0.150 | 0.290 | -0.240 |
| Median | 0.405 | -0.045 | 0.420 | -0.010 | 0.420 | -0.050 |
| Q3 | 0.690 | 0.055 | 0.620 | 0.120 | 0.610 | 0.100 |
| Maximum | 1.23 | 0.50 | 1.59 | 0.60 | 1.08 | 0.44 |
| Week 24 | | | | | | |
| N | 60 | 60 | 119 | 119 | 123 | 123 |
| Mean | 0.455 | -0.094 | 0.444 | -0.058 | 0.457 | -0.085 |
| SD | 0.2807 | 0.2553 | 0.2536 | 0.2308 | 0.2152 | 0.2116 |
| Minimum | 0.00 | -0.81 | 0.00 | -1.00 | 0.00 | -0.84 |
| Q1 | 0.270 | -0.205 | 0.290 | -0.170 | 0.310 | -0.200 |
| Median | 0.390 | -0.090 | 0.390 | -0.040 | 0.410 | -0.090 |
| Q3 | 0.555 | 0.000 | 0.540 | 0.080 | 0.560 | 0.030 |
| Maximum | 1.36 | 0.56 | 1.40 | 0.59 | 1.19 | 0.48 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（11/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 4 | | 21 | | 20 | |
| Mean | 11.15 | | 13.14 | | 12.36 | |
| SD | 4.520 | | 4.263 | | 4.989 | |
| Minimum | 7.1 | | 7.3 | | 4.2 | |
| Q1 | 7.25 | | 9.30 | | 8.30 | |
| Median | 11.00 | | 13.40 | | 12.05 | |
| Q3 | 15.05 | | 16.30 | | 17.10 | |
| Maximum | 15.5 | | 22.9 | | 24.0 | |
| Week -4 | | | | | | |
| N | 4 | | 21 | | 20 | |
| Mean | 12.88 | | 12.07 | | 11.78 | |
| SD | 3.680 | | 3.926 | | 4.014 | |
| Minimum | 9.1 | | 5.3 | | 6.0 | |
| Q1 | 9.75 | | 8.60 | | 8.40 | |
| Median | 12.90 | | 12.30 | | 11.45 | |
| Q3 | 16.00 | | 14.60 | | 14.45 | |
| Maximum | 16.6 | | 20.8 | | 20.8 | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（12/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 4 | | 21 | | 20 | |
| Mean | 13.35 | | 13.61 | | 13.70 | |
| SD | 4.020 | | 4.005 | | 4.931 | |
| Minimum | 7.7 | | 4.9 | | 4.5 | |
| Q1 | 10.50 | | 11.50 | | 10.30 | |
| Median | 14.55 | | 13.40 | | 13.90 | |
| Q3 | 16.20 | | 15.50 | | 15.45 | |
| Maximum | 16.6 | | 22.0 | | 26.9 | |
| Week 2 | | | | | | |
| N | 4 | 4 | 21 | 21 | 20 | 20 |
| Mean | 10.68 | -2.68 | 13.53 | -0.08 | 12.66 | -1.04 |
| SD | 2.009 | 2.460 | 4.590 | 2.800 | 4.325 | 4.283 |
| Minimum | 8.7 | -4.1 | 6.5 | -7.3 | 4.5 | -13.1 |
| Q1 | 8.95 | -4.05 | 10.20 | -1.40 | 8.50 | -2.05 |
| Median | 10.70 | -3.80 | 12.90 | 0.10 | 12.75 | 0.00 |
| Q3 | 12.40 | -1.30 | 16.90 | 1.30 | 15.30 | 1.25 |
| Maximum | 12.6 | 1.0 | 25.5 | 5.5 | 21.6 | 4.6 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（13/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 9.83 | -3.53 | 12.93 | -1.12 | 13.07 | -0.63 |
| SD | 2.037 | 3.400 | 4.950 | 3.743 | 3.876 | 4.669 |
| Minimum | 8.2 | -6.5 | 6.7 | -6.7 | 5.3 | -17.2 |
| Q1 | 8.60 | -5.80 | 9.70 | -3.55 | 9.80 | -1.05 |
| Median | 9.15 | -4.45 | 11.20 | -1.90 | 13.10 | 0.15 |
| Q3 | 11.05 | -1.25 | 15.75 | 0.15 | 16.25 | 1.75 |
| Maximum | 12.8 | 1.3 | 27.3 | 8.0 | 20.0 | 4.4 |
| Week 8 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 11.78 | -1.58 | 13.62 | -0.43 | 13.20 | -0.50 |
| SD | 4.010 | 1.775 | 4.270 | 3.849 | 3.508 | 4.406 |
| Minimum | 7.4 | -3.2 | 7.4 | -9.0 | 7.8 | -12.2 |
| Q1 | 8.75 | -3.10 | 10.45 | -2.65 | 9.90 | -2.75 |
| Median | 11.45 | -1.65 | 13.75 | -0.25 | 13.95 | 0.30 |
| Q3 | 14.80 | -0.05 | 15.40 | 1.65 | 16.25 | 1.75 |
| Maximum | 16.8 | 0.2 | 22.7 | 6.3 | 18.7 | 9.4 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（14/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 10.28 | -3.08 | 14.51 | 0.47 | 13.49 | -0.21 |
| SD | 3.517 | 4.569 | 6.294 | 4.478 | 4.206 | 4.557 |
| Minimum | 7.3 | -9.2 | 5.7 | -6.2 | 6.1 | -15.3 |
| Q1 | 7.35 | -6.50 | 10.40 | -2.30 | 11.35 | -1.95 |
| Median | 9.70 | -2.10 | 13.20 | -0.35 | 13.35 | -0.25 |
| Q3 | 13.20 | 0.35 | 16.55 | 2.35 | 16.80 | 2.70 |
| Maximum | 14.4 | 1.1 | 32.2 | 10.5 | 21.6 | 5.9 |
| Week 16 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 9.83 | -3.53 | 12.76 | -1.29 | 11.94 | -1.76 |
| SD | 1.746 | 3.231 | 4.108 | 3.685 | 3.488 | 4.337 |
| Minimum | 7.9 | -5.4 | 6.6 | -8.7 | 5.6 | -15.6 |
| Q1 | 8.45 | -5.35 | 10.05 | -3.00 | 9.40 | -3.10 |
| Median | 9.75 | -5.00 | 12.20 | -1.85 | 11.50 | -0.35 |
| Q3 | 11.20 | -1.70 | 14.75 | 0.70 | 13.75 | 1.15 |
| Maximum | 11.9 | 1.3 | 24.5 | 7.2 | 20.9 | 2.4 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（15/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 9.55 | -3.80 | 13.61 | -0.44 | 12.01 | -1.69 |
| SD | 2.714 | 3.856 | 4.121 | 4.473 | 2.995 | 4.737 |
| Minimum | 7.4 | -7.5 | 7.8 | -8.6 | 5.3 | -18.6 |
| Q1 | 7.85 | -6.70 | 11.45 | -2.40 | 9.40 | -3.00 |
| Median | 8.65 | -4.50 | 13.75 | -0.40 | 13.10 | -0.90 |
| Q3 | 11.25 | -0.90 | 15.40 | 2.30 | 14.20 | 1.05 |
| Maximum | 13.5 | 1.3 | 23.6 | 9.5 | 15.9 | 3.6 |
| Week 24 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 9.95 | -3.40 | 12.90 | -1.15 | 13.10 | -0.60 |
| SD | 4.494 | 4.715 | 4.433 | 3.904 | 3.867 | 2.839 |
| Minimum | 6.0 | -9.8 | 7.5 | -9.7 | 5.6 | -5.6 |
| Q1 | 6.10 | -6.70 | 9.60 | -3.55 | 10.35 | -2.55 |
| Median | 9.60 | -2.55 | 12.10 | -1.55 | 13.00 | -0.40 |
| Q3 | 13.80 | -0.10 | 16.35 | 0.95 | 15.85 | 1.00 |
| Maximum | 14.6 | 1.3 | 24.7 | 7.4 | 21.3 | 5.3 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（16/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 4 | | 21 | | 20 | |
| Mean | 0.638 | | 0.553 | | 0.550 | |
| SD | 0.3634 | | 0.1811 | | 0.1484 | |
| Minimum | 0.36 | | 0.28 | | 0.30 | |
| Q1 | 0.380 | | 0.460 | | 0.425 | |
| Median | 0.520 | | 0.520 | | 0.550 | |
| Q3 | 0.895 | | 0.660 | | 0.665 | |
| Maximum | 1.15 | | 0.99 | | 0.90 | |
| Week -4 | | | | | | |
| N | 4 | | 21 | | 20 | |
| Mean | 0.743 | | 0.565 | | 0.652 | |
| SD | 0.3185 | | 0.2548 | | 0.3302 | |
| Minimum | 0.47 | | 0.26 | | 0.18 | |
| Q1 | 0.520 | | 0.360 | | 0.505 | |
| Median | 0.655 | | 0.490 | | 0.580 | |
| Q3 | 0.965 | | 0.660 | | 0.760 | |
| Maximum | 1.19 | | 1.20 | | 1.88 | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（17/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 4 | | 21 | | 20 | |
| Mean | 0.918 | | 0.632 | | 0.664 | |
| SD | 0.3999 | | 0.2665 | | 0.2303 | |
| Minimum | 0.62 | | 0.30 | | 0.20 | |
| Q1 | 0.660 | | 0.440 | | 0.520 | |
| Median | 0.775 | | 0.550 | | 0.665 | |
| Q3 | 1.175 | | 0.840 | | 0.835 | |
| Maximum | 1.50 | | 1.25 | | 1.16 | |
| Week 2 | | | | | | |
| N | 4 | 4 | 21 | 21 | 20 | 20 |
| Mean | 0.695 | -0.223 | 0.627 | -0.006 | 0.640 | -0.024 |
| SD | 0.3701 | 0.2241 | 0.1997 | 0.2383 | 0.1895 | 0.2419 |
| Minimum | 0.32 | -0.38 | 0.39 | -0.80 | 0.27 | -0.55 |
| Q1 | 0.430 | -0.345 | 0.430 | -0.110 | 0.520 | -0.190 |
| Median | 0.635 | -0.310 | 0.620 | 0.050 | 0.655 | -0.005 |
| Q3 | 0.960 | -0.100 | 0.710 | 0.130 | 0.745 | 0.135 |
| Maximum | 1.19 | 0.11 | 1.03 | 0.41 | 0.98 | 0.41 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（18/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 0.625 | -0.293 | 0.646 | 0.001 | 0.723 | 0.059 |
| SD | 0.3379 | 0.2555 | 0.2235 | 0.2267 | 0.2181 | 0.2190 |
| Minimum | 0.31 | -0.54 | 0.18 | -0.49 | 0.12 | -0.69 |
| Q1 | 0.375 | -0.480 | 0.525 | -0.160 | 0.585 | -0.025 |
| Median | 0.555 | -0.340 | 0.645 | -0.020 | 0.730 | 0.070 |
| Q3 | 0.875 | -0.105 | 0.725 | 0.140 | 0.870 | 0.200 |
| Maximum | 1.08 | 0.05 | 1.09 | 0.44 | 1.03 | 0.31 |
| Week 8 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 0.670 | -0.248 | 0.675 | 0.029 | 0.740 | 0.077 |
| SD | 0.4085 | 0.1320 | 0.3731 | 0.3377 | 0.2863 | 0.3262 |
| Minimum | 0.43 | -0.42 | 0.19 | -0.69 | 0.30 | -0.45 |
| Q1 | 0.440 | -0.335 | 0.415 | -0.165 | 0.570 | -0.125 |
| Median | 0.485 | -0.235 | 0.595 | 0.060 | 0.755 | 0.070 |
| Q3 | 0.900 | -0.160 | 0.870 | 0.140 | 0.880 | 0.260 |
| Maximum | 1.28 | -0.10 | 1.83 | 0.96 | 1.64 | 0.99 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（19/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 0.610 | -0.308 | 0.613 | -0.033 | 0.752 | 0.089 |
| SD | 0.2702 | 0.5305 | 0.2872 | 0.2564 | 0.2742 | 0.2859 |
| Minimum | 0.29 | -0.92 | 0.26 | -0.50 | 0.25 | -0.40 |
| Q1 | 0.435 | -0.740 | 0.400 | -0.190 | 0.545 | -0.090 |
| Median | 0.600 | -0.280 | 0.510 | -0.070 | 0.800 | 0.095 |
| Q3 | 0.785 | 0.125 | 0.790 | 0.145 | 0.855 | 0.260 |
| Maximum | 0.95 | 0.25 | 1.31 | 0.50 | 1.39 | 0.74 |
| Week 16 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 0.553 | -0.365 | 0.653 | 0.008 | 0.617 | -0.047 |
| SD | 0.2752 | 0.3465 | 0.2874 | 0.2296 | 0.2102 | 0.2833 |
| Minimum | 0.27 | -0.66 | 0.26 | -0.43 | 0.27 | -0.59 |
| Q1 | 0.320 | -0.620 | 0.445 | -0.100 | 0.530 | -0.330 |
| Median | 0.550 | -0.455 | 0.575 | -0.055 | 0.625 | -0.030 |
| Q3 | 0.785 | -0.110 | 0.850 | 0.160 | 0.755 | 0.150 |
| Maximum | 0.84 | 0.11 | 1.46 | 0.59 | 1.01 | 0.42 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（20/40）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=4) | | QD (N=21) | | BID (N=20) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 0.543 | -0.375 | 0.582 | -0.064 | 0.615 | -0.049 |
| SD | 0.2893 | 0.3022 | 0.3201 | 0.2752 | 0.2088 | 0.2743 |
| Minimum | 0.28 | -0.61 | 0.13 | -0.65 | 0.22 | -0.73 |
| Q1 | 0.305 | -0.590 | 0.380 | -0.240 | 0.455 | -0.170 |
| Median | 0.500 | -0.470 | 0.485 | -0.060 | 0.615 | -0.065 |
| Q3 | 0.780 | -0.160 | 0.740 | 0.075 | 0.770 | 0.160 |
| Maximum | 0.89 | 0.05 | 1.48 | 0.46 | 1.13 | 0.45 |
| Week 24 | | | | | | |
| N | 4 | 4 | 20 | 20 | 20 | 20 |
| Mean | 0.573 | -0.345 | 0.520 | -0.126 | 0.633 | -0.031 |
| SD | 0.2347 | 0.2641 | 0.3026 | 0.2515 | 0.2110 | 0.2743 |
| Minimum | 0.33 | -0.62 | 0.14 | -0.58 | 0.20 | -0.61 |
| Q1 | 0.400 | -0.570 | 0.305 | -0.275 | 0.525 | -0.210 |
| Median | 0.540 | -0.335 | 0.470 | -0.100 | 0.580 | -0.070 |
| Q3 | 0.745 | -0.120 | 0.645 | 0.015 | 0.825 | 0.190 |
| Maximum | 0.88 | -0.09 | 1.33 | 0.46 | 1.04 | 0.49 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（21/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 1 | | 4 | | 5 | |
| Mean | 11.70 | | 12.13 | | 14.88 | |
| SD | | | 4.644 | | 4.041 | |
| Minimum | 11.7 | | 7.7 | | 8.5 | |
| Q1 | 11.70 | | 8.65 | | 13.30 | |
| Median | 11.70 | | 11.25 | | 16.90 | |
| Q3 | 11.70 | | 15.60 | | 17.40 | |
| Maximum | 11.7 | | 18.3 | | 18.3 | |
| Week -4 | | | | | | |
| N | 1 | | 4 | | 5 | |
| Mean | 10.20 | | 13.78 | | 12.08 | |
| SD | | | 4.304 | | 5.159 | |
| Minimum | 10.2 | | 9.4 | | 6.6 | |
| Q1 | 10.20 | | 10.80 | | 9.70 | |
| Median | 10.20 | | 13.05 | | 10.40 | |
| Q3 | 10.20 | | 16.75 | | 13.50 | |
| Maximum | 10.2 | | 19.6 | | 20.2 | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（22/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 1 | | 4 | | 5 | |
| Mean | 8.90 | | 12.40 | | 11.84 | |
| SD | | | 1.134 | | 2.686 | |
| Minimum | 8.9 | | 10.9 | | 8.1 | |
| Q1 | 8.90 | | 11.60 | | 11.00 | |
| Median | 8.90 | | 12.55 | | 11.20 | |
| Q3 | 8.90 | | 13.20 | | 14.20 | |
| Maximum | 8.9 | | 13.6 | | 14.7 | |
| Week 2 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 7.20 | -1.70 | 13.58 | 1.18 | 11.26 | -0.58 |
| SD | | | 3.474 | 2.615 | 4.404 | 3.065 |
| Minimum | 7.2 | -1.7 | 8.8 | -2.1 | 6.2 | -4.2 |
| Q1 | 7.20 | -1.70 | 11.00 | -0.85 | 9.20 | -2.00 |
| Median | 7.20 | -1.70 | 14.65 | 1.45 | 10.00 | -1.90 |
| Q3 | 7.20 | -1.70 | 16.15 | 3.20 | 13.10 | 2.10 |
| Maximum | 7.2 | -1.7 | 16.2 | 3.9 | 17.8 | 3.1 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（23/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 14.40 | 5.50 | 14.18 | 1.78 | 11.22 | -0.62 |
| SD | | | 5.199 | 4.189 | 3.662 | 2.668 |
| Minimum | 14.4 | 5.5 | 9.0 | -1.9 | 6.8 | -4.2 |
| Q1 | 14.40 | 5.50 | 11.05 | -0.75 | 9.60 | -1.60 |
| Median | 14.40 | 5.50 | 13.15 | 0.60 | 10.00 | -1.30 |
| Q3 | 14.40 | 5.50 | 17.30 | 4.30 | 13.50 | 1.50 |
| Maximum | 14.4 | 5.5 | 21.4 | 7.8 | 16.2 | 2.5 |
| Week 8 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 12.50 | 3.60 | 13.05 | 0.65 | 13.24 | 1.40 |
| SD | | | 4.669 | 3.804 | 3.828 | 2.449 |
| Minimum | 12.5 | 3.6 | 8.9 | -2.3 | 8.3 | -1.0 |
| Q1 | 12.50 | 3.60 | 9.70 | -2.15 | 11.00 | -0.20 |
| Median | 12.50 | 3.60 | 11.90 | -0.50 | 13.20 | 0.20 |
| Q3 | 12.50 | 3.60 | 16.40 | 3.45 | 15.60 | 3.40 |
| Maximum | 12.5 | 3.6 | 19.5 | 5.9 | 18.1 | 4.6 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（24/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 7.10 | -1.80 | 11.93 | -0.48 | 11.84 | 0.00 |
| SD | | | 4.216 | 3.572 | 1.857 | 2.075 |
| Minimum | 7.1 | -1.8 | 8.5 | -4.3 | 9.8 | -2.4 |
| Q1 | 7.10 | -1.80 | 9.00 | -2.85 | 10.20 | -1.00 |
| Median | 7.10 | -1.80 | 10.65 | -0.95 | 11.80 | -0.90 |
| Q3 | 7.10 | -1.80 | 14.85 | 1.90 | 13.60 | 1.70 |
| Maximum | 7.1 | -1.8 | 17.9 | 4.3 | 13.8 | 2.6 |
| Week 16 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 10.10 | 1.20 | 13.33 | 0.93 | 12.86 | 1.02 |
| SD | | | 5.502 | 5.258 | 5.378 | 4.013 |
| Minimum | 10.1 | 1.2 | 7.2 | -5.6 | 6.6 | -3.7 |
| Q1 | 10.10 | 1.20 | 9.60 | -2.95 | 10.50 | -1.50 |
| Median | 10.10 | 1.20 | 12.80 | 1.20 | 11.40 | 0.20 |
| Q3 | 10.10 | 1.20 | 17.05 | 4.80 | 14.90 | 3.90 |
| Maximum | 10.1 | 1.2 | 20.5 | 6.9 | 20.9 | 6.2 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（25/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 9.00 | 0.10 | 14.05 | 1.65 | 13.78 | 1.94 |
| SD | | | 4.683 | 3.770 | 2.196 | 2.828 |
| Minimum | 9.0 | 0.1 | 8.0 | -2.9 | 11.3 | -2.4 |
| Q1 | 9.00 | 0.10 | 10.40 | -1.45 | 11.80 | 0.90 |
| Median | 9.00 | 0.10 | 14.90 | 2.35 | 14.00 | 3.00 |
| Q3 | 9.00 | 0.10 | 17.70 | 4.75 | 15.60 | 3.20 |
| Maximum | 9.0 | 0.1 | 18.4 | 4.8 | 16.2 | 5.0 |
| Week 24 | | | | | | |
| N | 0 | 0 | 4 | 4 | 5 | 5 |
| Mean | | | 14.20 | 1.80 | 14.64 | 2.80 |
| SD | | | 6.506 | 5.702 | 2.685 | 4.683 |
| Minimum | | | 9.4 | -2.9 | 12.3 | -1.9 |
| Q1 | | | 10.05 | -1.55 | 12.50 | 1.20 |
| Median | | | 11.85 | 0.00 | 13.80 | 1.30 |
| Q3 | | | 18.35 | 5.15 | 15.90 | 2.80 |
| Maximum | | | 23.7 | 10.1 | 18.7 | 10.6 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（26/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 1 | | 4 | | 5 | |
| Mean | 0.520 | | 0.763 | | 0.502 | |
| SD | | | 0.1727 | | 0.2142 | |
| Minimum | 0.52 | | 0.55 | | 0.21 | |
| Q1 | 0.520 | | 0.645 | | 0.390 | |
| Median | 0.520 | | 0.765 | | 0.550 | |
| Q3 | 0.520 | | 0.880 | | 0.580 | |
| Maximum | 0.52 | | 0.97 | | 0.78 | |
| Week -4 | | | | | | |
| N | 1 | | 4 | | 5 | |
| Mean | 0.470 | | 0.755 | | 0.440 | |
| SD | | | 0.3967 | | 0.1231 | |
| Minimum | 0.47 | | 0.40 | | 0.25 | |
| Q1 | 0.470 | | 0.480 | | 0.380 | |
| Median | 0.470 | | 0.655 | | 0.520 | |
| Q3 | 0.470 | | 1.030 | | 0.520 | |
| Maximum | 0.47 | | 1.31 | | 0.53 | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（27/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 1 | | 4 | | 5 | |
| Mean | 0.470 | | 0.898 | | 0.490 | |
| SD | | | 0.3490 | | 0.2225 | |
| Minimum | 0.47 | | 0.53 | | 0.21 | |
| Q1 | 0.470 | | 0.640 | | 0.340 | |
| Median | 0.470 | | 0.855 | | 0.520 | |
| Q3 | 0.470 | | 1.155 | | 0.600 | |
| Maximum | 0.47 | | 1.35 | | 0.78 | |
| Week 2 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 0.310 | -0.160 | 0.933 | 0.035 | 0.438 | -0.052 |
| SD | | | 0.2032 | 0.3242 | 0.1379 | 0.1657 |
| Minimum | 0.31 | -0.16 | 0.70 | -0.26 | 0.26 | -0.22 |
| Q1 | 0.310 | -0.160 | 0.780 | -0.215 | 0.320 | -0.200 |
| Median | 0.310 | -0.160 | 0.925 | -0.030 | 0.510 | -0.060 |
| Q3 | 0.310 | -0.160 | 1.085 | 0.285 | 0.540 | 0.050 |
| Maximum | 0.31 | -0.16 | 1.18 | 0.46 | 0.56 | 0.17 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（28/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 0.550 | 0.080 | 0.785 | -0.113 | 0.422 | -0.068 |
| SD | | | 0.4711 | 0.2337 | 0.1502 | 0.1615 |
| Minimum | 0.55 | 0.08 | 0.51 | -0.37 | 0.19 | -0.24 |
| Q1 | 0.550 | 0.080 | 0.530 | -0.305 | 0.350 | -0.170 |
| Median | 0.550 | 0.080 | 0.570 | -0.110 | 0.510 | -0.090 |
| Q3 | 0.550 | 0.080 | 1.040 | 0.080 | 0.520 | -0.020 |
| Maximum | 0.55 | 0.08 | 1.49 | 0.14 | 0.54 | 0.18 |
| Week 8 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 0.440 | -0.030 | 0.953 | 0.055 | 0.624 | 0.134 |
| SD | | | 0.1544 | 0.2509 | 0.2147 | 0.1330 |
| Minimum | 0.44 | -0.03 | 0.82 | -0.20 | 0.26 | -0.03 |
| Q1 | 0.440 | -0.030 | 0.830 | -0.160 | 0.650 | 0.050 |
| Median | 0.440 | -0.030 | 0.920 | 0.065 | 0.650 | 0.130 |
| Q3 | 0.440 | -0.030 | 1.075 | 0.270 | 0.750 | 0.210 |
| Maximum | 0.44 | -0.03 | 1.15 | 0.29 | 0.81 | 0.31 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（29/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 0.370 | -0.100 | 0.798 | -0.100 | 0.506 | 0.016 |
| SD | | | 0.1242 | 0.3224 | 0.2444 | 0.1448 |
| Minimum | 0.37 | -0.10 | 0.63 | -0.57 | 0.14 | -0.12 |
| Q1 | 0.370 | -0.100 | 0.705 | -0.310 | 0.400 | -0.070 |
| Median | 0.370 | -0.100 | 0.825 | 0.025 | 0.550 | -0.070 |
| Q3 | 0.370 | -0.100 | 0.890 | 0.110 | 0.710 | 0.130 |
| Maximum | 0.37 | -0.10 | 0.91 | 0.12 | 0.73 | 0.21 |
| Week 16 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 0.480 | 0.010 | 0.835 | -0.063 | 0.602 | 0.112 |
| SD | | | 0.0332 | 0.3297 | 0.2280 | 0.1696 |
| Minimum | 0.48 | 0.01 | 0.79 | -0.49 | 0.25 | -0.15 |
| Q1 | 0.480 | 0.010 | 0.810 | -0.295 | 0.560 | 0.040 |
| Median | 0.480 | 0.010 | 0.845 | -0.030 | 0.630 | 0.180 |
| Q3 | 0.480 | 0.010 | 0.860 | 0.170 | 0.700 | 0.220 |
| Maximum | 0.48 | 0.01 | 0.86 | 0.30 | 0.87 | 0.27 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（30/40）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=1) | | QD (N=4) | | BID (N=5) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 1 | 1 | 4 | 4 | 5 | 5 |
| Mean | 0.310 | -0.160 | 0.725 | -0.173 | 0.612 | 0.122 |
| SD | | | 0.3121 | 0.2490 | 0.2915 | 0.1813 |
| Minimum | 0.31 | -0.16 | 0.48 | -0.48 | 0.26 | -0.04 |
| Q1 | 0.310 | -0.160 | 0.530 | -0.325 | 0.460 | 0.050 |
| Median | 0.310 | -0.160 | 0.620 | -0.170 | 0.570 | 0.050 |
| Q3 | 0.310 | -0.160 | 0.920 | -0.020 | 0.740 | 0.120 |
| Maximum | 0.31 | -0.16 | 1.18 | 0.13 | 1.03 | 0.43 |
| Week 24 | | | | | | |
| N | 0 | 0 | 4 | 4 | 5 | 5 |
| Mean | | | 0.800 | -0.098 | 0.530 | 0.040 |
| SD | | | 0.3798 | 0.1253 | 0.2559 | 0.1391 |
| Minimum | | | 0.38 | -0.24 | 0.28 | -0.20 |
| Q1 | | | 0.550 | -0.195 | 0.320 | 0.060 |
| Median | | | 0.760 | -0.100 | 0.490 | 0.070 |
| Q3 | | | 1.050 | 0.000 | 0.660 | 0.120 |
| Maximum | | | 1.30 | 0.05 | 0.90 | 0.15 |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（31/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 0 | | 0 | | 0 | |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week -4 | | | | | | |
| N | 0 | | 0 | | 0 | |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（32/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 0 | | 0 | | 0 | |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 2 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（33/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 8 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（34/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 16 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（35/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 24 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（36/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 0 | | 0 | | 0 | |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week -4 | | | | | | |
| N | 0 | | 0 | | 0 | |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（37/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 0 | | 0 | | 0 | |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 2 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（38/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 8 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（39/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 16 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-20　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322-MET/CCT-001 試験）（40/40）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=0) | | QD (N=0) | | BID (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 20 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |
| Week 24 | | | | | | |
| N | 0 | 0 | 0 | 0 | 0 | 0 |
| Mean | | | | | | |
| SD | | | | | | |
| Minimum | | | | | | |
| Q1 | | | | | | |
| Median | | | | | | |
| Q3 | | | | | | |
| Maximum | | | | | | |

添付資料（5.3.5.3-3）Table 2.3.1.3

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（1/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) Observed Value at Visit | Placebo (N=44) Change from Baseline | 12.5 mg (N=48) Observed Value at Visit | 12.5 mg (N=48) Change from Baseline | 25 mg (N=38) Observed Value at Visit | 25 mg (N=38) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 44 | | 48 | | 38 | |
| Mean | 12.20 | | 11.21 | | 10.03 | |
| SD | 3.806 | | 3.947 | | 3.978 | |
| Minimum | 5.8 | | 4.6 | | 3.4 | |
| Q1 | 9.35 | | 8.50 | | 7.60 | |
| Median | 11.90 | | 10.90 | | 9.30 | |
| Q3 | 13.75 | | 13.70 | | 12.90 | |
| Maximum | 22.1 | | 20.7 | | 17.5 | |
| Week -4 | | | | | | |
| N | 44 | | 48 | | 38 | |
| Mean | 11.62 | | 11.44 | | 12.11 | |
| SD | 4.146 | | 5.086 | | 4.002 | |
| Minimum | 5.7 | | 4.5 | | 3.3 | |
| Q1 | 8.65 | | 7.95 | | 9.90 | |
| Median | 11.20 | | 10.35 | | 11.35 | |
| Q3 | 13.70 | | 12.85 | | 15.00 | |
| Maximum | 24.5 | | 30.1 | | 22.3 | |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（2/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) | | 12.5 mg (N=48) | | 25 mg (N=38) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 44 | | 48 | | 38 | |
| Mean | 11.72 | | 11.02 | | 10.49 | |
| SD | 5.149 | | 4.999 | | 4.375 | |
| Minimum | 2.7 | | 4.3 | | 3.7 | |
| Q1 | 8.40 | | 7.70 | | 6.70 | |
| Median | 11.20 | | 10.20 | | 10.75 | |
| Q3 | 14.65 | | 13.00 | | 12.90 | |
| Maximum | 30.6 | | 30.7 | | 20.8 | |
| Week 2 | | | | | | |
| N | 44 | 44 | 48 | 48 | 38 | 38 |
| Mean | 11.90 | 0.18 | 11.02 | 0.00 | 9.58 | -0.91 |
| SD | 4.721 | 5.336 | 7.684 | 4.842 | 3.303 | 4.320 |
| Minimum | 2.6 | -18.1 | 4.4 | -7.9 | 3.6 | -11.2 |
| Q1 | 8.25 | -1.90 | 6.75 | -3.20 | 7.00 | -3.30 |
| Median | 11.35 | -0.15 | 9.35 | -0.35 | 9.20 | -0.10 |
| Q3 | 15.25 | 4.70 | 11.95 | 1.60 | 12.20 | 1.40 |
| Maximum | 21.0 | 9.0 | 53.1 | 22.4 | 17.8 | 6.1 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（3/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) | | 12.5 mg (N=48) | | 25 mg (N=38) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 44 | 44 | 47 | 47 | 38 | 38 |
| Mean | 11.33 | -0.39 | 10.98 | -0.18 | 10.27 | -0.23 |
| SD | 4.495 | 5.204 | 8.103 | 5.673 | 4.690 | 6.181 |
| Minimum | 2.8 | -16.8 | 3.5 | -10.8 | 1.5 | -12.9 |
| Q1 | 7.85 | -3.00 | 6.90 | -3.50 | 7.50 | -3.50 |
| Median | 10.95 | 0.00 | 9.30 | -0.30 | 9.10 | 0.30 |
| Q3 | 14.05 | 2.10 | 12.40 | 1.80 | 12.10 | 3.10 |
| Maximum | 23.2 | 10.9 | 53.1 | 22.4 | 24.7 | 15.8 |
| Week 8 | | | | | | |
| N | 44 | 44 | 47 | 47 | 37 | 37 |
| Mean | 11.64 | -0.08 | 10.43 | -0.73 | 9.49 | -0.82 |
| SD | 4.490 | 5.407 | 5.332 | 4.158 | 3.776 | 4.630 |
| Minimum | 3.0 | -19.9 | 3.6 | -13.2 | 3.2 | -12.0 |
| Q1 | 7.80 | -2.95 | 7.00 | -3.10 | 6.90 | -2.90 |
| Median | 11.10 | 0.25 | 9.70 | -0.90 | 9.10 | -1.60 |
| Q3 | 15.20 | 3.05 | 12.20 | 1.80 | 11.70 | 0.70 |
| Maximum | 20.3 | 11.3 | 34.1 | 8.3 | 17.6 | 10.9 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（4/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) | | 12.5 mg (N=48) | | 25 mg (N=38) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 44 | 44 | 47 | 47 | 37 | 37 |
| Mean | 12.36 | 0.64 | 10.12 | -1.04 | 9.82 | -0.49 |
| SD | 6.140 | 6.990 | 3.793 | 3.910 | 4.654 | 3.443 |
| Minimum | 3.5 | -15.2 | 4.3 | -19.0 | 3.9 | -6.6 |
| Q1 | 7.75 | -3.40 | 7.20 | -2.60 | 6.20 | -2.70 |
| Median | 10.80 | -0.10 | 9.30 | -0.20 | 8.40 | -0.20 |
| Q3 | 14.95 | 3.65 | 12.90 | 1.00 | 12.30 | 1.20 |
| Maximum | 30.6 | 20.6 | 20.1 | 5.6 | 22.0 | 7.0 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（5/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) Observed Value at Visit | Placebo (N=44) Change from Baseline | 12.5 mg (N=48) Observed Value at Visit | 12.5 mg (N=48) Change from Baseline | 25 mg (N=38) Observed Value at Visit | 25 mg (N=38) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 44 | | 48 | | 38 | |
| Mean | 0.582 | | 0.590 | | 0.549 | |
| SD | 0.1955 | | 0.2746 | | 0.2657 | |
| Minimum | 0.14 | | 0.21 | | 0.00 | |
| Q1 | 0.480 | | 0.425 | | 0.370 | |
| Median | 0.590 | | 0.560 | | 0.530 | |
| Q3 | 0.690 | | 0.645 | | 0.710 | |
| Maximum | 1.15 | | 1.90 | | 1.19 | |
| Week -4 | | | | | | |
| N | 44 | | 48 | | 38 | |
| Mean | 0.560 | | 0.568 | | 0.616 | |
| SD | 0.1942 | | 0.3092 | | 0.2089 | |
| Minimum | 0.21 | | 0.17 | | 0.22 | |
| Q1 | 0.425 | | 0.395 | | 0.460 | |
| Median | 0.550 | | 0.535 | | 0.660 | |
| Q3 | 0.665 | | 0.670 | | 0.760 | |
| Maximum | 1.12 | | 2.06 | | 1.26 | |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（6/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) | | 12.5 mg (N=48) | | 25 mg (N=38) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 44 | | 48 | | 38 | |
| Mean | 0.560 | | 0.545 | | 0.562 | |
| SD | 0.2273 | | 0.2018 | | 0.2626 | |
| Minimum | 0.20 | | 0.22 | | 0.20 | |
| Q1 | 0.410 | | 0.370 | | 0.380 | |
| Median | 0.525 | | 0.520 | | 0.525 | |
| Q3 | 0.690 | | 0.705 | | 0.640 | |
| Maximum | 1.06 | | 0.95 | | 1.35 | |
| Week 2 | | | | | | |
| N | 44 | 44 | 48 | 48 | 38 | 38 |
| Mean | 0.582 | 0.023 | 0.507 | -0.038 | 0.463 | -0.099 |
| SD | 0.2224 | 0.2411 | 0.2197 | 0.2242 | 0.1668 | 0.2568 |
| Minimum | 0.24 | -0.68 | 0.21 | -0.68 | 0.24 | -0.71 |
| Q1 | 0.450 | -0.085 | 0.355 | -0.195 | 0.330 | -0.220 |
| Median | 0.585 | 0.015 | 0.460 | -0.020 | 0.430 | -0.085 |
| Q3 | 0.750 | 0.175 | 0.590 | 0.110 | 0.610 | 0.100 |
| Maximum | 1.16 | 0.58 | 1.16 | 0.66 | 0.84 | 0.29 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（7/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=44) | | 12.5 mg (N=48) | | 25 mg (N=38) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 44 | 44 | 47 | 47 | 38 | 38 |
| Mean | 0.564 | 0.005 | 0.494 | -0.057 | 0.538 | -0.024 |
| SD | 0.2259 | 0.2307 | 0.1805 | 0.1839 | 0.2137 | 0.2655 |
| Minimum | 0.19 | -0.55 | 0.25 | -0.46 | 0.11 | -0.83 |
| Q1 | 0.410 | -0.110 | 0.380 | -0.190 | 0.380 | -0.120 |
| Median | 0.545 | 0.015 | 0.460 | -0.060 | 0.520 | -0.015 |
| Q3 | 0.675 | 0.100 | 0.600 | 0.080 | 0.620 | 0.140 |
| Maximum | 1.14 | 0.65 | 1.09 | 0.42 | 1.15 | 0.38 |
| Week 8 | | | | | | |
| N | 44 | 44 | 47 | 47 | 37 | 37 |
| Mean | 0.570 | 0.010 | 0.538 | -0.013 | 0.539 | -0.019 |
| SD | 0.2469 | 0.2340 | 0.2611 | 0.2625 | 0.2465 | 0.2821 |
| Minimum | 0.11 | -0.64 | 0.22 | -0.73 | 0.12 | -0.64 |
| Q1 | 0.395 | -0.110 | 0.370 | -0.170 | 0.400 | -0.200 |
| Median | 0.555 | -0.010 | 0.450 | 0.000 | 0.490 | -0.010 |
| Q3 | 0.745 | 0.130 | 0.620 | 0.130 | 0.640 | 0.080 |
| Maximum | 1.26 | 0.59 | 1.33 | 0.81 | 1.26 | 0.84 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（8/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=44) | | 12.5 mg (N=48) | | 25 mg (N=38) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 44 | 44 | 47 | 47 | 37 | 37 |
| Mean | 0.608 | 0.049 | 0.550 | -0.002 | 0.517 | -0.041 |
| SD | 0.2776 | 0.2711 | 0.2227 | 0.2055 | 0.2156 | 0.2259 |
| Minimum | 0.22 | -0.68 | 0.23 | -0.51 | 0.23 | -0.46 |
| Q1 | 0.435 | -0.085 | 0.420 | -0.130 | 0.390 | -0.180 |
| Median | 0.525 | 0.030 | 0.480 | 0.010 | 0.480 | 0.020 |
| Q3 | 0.740 | 0.175 | 0.660 | 0.110 | 0.600 | 0.090 |
| Maximum | 1.46 | 0.72 | 1.24 | 0.39 | 1.16 | 0.60 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（9/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=56) Observed Value at Visit | Placebo (N=56) Change from Baseline | 12.5 mg (N=44) Observed Value at Visit | 12.5 mg (N=44) Change from Baseline | 25 mg (N=58) Observed Value at Visit | 25 mg (N=58) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 56 | | 44 | | 58 | |
| Mean | 11.65 | | 12.20 | | 12.74 | |
| SD | 3.969 | | 5.514 | | 5.310 | |
| Minimum | 3.9 | | 3.7 | | 5.0 | |
| Q1 | 8.60 | | 7.90 | | 9.10 | |
| Median | 11.75 | | 10.95 | | 11.65 | |
| Q3 | 15.30 | | 15.35 | | 15.80 | |
| Maximum | 19.1 | | 26.2 | | 32.8 | |
| Week -4 | | | | | | |
| N | 56 | | 44 | | 58 | |
| Mean | 13.92 | | 12.29 | | 13.10 | |
| SD | 4.997 | | 5.926 | | 4.348 | |
| Minimum | 4.9 | | 4.2 | | 5.6 | |
| Q1 | 10.60 | | 7.75 | | 10.20 | |
| Median | 12.60 | | 10.85 | | 12.20 | |
| Q3 | 16.40 | | 15.50 | | 15.30 | |
| Maximum | 26.9 | | 28.3 | | 24.3 | |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（10/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 56 | | 44 | | 58 | |
| Mean | 13.11 | | 11.66 | | 11.21 | |
| SD | 5.805 | | 5.082 | | 3.793 | |
| Minimum | 2.8 | | 3.3 | | 4.4 | |
| Q1 | 9.45 | | 7.85 | | 8.20 | |
| Median | 12.70 | | 11.05 | | 11.25 | |
| Q3 | 15.30 | | 15.55 | | 13.70 | |
| Maximum | 32.0 | | 25.3 | | 19.3 | |
| Week 2 | | | | | | |
| N | 56 | 56 | 44 | 44 | 58 | 58 |
| Mean | 12.61 | -0.51 | 10.28 | -1.38 | 10.73 | -0.48 |
| SD | 5.072 | 5.369 | 4.468 | 3.923 | 4.046 | 4.274 |
| Minimum | 3.9 | -17.5 | 3.3 | -8.7 | 3.5 | -8.6 |
| Q1 | 9.05 | -3.10 | 7.20 | -4.10 | 8.00 | -2.70 |
| Median | 12.10 | 0.50 | 9.70 | -0.90 | 10.05 | -1.05 |
| Q3 | 14.65 | 2.00 | 12.45 | 1.00 | 13.70 | 1.70 |
| Maximum | 28.0 | 16.0 | 22.9 | 10.1 | 24.5 | 16.7 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（11/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 56 | 56 | 43 | 43 | 57 | 57 |
| Mean | 12.17 | -0.94 | 11.59 | -0.10 | 10.31 | -0.89 |
| SD | 5.687 | 6.468 | 6.747 | 6.317 | 4.438 | 3.939 |
| Minimum | 2.9 | -23.2 | 4.3 | -14.7 | 3.5 | -9.0 |
| Q1 | 8.25 | -4.45 | 6.70 | -3.00 | 6.90 | -3.00 |
| Median | 11.05 | -1.25 | 11.00 | -0.30 | 9.90 | -1.10 |
| Q3 | 14.20 | 2.75 | 14.20 | 2.30 | 12.90 | 1.60 |
| Maximum | 31.0 | 15.3 | 38.5 | 24.4 | 26.8 | 15.1 |
| Week 8 | | | | | | |
| N | 56 | 56 | 44 | 44 | 57 | 57 |
| Mean | 13.25 | 0.13 | 10.16 | -1.50 | 11.17 | -0.03 |
| SD | 5.161 | 5.351 | 4.721 | 3.614 | 4.396 | 3.576 |
| Minimum | 3.4 | -18.6 | 2.5 | -12.3 | 4.0 | -7.7 |
| Q1 | 9.55 | -2.35 | 6.10 | -4.35 | 7.80 | -2.20 |
| Median | 12.60 | 0.70 | 9.65 | -1.20 | 11.00 | 0.10 |
| Q3 | 16.65 | 3.40 | 13.20 | 0.70 | 13.30 | 1.80 |
| Maximum | 30.2 | 12.2 | 22.0 | 4.9 | 22.9 | 15.1 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（12/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 56 | 56 | 44 | 44 | 57 | 57 |
| Mean | 13.75 | 0.64 | 10.52 | -1.14 | 10.98 | -0.22 |
| SD | 4.989 | 5.363 | 4.405 | 4.100 | 5.956 | 5.585 |
| Minimum | 4.9 | -12.6 | 2.9 | -11.3 | 3.7 | -8.3 |
| Q1 | 9.90 | -2.60 | 7.05 | -3.95 | 7.60 | -3.30 |
| Median | 13.55 | 0.30 | 9.90 | -0.85 | 10.00 | -1.30 |
| Q3 | 16.25 | 3.05 | 14.05 | 2.10 | 12.60 | 1.50 |
| Maximum | 25.6 | 16.9 | 22.0 | 5.4 | 37.0 | 23.6 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（13/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 56 | | 44 | | 58 | |
| Mean | 0.613 | | 0.600 | | 0.689 | |
| SD | 0.3471 | | 0.2873 | | 0.3548 | |
| Minimum | 0.11 | | 0.20 | | 0.00 | |
| Q1 | 0.390 | | 0.420 | | 0.460 | |
| Median | 0.535 | | 0.520 | | 0.620 | |
| Q3 | 0.730 | | 0.745 | | 0.880 | |
| Maximum | 1.99 | | 1.32 | | 1.76 | |
| Week -4 | | | | | | |
| N | 56 | | 44 | | 58 | |
| Mean | 0.646 | | 0.636 | | 0.687 | |
| SD | 0.2434 | | 0.2995 | | 0.2992 | |
| Minimum | 0.22 | | 0.21 | | 0.16 | |
| Q1 | 0.430 | | 0.400 | | 0.470 | |
| Median | 0.655 | | 0.590 | | 0.650 | |
| Q3 | 0.810 | | 0.795 | | 0.880 | |
| Maximum | 1.39 | | 1.44 | | 1.50 | |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（14/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 56 | | 44 | | 58 | |
| Mean | 0.683 | | 0.626 | | 0.629 | |
| SD | 0.3444 | | 0.2846 | | 0.2597 | |
| Minimum | 0.16 | | 0.22 | | 0.12 | |
| Q1 | 0.395 | | 0.410 | | 0.430 | |
| Median | 0.600 | | 0.580 | | 0.595 | |
| Q3 | 0.905 | | 0.785 | | 0.800 | |
| Maximum | 1.66 | | 1.59 | | 1.30 | |
| Week 2 | | | | | | |
| N | 56 | 56 | 44 | 44 | 58 | 58 |
| Mean | 0.657 | -0.026 | 0.575 | -0.051 | 0.587 | -0.042 |
| SD | 0.2825 | 0.2588 | 0.2533 | 0.2317 | 0.2336 | 0.2331 |
| Minimum | 0.19 | -0.89 | 0.16 | -0.70 | 0.15 | -0.77 |
| Q1 | 0.430 | -0.110 | 0.410 | -0.200 | 0.430 | -0.160 |
| Median | 0.565 | 0.000 | 0.530 | -0.045 | 0.550 | -0.045 |
| Q3 | 0.845 | 0.120 | 0.665 | 0.135 | 0.720 | 0.090 |
| Maximum | 1.25 | 0.59 | 1.22 | 0.41 | 1.20 | 0.40 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（15/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 56 | 56 | 43 | 43 | 57 | 57 |
| Mean | 0.658 | -0.025 | 0.608 | -0.019 | 0.568 | -0.070 |
| SD | 0.2806 | 0.3415 | 0.2600 | 0.2710 | 0.2376 | 0.2784 |
| Minimum | 0.26 | -1.22 | 0.13 | -0.92 | 0.25 | -1.05 |
| Q1 | 0.450 | -0.195 | 0.440 | -0.190 | 0.400 | -0.230 |
| Median | 0.590 | 0.025 | 0.610 | -0.020 | 0.510 | -0.080 |
| Q3 | 0.820 | 0.150 | 0.830 | 0.220 | 0.690 | 0.090 |
| Maximum | 1.62 | 1.07 | 1.17 | 0.41 | 1.48 | 0.59 |
| Week 8 | | | | | | |
| N | 56 | 56 | 44 | 44 | 57 | 57 |
| Mean | 0.665 | -0.018 | 0.578 | -0.048 | 0.622 | -0.016 |
| SD | 0.2780 | 0.2537 | 0.2805 | 0.2659 | 0.2627 | 0.1971 |
| Minimum | 0.21 | -0.64 | 0.23 | -0.57 | 0.14 | -0.51 |
| Q1 | 0.475 | -0.160 | 0.410 | -0.225 | 0.410 | -0.150 |
| Median | 0.630 | 0.010 | 0.490 | -0.050 | 0.640 | -0.030 |
| Q3 | 0.800 | 0.190 | 0.700 | 0.110 | 0.750 | 0.110 |
| Maximum | 1.67 | 0.48 | 1.68 | 0.69 | 1.23 | 0.44 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-21　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（16/16）

eGFR (mL/min/1.73m$^2$ ) at Week 0: 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=56) | | 12.5 mg (N=44) | | 25 mg (N=58) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 56 | 56 | 44 | 44 | 57 | 57 |
| Mean | 0.700 | 0.018 | 0.599 | -0.027 | 0.632 | -0.006 |
| SD | 0.3163 | 0.3513 | 0.2395 | 0.2271 | 0.2840 | 0.2589 |
| Minimum | 0.19 | -0.90 | 0.17 | -0.52 | 0.12 | -0.83 |
| Q1 | 0.465 | -0.175 | 0.430 | -0.205 | 0.440 | -0.110 |
| Median | 0.635 | 0.035 | 0.585 | -0.005 | 0.550 | -0.010 |
| Q3 | 0.885 | 0.175 | 0.710 | 0.110 | 0.860 | 0.120 |
| Maximum | 1.62 | 0.78 | 1.15 | 0.61 | 1.30 | 0.74 |

添付資料（5.3.5.3-2）Table 1.3.1.1

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（1/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) Observed Value at Visit | Placebo (N=71) Change from Baseline | 12.5 mg (N=83) Observed Value at Visit | 12.5 mg (N=83) Change from Baseline | 25 mg (N=82) Observed Value at Visit | 25 mg (N=82) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 71 | | 83 | | 82 | |
| Mean | 11.78 | | 11.61 | | 11.27 | |
| SD | 4.064 | | 4.855 | | 5.001 | |
| Minimum | 3.9 | | 3.7 | | 3.4 | |
| Q1 | 8.70 | | 8.00 | | 7.60 | |
| Median | 12.00 | | 10.60 | | 10.05 | |
| Q3 | 14.30 | | 14.40 | | 14.50 | |
| Maximum | 22.1 | | 26.2 | | 32.8 | |
| Week -4 | | | | | | |
| N | 71 | | 83 | | 82 | |
| Mean | 12.64 | | 11.51 | | 12.60 | |
| SD | 4.893 | | 5.530 | | 4.345 | |
| Minimum | 4.9 | | 4.2 | | 3.3 | |
| Q1 | 8.80 | | 7.80 | | 10.00 | |
| Median | 12.10 | | 10.30 | | 11.60 | |
| Q3 | 14.80 | | 13.00 | | 15.10 | |
| Maximum | 26.0 | | 30.1 | | 24.3 | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（2/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) | | 12.5 mg (N=83) | | 25 mg (N=82) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 71 | | 83 | | 82 | |
| Mean | 11.68 | | 10.87 | | 10.59 | |
| SD | 5.359 | | 4.925 | | 4.073 | |
| Minimum | 2.7 | | 3.3 | | 3.7 | |
| Q1 | 7.40 | | 7.60 | | 7.30 | |
| Median | 11.40 | | 10.20 | | 10.90 | |
| Q3 | 15.10 | | 13.40 | | 13.30 | |
| Maximum | 30.6 | | 30.7 | | 20.8 | |
| Week 2 | | | | | | |
| N | 71 | 71 | 83 | 83 | 82 | 82 |
| Mean | 11.87 | 0.19 | 10.50 | -0.38 | 10.20 | -0.39 |
| SD | 4.926 | 5.210 | 6.601 | 4.410 | 3.856 | 4.182 |
| Minimum | 2.6 | -18.1 | 3.3 | -7.9 | 3.5 | -11.2 |
| Q1 | 8.20 | -2.10 | 6.80 | -3.40 | 7.60 | -2.10 |
| Median | 11.80 | 0.50 | 9.30 | -0.40 | 9.70 | -0.45 |
| Q3 | 14.80 | 2.90 | 11.80 | 1.60 | 12.30 | 1.70 |
| Maximum | 28.0 | 16.0 | 53.1 | 22.4 | 24.5 | 16.7 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（3/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) | | 12.5 mg (N=83) | | 25 mg (N=82) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 71 | 71 | 81 | 81 | 81 | 81 |
| Mean | 11.03 | -0.65 | 11.11 | 0.16 | 10.40 | -0.18 |
| SD | 5.077 | 5.541 | 7.772 | 6.064 | 4.663 | 5.040 |
| Minimum | 2.8 | -16.8 | 3.5 | -14.7 | 1.5 | -12.9 |
| Q1 | 7.60 | -4.00 | 6.70 | -2.60 | 7.10 | -3.00 |
| Median | 10.50 | -0.30 | 9.30 | -0.20 | 9.90 | 0.10 |
| Q3 | 13.80 | 2.10 | 12.80 | 2.20 | 12.90 | 2.60 |
| Maximum | 31.0 | 15.3 | 53.1 | 24.4 | 26.8 | 15.8 |
| Week 8 | | | | | | |
| N | 71 | 71 | 82 | 82 | 80 | 80 |
| Mean | 11.63 | -0.05 | 10.03 | -0.93 | 10.37 | -0.12 |
| SD | 4.573 | 4.929 | 4.955 | 3.708 | 4.305 | 4.089 |
| Minimum | 3.0 | -19.9 | 2.5 | -12.3 | 3.2 | -12.0 |
| Q1 | 8.50 | -2.50 | 6.40 | -2.70 | 7.50 | -2.40 |
| Median | 11.50 | 0.30 | 9.40 | -1.05 | 9.65 | -0.55 |
| Q3 | 15.40 | 2.30 | 12.70 | 1.60 | 12.35 | 2.00 |
| Maximum | 22.1 | 10.1 | 34.1 | 8.3 | 22.9 | 15.1 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（4/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) | | 12.5 mg (N=83) | | 25 mg (N=82) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 71 | 71 | 82 | 82 | 80 | 80 |
| Mean | 12.30 | 0.62 | 10.07 | -0.89 | 10.08 | -0.41 |
| SD | 5.125 | 5.464 | 4.100 | 3.910 | 4.755 | 4.357 |
| Minimum | 3.5 | -15.2 | 2.9 | -19.0 | 3.7 | -6.6 |
| Q1 | 8.20 | -2.50 | 6.90 | -2.60 | 6.40 | -3.20 |
| Median | 11.80 | 0.40 | 9.30 | -0.20 | 9.75 | -0.60 |
| Q3 | 14.90 | 3.00 | 13.10 | 1.50 | 12.25 | 1.45 |
| Maximum | 27.5 | 18.3 | 22.0 | 5.6 | 31.4 | 23.6 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（5/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) Observed Value at Visit | Placebo (N=71) Change from Baseline | 12.5 mg (N=83) Observed Value at Visit | 12.5 mg (N=83) Change from Baseline | 25 mg (N=82) Observed Value at Visit | 25 mg (N=82) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 71 | | 83 | | 82 | |
| Mean | 0.579 | | 0.596 | | 0.604 | |
| SD | 0.2852 | | 0.2906 | | 0.3148 | |
| Minimum | 0.11 | | 0.20 | | 0.00 | |
| Q1 | 0.400 | | 0.410 | | 0.390 | |
| Median | 0.560 | | 0.510 | | 0.555 | |
| Q3 | 0.700 | | 0.740 | | 0.740 | |
| Maximum | 1.99 | | 1.90 | | 1.76 | |
| Week -4 | | | | | | |
| N | 71 | | 83 | | 82 | |
| Mean | 0.614 | | 0.593 | | 0.650 | |
| SD | 0.2415 | | 0.3105 | | 0.2718 | |
| Minimum | 0.21 | | 0.17 | | 0.16 | |
| Q1 | 0.410 | | 0.390 | | 0.460 | |
| Median | 0.600 | | 0.540 | | 0.650 | |
| Q3 | 0.740 | | 0.720 | | 0.770 | |
| Maximum | 1.39 | | 2.06 | | 1.50 | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（6/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) Observed Value at Visit | Placebo (N=71) Change from Baseline | 12.5 mg (N=83) Observed Value at Visit | 12.5 mg (N=83) Change from Baseline | 25 mg (N=82) Observed Value at Visit | 25 mg (N=82) Change from Baseline |
|---|---|---|---|---|---|---|
| Week 0 | | | | | | |
| N | 71 | | 83 | | 82 | |
| Mean | 0.600 | | 0.562 | | 0.569 | |
| SD | 0.3086 | | 0.2437 | | 0.2461 | |
| Minimum | 0.16 | | 0.22 | | 0.12 | |
| Q1 | 0.370 | | 0.390 | | 0.400 | |
| Median | 0.530 | | 0.520 | | 0.530 | |
| Q3 | 0.770 | | 0.720 | | 0.670 | |
| Maximum | 1.66 | | 1.59 | | 1.35 | |
| Week 2 | | | | | | |
| N | 71 | 71 | 83 | 83 | 82 | 82 |
| Mean | 0.608 | 0.008 | 0.533 | -0.028 | 0.528 | -0.041 |
| SD | 0.2589 | 0.2495 | 0.2457 | 0.2225 | 0.2106 | 0.2195 |
| Minimum | 0.19 | -0.89 | 0.16 | -0.70 | 0.15 | -0.71 |
| Q1 | 0.410 | -0.090 | 0.360 | -0.160 | 0.350 | -0.180 |
| Median | 0.560 | 0.010 | 0.480 | -0.010 | 0.505 | -0.035 |
| Q3 | 0.780 | 0.170 | 0.620 | 0.120 | 0.650 | 0.100 |
| Maximum | 1.25 | 0.59 | 1.22 | 0.66 | 1.20 | 0.40 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（7/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) | | 12.5 mg (N=83) | | 25 mg (N=82) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 71 | 71 | 81 | 81 | 81 | 81 |
| Mean | 0.581 | -0.019 | 0.542 | -0.024 | 0.559 | -0.016 |
| SD | 0.2594 | 0.3084 | 0.2366 | 0.2264 | 0.2351 | 0.2562 |
| Minimum | 0.19 | -1.22 | 0.13 | -0.92 | 0.11 | -0.83 |
| Q1 | 0.430 | -0.150 | 0.380 | -0.170 | 0.380 | -0.140 |
| Median | 0.530 | 0.010 | 0.510 | -0.030 | 0.520 | -0.010 |
| Q3 | 0.690 | 0.140 | 0.670 | 0.160 | 0.660 | 0.130 |
| Maximum | 1.62 | 1.07 | 1.17 | 0.42 | 1.48 | 0.59 |
| Week 8 | | | | | | |
| N | 71 | 71 | 82 | 82 | 80 | 80 |
| Mean | 0.585 | -0.015 | 0.554 | -0.012 | 0.567 | -0.006 |
| SD | 0.2600 | 0.2350 | 0.2774 | 0.2546 | 0.2601 | 0.2338 |
| Minimum | 0.11 | -0.64 | 0.22 | -0.73 | 0.12 | -0.64 |
| Q1 | 0.430 | -0.120 | 0.370 | -0.170 | 0.380 | -0.165 |
| Median | 0.550 | 0.010 | 0.480 | -0.010 | 0.500 | -0.010 |
| Q3 | 0.700 | 0.130 | 0.620 | 0.130 | 0.710 | 0.120 |
| Maximum | 1.67 | 0.59 | 1.68 | 0.81 | 1.26 | 0.84 |

添付資料（5.3.5.3-2）Table 1.3.1.2

表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（8/32）

Severity of Liver Function at Week 0: None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=71) | | 12.5 mg (N=83) | | 25 mg (N=82) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 71 | 71 | 82 | 82 | 80 | 80 |
| Mean | 0.611 | 0.011 | 0.564 | -0.001 | 0.571 | -0.002 |
| SD | 0.2658 | 0.2932 | 0.2336 | 0.2128 | 0.2642 | 0.2123 |
| Minimum | 0.19 | -0.90 | 0.17 | -0.52 | 0.12 | -0.46 |
| Q1 | 0.410 | -0.130 | 0.420 | -0.130 | 0.385 | -0.120 |
| Median | 0.560 | 0.020 | 0.510 | 0.010 | 0.500 | 0.020 |
| Q3 | 0.770 | 0.170 | 0.680 | 0.110 | 0.690 | 0.105 |
| Maximum | 1.53 | 0.60 | 1.24 | 0.61 | 1.30 | 0.74 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（9/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 18 | | 4 | | 8 | |
| Mean | 11.83 | | 12.23 | | 13.28 | |
| SD | 3.935 | | 1.396 | | 2.653 | |
| Minimum | 6.4 | | 10.8 | | 10.3 | |
| Q1 | 8.50 | | 11.15 | | 10.90 | |
| Median | 10.65 | | 12.05 | | 13.00 | |
| Q3 | 16.00 | | 13.30 | | 15.30 | |
| Maximum | 18.8 | | 14.0 | | 17.5 | |
| Week -4 | | | | | | |
| N | 18 | | 4 | | 8 | |
| Mean | 13.65 | | 13.90 | | 12.89 | |
| SD | 5.185 | | 3.324 | | 2.305 | |
| Minimum | 7.1 | | 11.2 | | 10.1 | |
| Q1 | 9.40 | | 11.75 | | 10.55 | |
| Median | 13.35 | | 12.85 | | 13.25 | |
| Q3 | 15.80 | | 16.05 | | 14.45 | |
| Maximum | 26.9 | | 18.7 | | 16.5 | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（10/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 18 | | 4 | | 8 | |
| Mean | 13.94 | | 14.85 | | 11.78 | |
| SD | 5.337 | | 3.455 | | 1.741 | |
| Minimum | 8.6 | | 9.9 | | 9.7 | |
| Q1 | 10.00 | | 12.60 | | 10.20 | |
| Median | 12.55 | | 15.85 | | 11.70 | |
| Q3 | 17.40 | | 17.10 | | 13.10 | |
| Maximum | 28.8 | | 17.8 | | 14.5 | |
| Week 2 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 11.87 | -2.07 | 12.78 | -2.08 | 10.75 | -1.03 |
| SD | 4.524 | 5.771 | 3.188 | 4.590 | 3.537 | 4.795 |
| Minimum | 4.6 | -16.1 | 9.1 | -8.7 | 6.5 | -6.5 |
| Q1 | 9.00 | -4.50 | 10.15 | -5.15 | 7.80 | -5.60 |
| Median | 11.00 | -1.45 | 13.00 | -0.45 | 9.95 | -1.20 |
| Q3 | 14.40 | 2.80 | 15.40 | 1.00 | 14.30 | 3.10 |
| Maximum | 24.3 | 5.7 | 16.0 | 1.3 | 15.4 | 5.7 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（11/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 13.47 | -0.47 | 13.78 | -1.08 | 8.98 | -2.80 |
| SD | 5.778 | 6.145 | 3.371 | 5.302 | 2.258 | 0.847 |
| Minimum | 5.6 | -11.6 | 11.0 | -6.6 | 5.5 | -4.2 |
| Q1 | 9.50 | -5.10 | 11.10 | -5.45 | 7.50 | -3.30 |
| Median | 12.50 | 0.10 | 13.00 | -1.30 | 9.05 | -2.80 |
| Q3 | 15.10 | 4.00 | 16.45 | 3.30 | 10.55 | -2.25 |
| Maximum | 29.5 | 12.7 | 18.1 | 4.9 | 12.1 | -1.5 |
| Week 8 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 13.64 | -0.31 | 14.58 | -0.28 | 10.41 | -1.36 |
| SD | 4.124 | 7.081 | 2.722 | 3.324 | 2.563 | 2.180 |
| Minimum | 6.9 | -12.7 | 12.1 | -5.1 | 6.6 | -6.0 |
| Q1 | 10.20 | -4.80 | 12.40 | -2.45 | 8.40 | -2.20 |
| Median | 13.95 | 1.50 | 14.10 | 0.90 | 10.70 | -0.80 |
| Q3 | 15.70 | 5.30 | 16.75 | 1.90 | 12.10 | 0.20 |
| Maximum | 22.0 | 12.2 | 18.0 | 2.2 | 14.3 | 0.7 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（12/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 14.89 | 0.94 | 13.30 | -1.55 | 10.33 | -1.45 |
| SD | 6.177 | 7.502 | 2.195 | 2.253 | 3.231 | 4.074 |
| Minimum | 7.3 | -11.9 | 11.5 | -3.6 | 7.5 | -6.9 |
| Q1 | 10.20 | -4.90 | 11.60 | -3.10 | 7.95 | -3.75 |
| Median | 13.85 | 0.30 | 12.75 | -2.10 | 9.60 | -1.20 |
| Q3 | 18.20 | 6.70 | 15.00 | 0.00 | 11.40 | -0.90 |
| Maximum | 30.6 | 17.1 | 16.2 | 1.6 | 17.2 | 7.0 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（13/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 18 | | 4 | | 8 | |
| Mean | 0.585 | | 0.575 | | 0.808 | |
| SD | 0.2389 | | 0.1971 | | 0.2949 | |
| Minimum | 0.11 | | 0.31 | | 0.45 | |
| Q1 | 0.410 | | 0.425 | | 0.555 | |
| Median | 0.600 | | 0.630 | | 0.795 | |
| Q3 | 0.730 | | 0.725 | | 1.005 | |
| Maximum | 1.02 | | 0.73 | | 1.30 | |
| Week -4 | | | | | | |
| N | 18 | | 4 | | 8 | |
| Mean | 0.561 | | 0.495 | | 0.713 | |
| SD | 0.1730 | | 0.1136 | | 0.2663 | |
| Minimum | 0.30 | | 0.37 | | 0.42 | |
| Q1 | 0.430 | | 0.400 | | 0.500 | |
| Median | 0.560 | | 0.500 | | 0.655 | |
| Q3 | 0.680 | | 0.590 | | 0.930 | |
| Maximum | 0.90 | | 0.61 | | 1.11 | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（14/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 18 | | 4 | | 8 | |
| Mean | 0.674 | | 0.703 | | 0.786 | |
| SD | 0.2792 | | 0.2364 | | 0.2912 | |
| Minimum | 0.29 | | 0.41 | | 0.41 | |
| Q1 | 0.470 | | 0.515 | | 0.555 | |
| Median | 0.620 | | 0.730 | | 0.760 | |
| Q3 | 0.950 | | 0.890 | | 0.975 | |
| Maximum | 1.22 | | 0.94 | | 1.30 | |
| Week 2 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 0.593 | -0.081 | 0.520 | -0.183 | 0.626 | -0.160 |
| SD | 0.2384 | 0.2678 | 0.0668 | 0.2196 | 0.2553 | 0.3480 |
| Minimum | 0.26 | -0.68 | 0.44 | -0.45 | 0.33 | -0.77 |
| Q1 | 0.430 | -0.200 | 0.465 | -0.360 | 0.465 | -0.370 |
| Median | 0.600 | -0.020 | 0.530 | -0.155 | 0.525 | -0.080 |
| Q3 | 0.780 | 0.080 | 0.575 | -0.005 | 0.810 | 0.040 |
| Maximum | 1.16 | 0.25 | 0.58 | 0.03 | 1.08 | 0.31 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（15/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 0.696 | 0.022 | 0.578 | -0.125 | 0.531 | -0.255 |
| SD | 0.2487 | 0.2908 | 0.0556 | 0.2100 | 0.2176 | 0.3686 |
| Minimum | 0.35 | -0.55 | 0.51 | -0.38 | 0.25 | -1.05 |
| Q1 | 0.570 | -0.170 | 0.535 | -0.290 | 0.400 | -0.355 |
| Median | 0.665 | 0.030 | 0.580 | -0.110 | 0.485 | -0.160 |
| Q3 | 0.820 | 0.150 | 0.620 | 0.040 | 0.650 | -0.060 |
| Maximum | 1.37 | 0.55 | 0.64 | 0.10 | 0.93 | 0.16 |
| Week 8 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 0.695 | 0.021 | 0.625 | -0.078 | 0.720 | -0.066 |
| SD | 0.2138 | 0.2985 | 0.2082 | 0.2855 | 0.1878 | 0.2485 |
| Minimum | 0.25 | -0.64 | 0.43 | -0.48 | 0.49 | -0.53 |
| Q1 | 0.570 | -0.160 | 0.445 | -0.260 | 0.635 | -0.180 |
| Median | 0.730 | 0.055 | 0.630 | -0.010 | 0.695 | -0.080 |
| Q3 | 0.870 | 0.230 | 0.805 | 0.105 | 0.735 | 0.120 |
| Maximum | 1.06 | 0.48 | 0.81 | 0.19 | 1.14 | 0.28 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（16/32）

Severity of Liver Function at Week 0: 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=18) | | 12.5 mg (N=4) | | 25 mg (N=8) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 18 | 18 | 4 | 4 | 8 | 8 |
| Mean | 0.754 | 0.081 | 0.608 | -0.095 | 0.628 | -0.159 |
| SD | 0.3058 | 0.3703 | 0.1559 | 0.1905 | 0.2130 | 0.3849 |
| Minimum | 0.32 | -0.68 | 0.39 | -0.34 | 0.28 | -0.83 |
| Q1 | 0.520 | -0.140 | 0.495 | -0.235 | 0.495 | -0.415 |
| Median | 0.740 | 0.065 | 0.655 | -0.075 | 0.625 | -0.140 |
| Q3 | 0.930 | 0.180 | 0.720 | 0.045 | 0.765 | 0.215 |
| Maximum | 1.48 | 0.74 | 0.73 | 0.11 | 0.97 | 0.24 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（17/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=10) Observed Value at Visit | Placebo (N=10) Change from Baseline | 12.5 mg (N=4) Observed Value at Visit | 12.5 mg (N=4) Change from Baseline | 25 mg (N=6) Observed Value at Visit | 25 mg (N=6) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 10 | | 4 | | 6 | |
| Mean | 12.63 | | 10.30 | | 14.92 | |
| SD | 2.765 | | 2.563 | | 6.165 | |
| Minimum | 7.0 | | 7.7 | | 4.9 | |
| Q1 | 11.40 | | 8.10 | | 11.00 | |
| Median | 12.65 | | 10.45 | | 16.25 | |
| Q3 | 15.10 | | 12.50 | | 19.30 | |
| Maximum | 16.3 | | 12.6 | | 21.8 | |
| Week -4 | | | | | | |
| N | 10 | | 4 | | 6 | |
| Mean | 13.36 | | 15.38 | | 14.00 | |
| SD | 3.207 | | 5.638 | | 4.798 | |
| Minimum | 10.4 | | 12.0 | | 8.1 | |
| Q1 | 11.00 | | 12.25 | | 10.20 | |
| Median | 12.05 | | 12.85 | | 13.30 | |
| Q3 | 13.70 | | 18.50 | | 18.90 | |
| Maximum | 19.8 | | 23.8 | | 20.2 | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（18/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=10) | | 12.5 mg (N=4) | | 25 mg (N=6) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 10 | | 4 | | 6 | |
| Mean | 15.72 | | 14.48 | | 14.37 | |
| SD | 6.310 | | 4.147 | | 4.216 | |
| Minimum | 8.2 | | 10.4 | | 6.3 | |
| Q1 | 13.10 | | 11.70 | | 14.20 | |
| Median | 14.45 | | 13.65 | | 15.35 | |
| Q3 | 16.70 | | 17.25 | | 17.40 | |
| Maximum | 32.0 | | 20.2 | | 17.6 | |
| Week 2 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 15.38 | -0.34 | 11.35 | -3.13 | 10.67 | -3.70 |
| SD | 4.488 | 5.139 | 1.943 | 4.245 | 3.799 | 4.382 |
| Minimum | 8.8 | -7.9 | 8.8 | -7.9 | 6.4 | -10.3 |
| Q1 | 13.60 | -6.00 | 9.90 | -6.70 | 7.30 | -6.60 |
| Median | 15.00 | 1.15 | 11.65 | -2.60 | 10.00 | -3.55 |
| Q3 | 18.10 | 3.10 | 12.80 | 0.45 | 14.30 | 0.10 |
| Maximum | 24.4 | 6.7 | 13.3 | 0.6 | 16.0 | 1.7 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（19/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=10) | | 12.5 mg (N=4) | | 25 mg (N=6) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 14.55 | -1.17 | 10.85 | -3.63 | 10.60 | -3.77 |
| SD | 3.616 | 8.636 | 3.131 | 3.133 | 5.027 | 5.338 |
| Minimum | 8.8 | -23.2 | 7.3 | -5.7 | 6.2 | -10.3 |
| Q1 | 12.00 | -2.40 | 8.60 | -5.55 | 7.30 | -9.00 |
| Median | 14.25 | 0.15 | 10.65 | -4.90 | 8.05 | -3.15 |
| Q3 | 16.40 | 3.20 | 13.10 | -1.70 | 16.60 | -0.10 |
| Maximum | 21.9 | 7.5 | 14.8 | 1.0 | 17.4 | 3.1 |
| Week 8 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 17.16 | 1.44 | 8.68 | -5.80 | 12.47 | -1.90 |
| SD | 6.208 | 5.329 | 3.167 | 6.551 | 4.976 | 4.919 |
| Minimum | 9.1 | -7.6 | 5.9 | -13.2 | 6.9 | -8.6 |
| Q1 | 12.60 | -1.80 | 6.45 | -10.15 | 8.70 | -7.70 |
| Median | 17.10 | 1.60 | 7.85 | -6.35 | 11.65 | 0.35 |
| Q3 | 19.50 | 4.60 | 10.90 | -1.45 | 16.70 | 1.80 |
| Maximum | 30.2 | 11.3 | 13.1 | 2.7 | 19.2 | 2.4 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（20/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=10) | | 12.5 mg (N=4) | | 25 mg (N=6) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 16.36 | 0.64 | 12.28 | -2.20 | 16.67 | 2.30 |
| SD | 6.001 | 8.265 | 4.746 | 4.452 | 11.783 | 10.072 |
| Minimum | 7.6 | -9.3 | 6.8 | -6.2 | 6.0 | -8.3 |
| Q1 | 14.10 | -5.10 | 8.50 | -5.15 | 8.10 | -5.60 |
| Median | 14.85 | -0.75 | 12.35 | -3.35 | 13.65 | 0.40 |
| Q3 | 19.20 | 2.20 | 16.05 | 0.75 | 21.60 | 7.30 |
| Maximum | 28.8 | 20.6 | 17.6 | 4.1 | 37.0 | 19.6 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（21/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=10) Observed Value at Visit | Placebo (N=10) Change from Baseline | 12.5 mg (N=4) Observed Value at Visit | 12.5 mg (N=4) Change from Baseline | 25 mg (N=6) Observed Value at Visit | 25 mg (N=6) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 10 | | 4 | | 6 | |
| Mean | 0.782 | | 0.580 | | 0.810 | |
| SD | 0.3721 | | 0.1296 | | 0.4698 | |
| Minimum | 0.40 | | 0.44 | | 0.15 | |
| Q1 | 0.540 | | 0.480 | | 0.640 | |
| Median | 0.610 | | 0.570 | | 0.715 | |
| Q3 | 1.150 | | 0.680 | | 1.100 | |
| Maximum | 1.39 | | 0.74 | | 1.54 | |
| Week -4 | | | | | | |
| N | 10 | | 4 | | 6 | |
| Mean | 0.655 | | 0.850 | | 0.702 | |
| SD | 0.2108 | | 0.2650 | | 0.2506 | |
| Minimum | 0.30 | | 0.61 | | 0.33 | |
| Q1 | 0.500 | | 0.655 | | 0.600 | |
| Median | 0.675 | | 0.790 | | 0.655 | |
| Q3 | 0.860 | | 1.045 | | 0.980 | |
| Maximum | 0.90 | | 1.21 | | 0.99 | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（22/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=10) | | 12.5 mg (N=4) | | 25 mg (N=6) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 10 | | 4 | | 6 | |
| Mean | 0.750 | | 0.848 | | 0.818 | |
| SD | 0.3134 | | 0.1181 | | 0.2686 | |
| Minimum | 0.48 | | 0.68 | | 0.36 | |
| Q1 | 0.520 | | 0.765 | | 0.710 | |
| Median | 0.710 | | 0.885 | | 0.855 | |
| Q3 | 0.810 | | 0.930 | | 1.010 | |
| Maximum | 1.56 | | 0.94 | | 1.12 | |
| Week 2 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 0.799 | 0.049 | 0.678 | -0.170 | 0.560 | -0.258 |
| SD | 0.2682 | 0.2384 | 0.1715 | 0.2832 | 0.2727 | 0.3222 |
| Minimum | 0.43 | -0.46 | 0.57 | -0.37 | 0.25 | -0.76 |
| Q1 | 0.540 | -0.050 | 0.570 | -0.325 | 0.290 | -0.500 |
| Median | 0.850 | 0.045 | 0.605 | -0.280 | 0.560 | -0.170 |
| Q3 | 1.010 | 0.130 | 0.785 | -0.015 | 0.830 | -0.020 |
| Maximum | 1.16 | 0.48 | 0.93 | 0.25 | 0.87 | 0.07 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（23/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=10) | | 12.5 mg (N=4) | | 25 mg (N=6) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 0.753 | 0.003 | 0.650 | -0.198 | 0.557 | -0.262 |
| SD | 0.2409 | 0.2440 | 0.1717 | 0.2803 | 0.1484 | 0.1399 |
| Minimum | 0.43 | -0.52 | 0.52 | -0.38 | 0.29 | -0.45 |
| Q1 | 0.520 | -0.070 | 0.540 | -0.355 | 0.490 | -0.400 |
| Median | 0.780 | 0.045 | 0.590 | -0.315 | 0.600 | -0.225 |
| Q3 | 0.920 | 0.180 | 0.760 | -0.040 | 0.670 | -0.200 |
| Maximum | 1.14 | 0.33 | 0.90 | 0.22 | 0.69 | -0.07 |
| Week 8 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 0.782 | 0.032 | 0.563 | -0.285 | 0.717 | -0.102 |
| SD | 0.3509 | 0.2289 | 0.2401 | 0.3537 | 0.2627 | 0.2082 |
| Minimum | 0.23 | -0.25 | 0.41 | -0.53 | 0.41 | -0.38 |
| Q1 | 0.490 | -0.080 | 0.425 | -0.485 | 0.430 | -0.310 |
| Median | 0.735 | -0.020 | 0.460 | -0.425 | 0.725 | -0.050 |
| Q3 | 1.090 | 0.130 | 0.700 | -0.085 | 0.980 | 0.070 |
| Maximum | 1.32 | 0.52 | 0.92 | 0.24 | 1.03 | 0.11 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（24/32）

Severity of Liver Function at Week 0: 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=10) | | 12.5 mg (N=4) | | 25 mg (N=6) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 10 | 10 | 4 | 4 | 6 | 6 |
| Mean | 0.877 | 0.127 | 0.745 | -0.103 | 0.740 | -0.078 |
| SD | 0.4076 | 0.3765 | 0.2428 | 0.2586 | 0.3113 | 0.4054 |
| Minimum | 0.52 | -0.40 | 0.53 | -0.41 | 0.44 | -0.54 |
| Q1 | 0.570 | -0.100 | 0.585 | -0.310 | 0.510 | -0.480 |
| Median | 0.675 | 0.080 | 0.680 | -0.085 | 0.640 | -0.075 |
| Q3 | 1.160 | 0.190 | 0.905 | 0.105 | 0.950 | 0.150 |
| Maximum | 1.62 | 0.78 | 1.09 | 0.17 | 1.26 | 0.55 |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（25/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 1 | | 1 | | 0 | |
| Mean | 13.40 | | 21.40 | | | |
| SD | | | | | | |
| Minimum | 13.4 | | 21.4 | | | |
| Q1 | 13.40 | | 21.40 | | | |
| Median | 13.40 | | 21.40 | | | |
| Q3 | 13.40 | | 21.40 | | | |
| Maximum | 13.4 | | 21.4 | | | |
| Week -4 | | | | | | |
| N | 1 | | 1 | | 0 | |
| Mean | 13.60 | | 17.40 | | | |
| SD | | | | | | |
| Minimum | 13.6 | | 17.4 | | | |
| Q1 | 13.60 | | 17.40 | | | |
| Median | 13.60 | | 17.40 | | | |
| Q3 | 13.60 | | 17.40 | | | |
| Maximum | 13.6 | | 17.4 | | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（26/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 1 | | 1 | | 0 | |
| Mean | 12.70 | | 21.90 | | | |
| SD | | | | | | |
| Minimum | 12.7 | | 21.9 | | | |
| Q1 | 12.70 | | 21.90 | | | |
| Median | 12.70 | | 21.90 | | | |
| Q3 | 12.70 | | 21.90 | | | |
| Maximum | 12.7 | | 21.9 | | | |
| Week 2 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 19.10 | 6.40 | 13.70 | -8.20 | | |
| SD | | | | | | |
| Minimum | 19.1 | 6.4 | 13.7 | -8.2 | | |
| Q1 | 19.10 | 6.40 | 13.70 | -8.20 | | |
| Median | 19.10 | 6.40 | 13.70 | -8.20 | | |
| Q3 | 19.10 | 6.40 | 13.70 | -8.20 | | |
| Maximum | 19.1 | 6.4 | 13.7 | -8.2 | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（27/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 9.30 | -3.40 | 15.30 | -6.60 | | |
| SD | | | | | | |
| Minimum | 9.3 | -3.4 | 15.3 | -6.6 | | |
| Q1 | 9.30 | -3.40 | 15.30 | -6.60 | | |
| Median | 9.30 | -3.40 | 15.30 | -6.60 | | |
| Q3 | 9.30 | -3.40 | 15.30 | -6.60 | | |
| Maximum | 9.3 | -3.4 | 15.3 | -6.6 | | |
| Week 8 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 11.30 | -1.40 | 22.00 | 0.10 | | |
| SD | | | | | | |
| Minimum | 11.3 | -1.4 | 22.0 | 0.1 | | |
| Q1 | 11.30 | -1.40 | 22.00 | 0.10 | | |
| Median | 11.30 | -1.40 | 22.00 | 0.10 | | |
| Q3 | 11.30 | -1.40 | 22.00 | 0.10 | | |
| Maximum | 11.3 | -1.4 | 22.0 | 0.1 | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（28/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 8.90 | -3.80 | 10.60 | -11.30 | | |
| SD | | | | | | |
| Minimum | 8.9 | -3.8 | 10.6 | -11.3 | | |
| Q1 | 8.90 | -3.80 | 10.60 | -11.30 | | |
| Median | 8.90 | -3.80 | 10.60 | -11.30 | | |
| Q3 | 8.90 | -3.80 | 10.60 | -11.30 | | |
| Maximum | 8.9 | -3.8 | 10.6 | -11.3 | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（29/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=1) Observed Value at Visit | Placebo (N=1) Change from Baseline | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=0) Observed Value at Visit | 25 mg (N=0) Change from Baseline |
|---|---|---|---|---|---|---|
| Week -12 | | | | | | |
| N | 1 | | 1 | | 0 | |
| Mean | 0.480 | | 0.640 | | | |
| SD | | | | | | |
| Minimum | 0.48 | | 0.64 | | | |
| Q1 | 0.480 | | 0.640 | | | |
| Median | 0.480 | | 0.640 | | | |
| Q3 | 0.480 | | 0.640 | | | |
| Maximum | 0.48 | | 0.64 | | | |
| Week -4 | | | | | | |
| N | 1 | | 1 | | 0 | |
| Mean | 0.530 | | 0.660 | | | |
| SD | | | | | | |
| Minimum | 0.53 | | 0.66 | | | |
| Q1 | 0.530 | | 0.660 | | | |
| Median | 0.530 | | 0.660 | | | |
| Q3 | 0.530 | | 0.660 | | | |
| Maximum | 0.53 | | 0.66 | | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（30/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 1 | | 1 | | 0 | |
| Mean | 0.620 | | 0.890 | | | |
| SD | | | | | | |
| Minimum | 0.62 | | 0.89 | | | |
| Q1 | 0.620 | | 0.890 | | | |
| Median | 0.620 | | 0.890 | | | |
| Q3 | 0.620 | | 0.890 | | | |
| Maximum | 0.62 | | 0.89 | | | |
| Week 2 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 0.530 | -0.090 | 0.580 | -0.310 | | |
| SD | | | | | | |
| Minimum | 0.53 | -0.09 | 0.58 | -0.31 | | |
| Q1 | 0.530 | -0.090 | 0.580 | -0.310 | | |
| Median | 0.530 | -0.090 | 0.580 | -0.310 | | |
| Q3 | 0.530 | -0.090 | 0.580 | -0.310 | | |
| Maximum | 0.53 | -0.09 | 0.58 | -0.31 | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（31/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 0.350 | -0.270 | 0.620 | -0.270 | | |
| SD | | | | | | |
| Minimum | 0.35 | -0.27 | 0.62 | -0.27 | | |
| Q1 | 0.350 | -0.270 | 0.620 | -0.270 | | |
| Median | 0.350 | -0.270 | 0.620 | -0.270 | | |
| Q3 | 0.350 | -0.270 | 0.620 | -0.270 | | |
| Maximum | 0.35 | -0.27 | 0.62 | -0.27 | | |
| Week 8 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 0.450 | -0.170 | 0.590 | -0.300 | | |
| SD | | | | | | |
| Minimum | 0.45 | -0.17 | 0.59 | -0.30 | | |
| Q1 | 0.450 | -0.170 | 0.590 | -0.300 | | |
| Median | 0.450 | -0.170 | 0.590 | -0.300 | | |
| Q3 | 0.450 | -0.170 | 0.590 | -0.300 | | |
| Maximum | 0.45 | -0.17 | 0.59 | -0.30 | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-22　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/CCT-006 試験）（32/32）

Severity of Liver Function at Week 0: AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | Placebo (N=1) | | 12.5 mg (N=1) | | 25 mg (N=0) | |
|---|---|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 1 | 1 | 1 | 1 | 0 | 0 |
| Mean | 0.220 | -0.400 | 0.520 | -0.370 | | |
| SD | | | | | | |
| Minimum | 0.22 | -0.40 | 0.52 | -0.37 | | |
| Q1 | 0.220 | -0.400 | 0.520 | -0.370 | | |
| Median | 0.220 | -0.400 | 0.520 | -0.370 | | |
| Q3 | 0.220 | -0.400 | 0.520 | -0.370 | | |
| Maximum | 0.22 | -0.40 | 0.52 | -0.37 | | |

添付資料（5.3.5.3-2）Table 1.3.1.2

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（1/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 69 | | 61 | |
| Mean | 11.31 | | 10.87 | |
| SD | 5.281 | | 4.380 | |
| Minimum | 2.7 | | 3.7 | |
| Q1 | 7.90 | | 7.70 | |
| Median | 10.50 | | 10.50 | |
| Q3 | 13.30 | | 13.50 | |
| Maximum | 30.7 | | 20.8 | |
| Week 2 | | | | |
| N | 49 | 49 | 41 | 41 |
| Mean | 11.07 | 0.05 | 9.47 | -1.06 |
| SD | 7.611 | 4.802 | 3.228 | 4.192 |
| Minimum | 4.4 | -7.9 | 3.6 | -11.2 |
| Q1 | 6.80 | -3.10 | 7.00 | -3.30 |
| Median | 9.40 | -0.20 | 9.20 | -0.30 |
| Q3 | 12.30 | 1.90 | 12.00 | 1.30 |
| Maximum | 53.1 | 22.4 | 17.8 | 6.1 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（2/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 67 | 67 | 58 | 58 |
| Mean | 10.86 | -0.56 | 10.85 | -0.01 |
| SD | 7.087 | 5.721 | 4.838 | 5.887 |
| Minimum | 3.3 | -17.7 | 1.5 | -14.0 |
| Q1 | 7.10 | -3.50 | 7.30 | -3.10 |
| Median | 9.70 | -0.80 | 10.15 | 0.45 |
| Q3 | 12.60 | 1.80 | 13.30 | 3.40 |
| Maximum | 53.1 | 22.4 | 24.7 | 15.8 |
| Week 8 | | | | |
| N | 68 | 68 | 60 | 60 |
| Mean | 10.51 | -0.91 | 9.63 | -1.13 |
| SD | 4.801 | 4.763 | 3.373 | 4.697 |
| Minimum | 3.6 | -21.8 | 3.2 | -12.0 |
| Q1 | 7.20 | -3.15 | 7.80 | -4.35 |
| Median | 10.40 | -0.90 | 9.05 | -1.55 |
| Q3 | 12.40 | 1.75 | 11.50 | 2.30 |
| Maximum | 34.1 | 8.3 | 17.6 | 10.9 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（3/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 67 | 67 | 59 | 59 |
| Mean | 10.12 | -1.26 | 10.12 | -0.67 |
| SD | 3.788 | 4.641 | 4.204 | 3.943 |
| Minimum | 2.4 | -20.1 | 3.9 | -11.6 |
| Q1 | 7.50 | -3.30 | 6.60 | -3.80 |
| Median | 9.70 | -0.30 | 9.60 | 0.00 |
| Q3 | 12.60 | 1.10 | 12.40 | 1.80 |
| Maximum | 22.1 | 10.8 | 22.0 | 7.0 |
| Week 16 | | | | |
| N | 67 | 67 | 58 | 58 |
| Mean | 10.51 | -0.87 | 10.32 | -0.52 |
| SD | 4.214 | 4.968 | 4.704 | 4.362 |
| Minimum | 3.7 | -19.5 | 3.4 | -13.6 |
| Q1 | 7.90 | -3.50 | 6.90 | -3.30 |
| Median | 10.00 | -0.60 | 9.70 | -0.05 |
| Q3 | 12.10 | 2.20 | 12.40 | 2.00 |
| Maximum | 28.4 | 11.5 | 29.7 | 8.9 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（4/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 66 | 66 | 58 | 58 |
| Mean | 10.87 | -0.31 | 9.86 | -0.98 |
| SD | 5.280 | 4.257 | 3.184 | 3.639 |
| Minimum | 3.6 | -15.5 | 4.9 | -13.4 |
| Q1 | 7.10 | -2.40 | 7.60 | -3.70 |
| Median | 9.90 | -0.15 | 9.40 | -0.75 |
| Q3 | 13.20 | 2.50 | 11.00 | 1.70 |
| Maximum | 37.5 | 9.1 | 19.1 | 6.8 |
| Week 24 | | | | |
| N | 66 | 66 | 58 | 58 |
| Mean | 10.52 | -0.66 | 10.53 | -0.31 |
| SD | 3.615 | 4.891 | 3.790 | 4.311 |
| Minimum | 4.2 | -17.9 | 2.9 | -12.0 |
| Q1 | 7.60 | -3.50 | 8.30 | -2.10 |
| Median | 10.10 | -0.40 | 9.75 | -0.25 |
| Q3 | 12.70 | 3.20 | 12.60 | 1.80 |
| Maximum | 19.8 | 9.4 | 20.7 | 10.8 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（5/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 66 | 66 | 57 | 57 |
| Mean | 10.31 | -0.87 | 9.86 | -0.86 |
| SD | 4.032 | 4.312 | 3.755 | 4.164 |
| Minimum | 3.2 | -16.2 | 3.8 | -11.5 |
| Q1 | 7.10 | -2.90 | 7.00 | -3.10 |
| Median | 9.75 | -0.90 | 9.60 | -0.20 |
| Q3 | 12.90 | 1.50 | 12.10 | 1.60 |
| Maximum | 21.8 | 11.0 | 19.1 | 10.1 |
| Week 32 | | | | |
| N | 66 | 66 | 57 | 57 |
| Mean | 9.63 | -1.55 | 9.81 | -0.91 |
| SD | 3.622 | 5.408 | 3.799 | 4.819 |
| Minimum | 4.2 | -24.0 | 4.1 | -12.3 |
| Q1 | 6.90 | -3.30 | 7.20 | -3.60 |
| Median | 9.00 | -1.40 | 9.70 | -0.40 |
| Q3 | 12.10 | 1.80 | 11.50 | 1.90 |
| Maximum | 24.1 | 12.8 | 25.1 | 14.1 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（6/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 65 | 65 | 57 | 57 |
| Mean | 10.14 | -0.91 | 10.75 | 0.03 |
| SD | 4.311 | 5.303 | 4.493 | 4.757 |
| Minimum | 2.6 | -20.3 | 3.8 | -9.5 |
| Q1 | 7.00 | -3.20 | 7.80 | -3.80 |
| Median | 9.60 | -0.80 | 9.80 | 0.60 |
| Q3 | 12.30 | 1.50 | 13.20 | 3.50 |
| Maximum | 22.3 | 12.6 | 29.2 | 11.2 |
| Week 40 | | | | |
| N | 65 | 65 | 57 | 57 |
| Mean | 10.30 | -0.75 | 10.75 | 0.03 |
| SD | 5.047 | 6.009 | 4.177 | 4.507 |
| Minimum | 2.3 | -24.9 | 3.5 | -10.7 |
| Q1 | 7.00 | -2.90 | 7.70 | -3.00 |
| Median | 9.80 | -0.50 | 10.20 | 0.00 |
| Q3 | 12.50 | 1.10 | 13.60 | 3.40 |
| Maximum | 31.4 | 20.1 | 23.8 | 8.7 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（7/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 45 | 45 | 35 | 35 |
| Mean | 9.16 | -1.50 | 9.97 | -0.21 |
| SD | 3.220 | 4.425 | 3.218 | 4.214 |
| Minimum | 3.4 | -21.8 | 4.2 | -7.6 |
| Q1 | 6.90 | -3.30 | 7.30 | -3.40 |
| Median | 8.40 | -1.40 | 9.70 | -0.20 |
| Q3 | 11.40 | 0.90 | 12.00 | 2.90 |
| Maximum | 18.2 | 8.2 | 16.9 | 9.1 |
| Week 48 | | | | |
| N | 45 | 45 | 35 | 35 |
| Mean | 9.24 | -1.42 | 9.82 | -0.36 |
| SD | 3.524 | 4.570 | 3.665 | 4.283 |
| Minimum | 4.0 | -21.3 | 2.9 | -9.4 |
| Q1 | 6.80 | -3.10 | 7.60 | -3.00 |
| Median | 8.70 | -1.10 | 8.70 | -0.20 |
| Q3 | 11.30 | 1.50 | 12.30 | 1.70 |
| Maximum | 20.7 | 6.8 | 18.4 | 9.6 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（8/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) | | 25 mg (N=61) | |
|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 52 | | | | |
| N | 44 | 44 | 35 | 35 |
| Mean | 10.29 | -0.39 | 10.74 | 0.57 |
| SD | 3.858 | 3.801 | 4.509 | 4.442 |
| Minimum | 4.6 | -12.7 | 3.2 | -9.7 |
| Q1 | 7.10 | -1.90 | 7.50 | -3.00 |
| Median | 9.20 | -0.20 | 10.80 | 1.10 |
| Q3 | 12.35 | 2.50 | 14.00 | 3.00 |
| Maximum | 18.5 | 4.7 | 22.4 | 11.4 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（9/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 69 | | 61 | |
| Mean | 0.545 | | 0.566 | |
| SD | 0.2065 | | 0.2510 | |
| Minimum | 0.22 | | 0.20 | |
| Q1 | 0.370 | | 0.410 | |
| Median | 0.510 | | 0.540 | |
| Q3 | 0.720 | | 0.650 | |
| Maximum | 0.95 | | 1.35 | |
| Week 2 | | | | |
| N | 49 | 49 | 41 | 41 |
| Mean | 0.519 | -0.034 | 0.464 | -0.089 |
| SD | 0.2350 | 0.2240 | 0.1888 | 0.2551 |
| Minimum | 0.21 | -0.68 | 0.16 | -0.71 |
| Q1 | 0.360 | -0.180 | 0.310 | -0.220 |
| Median | 0.470 | -0.010 | 0.410 | -0.080 |
| Q3 | 0.600 | 0.120 | 0.610 | 0.100 |
| Maximum | 1.16 | 0.66 | 0.99 | 0.31 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（10/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 67 | 67 | 58 | 58 |
| Mean | 0.505 | -0.038 | 0.545 | -0.028 |
| SD | 0.2064 | 0.1963 | 0.2127 | 0.2548 |
| Minimum | 0.17 | -0.46 | 0.11 | -0.83 |
| Q1 | 0.370 | -0.170 | 0.380 | -0.120 |
| Median | 0.460 | -0.060 | 0.520 | -0.010 |
| Q3 | 0.620 | 0.070 | 0.650 | 0.110 |
| Maximum | 1.23 | 0.75 | 1.15 | 0.38 |
| Week 8 | | | | |
| N | 68 | 68 | 60 | 60 |
| Mean | 0.531 | -0.018 | 0.532 | -0.032 |
| SD | 0.2516 | 0.2528 | 0.2329 | 0.2657 |
| Minimum | 0.15 | -0.73 | 0.12 | -0.64 |
| Q1 | 0.385 | -0.175 | 0.395 | -0.190 |
| Median | 0.480 | -0.025 | 0.475 | -0.010 |
| Q3 | 0.585 | 0.125 | 0.650 | 0.075 |
| Maximum | 1.33 | 0.81 | 1.26 | 0.84 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（11/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 67 | 67 | 59 | 59 |
| Mean | 0.543 | -0.003 | 0.533 | -0.037 |
| SD | 0.2267 | 0.2204 | 0.2221 | 0.2697 |
| Minimum | 0.15 | -0.51 | 0.20 | -0.74 |
| Q1 | 0.420 | -0.130 | 0.390 | -0.240 |
| Median | 0.500 | 0.000 | 0.480 | 0.030 |
| Q3 | 0.680 | 0.110 | 0.650 | 0.150 |
| Maximum | 1.24 | 0.76 | 1.16 | 0.60 |
| Week 16 | | | | |
| N | 67 | 67 | 58 | 58 |
| Mean | 0.503 | -0.043 | 0.523 | -0.048 |
| SD | 0.2071 | 0.1885 | 0.2257 | 0.2372 |
| Minimum | 0.11 | -0.57 | 0.22 | -0.72 |
| Q1 | 0.350 | -0.200 | 0.350 | -0.170 |
| Median | 0.490 | -0.030 | 0.480 | -0.025 |
| Q3 | 0.630 | 0.070 | 0.680 | 0.130 |
| Maximum | 1.03 | 0.46 | 1.45 | 0.47 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（12/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 66 | 66 | 58 | 58 |
| Mean | 0.518 | -0.024 | 0.507 | -0.063 |
| SD | 0.2197 | 0.1968 | 0.2037 | 0.2480 |
| Minimum | 0.14 | -0.51 | 0.15 | -0.70 |
| Q1 | 0.350 | -0.140 | 0.360 | -0.240 |
| Median | 0.495 | -0.025 | 0.470 | -0.040 |
| Q3 | 0.610 | 0.090 | 0.600 | 0.100 |
| Maximum | 1.25 | 0.45 | 1.05 | 0.41 |
| Week 24 | | | | |
| N | 66 | 66 | 58 | 58 |
| Mean | 0.565 | 0.022 | 0.570 | -0.001 |
| SD | 0.2561 | 0.2325 | 0.2310 | 0.2135 |
| Minimum | 0.14 | -0.33 | 0.23 | -0.54 |
| Q1 | 0.380 | -0.170 | 0.450 | -0.130 |
| Median | 0.535 | -0.015 | 0.520 | -0.015 |
| Q3 | 0.680 | 0.190 | 0.680 | 0.110 |
| Maximum | 1.41 | 0.77 | 1.30 | 0.62 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（13/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 66 | 66 | 57 | 57 |
| Mean | 0.494 | -0.048 | 0.509 | -0.061 |
| SD | 0.1856 | 0.2058 | 0.2125 | 0.2819 |
| Minimum | 0.19 | -0.51 | 0.13 | -0.62 |
| Q1 | 0.380 | -0.180 | 0.350 | -0.190 |
| Median | 0.465 | -0.040 | 0.450 | -0.060 |
| Q3 | 0.600 | 0.060 | 0.610 | 0.090 |
| Maximum | 0.96 | 0.46 | 1.08 | 0.65 |
| Week 32 | | | | |
| N | 66 | 66 | 57 | 57 |
| Mean | 0.476 | -0.066 | 0.503 | -0.068 |
| SD | 0.2014 | 0.2182 | 0.2145 | 0.2756 |
| Minimum | 0.14 | -0.65 | 0.12 | -0.87 |
| Q1 | 0.310 | -0.200 | 0.380 | -0.240 |
| Median | 0.460 | -0.065 | 0.460 | -0.020 |
| Q3 | 0.560 | 0.070 | 0.630 | 0.110 |
| Maximum | 1.11 | 0.63 | 1.25 | 0.57 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（14/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 65 | 65 | 57 | 57 |
| Mean | 0.468 | -0.068 | 0.520 | -0.050 |
| SD | 0.1938 | 0.2432 | 0.2854 | 0.2655 |
| Minimum | 0.14 | -0.62 | 0.00 | -0.63 |
| Q1 | 0.340 | -0.190 | 0.350 | -0.240 |
| Median | 0.450 | -0.050 | 0.500 | -0.040 |
| Q3 | 0.550 | 0.050 | 0.580 | 0.130 |
| Maximum | 1.02 | 0.63 | 1.54 | 0.86 |
| Week 40 | | | | |
| N | 65 | 65 | 57 | 57 |
| Mean | 0.457 | -0.080 | 0.499 | -0.071 |
| SD | 0.1905 | 0.2087 | 0.2193 | 0.2668 |
| Minimum | 0.13 | -0.46 | 0.00 | -0.73 |
| Q1 | 0.300 | -0.210 | 0.410 | -0.210 |
| Median | 0.460 | -0.090 | 0.490 | -0.080 |
| Q3 | 0.570 | 0.050 | 0.600 | 0.080 |
| Maximum | 1.15 | 0.67 | 1.45 | 0.92 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（15/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 45 | 45 | 35 | 35 |
| Mean | 0.416 | -0.122 | 0.480 | -0.079 |
| SD | 0.1506 | 0.1686 | 0.1837 | 0.2751 |
| Minimum | 0.00 | -0.52 | 0.19 | -0.77 |
| Q1 | 0.300 | -0.220 | 0.360 | -0.240 |
| Median | 0.420 | -0.080 | 0.460 | -0.080 |
| Q3 | 0.520 | -0.010 | 0.540 | 0.110 |
| Maximum | 0.79 | 0.15 | 1.00 | 0.44 |
| Week 48 | | | | |
| N | 45 | 45 | 35 | 35 |
| Mean | 0.446 | -0.092 | 0.454 | -0.104 |
| SD | 0.1894 | 0.2028 | 0.1644 | 0.2169 |
| Minimum | 0.12 | -0.60 | 0.21 | -0.78 |
| Q1 | 0.310 | -0.180 | 0.350 | -0.220 |
| Median | 0.390 | -0.060 | 0.430 | -0.060 |
| Q3 | 0.540 | 0.010 | 0.550 | 0.060 |
| Maximum | 0.90 | 0.38 | 0.80 | 0.23 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（16/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): Min<= - <90
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=69) Observed Value at Visit | 12.5 mg (N=69) Change from Baseline | 25 mg (N=61) Observed Value at Visit | 25 mg (N=61) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 44 | 44 | 35 | 35 |
| Mean | 0.492 | -0.050 | 0.474 | -0.085 |
| SD | 0.2009 | 0.2008 | 0.2266 | 0.1731 |
| Minimum | 0.11 | -0.49 | 0.15 | -0.49 |
| Q1 | 0.360 | -0.170 | 0.300 | -0.200 |
| Median | 0.450 | -0.030 | 0.450 | -0.070 |
| Q3 | 0.650 | 0.075 | 0.590 | 0.050 |
| Maximum | 0.91 | 0.37 | 1.17 | 0.20 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（17/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 73 | | 84 | |
| Mean | 12.24 | | 11.80 | |
| SD | 5.481 | | 4.557 | |
| Minimum | 2.8 | | 4.4 | |
| Q1 | 8.50 | | 8.10 | |
| Median | 11.80 | | 11.70 | |
| Q3 | 15.20 | | 14.40 | |
| Maximum | 32.0 | | 27.9 | |
| Week 2 | | | | |
| N | 48 | 48 | 61 | 61 |
| Mean | 10.31 | -1.70 | 10.95 | -0.49 |
| SD | 4.461 | 4.578 | 4.117 | 4.217 |
| Minimum | 3.3 | -18.6 | 3.5 | -8.6 |
| Q1 | 7.20 | -4.70 | 8.10 | -2.70 |
| Median | 9.70 | -0.90 | 10.20 | -0.90 |
| Q3 | 12.95 | 1.00 | 13.80 | 1.70 |
| Maximum | 22.9 | 10.1 | 24.5 | 16.7 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（18/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 68 | 68 | 80 | 80 |
| Mean | 11.28 | -0.78 | 10.87 | -0.78 |
| SD | 5.859 | 5.828 | 4.983 | 5.039 |
| Minimum | 4.3 | -14.7 | 3.5 | -14.8 |
| Q1 | 6.80 | -4.10 | 7.25 | -3.15 |
| Median | 11.10 | -0.95 | 10.05 | -0.80 |
| Q3 | 13.65 | 1.85 | 13.40 | 2.05 |
| Maximum | 38.5 | 24.4 | 33.0 | 17.3 |
| Week 8 | | | | |
| N | 73 | 73 | 83 | 83 |
| Mean | 10.57 | -1.66 | 11.54 | -0.26 |
| SD | 4.819 | 4.373 | 4.504 | 4.376 |
| Minimum | 2.5 | -22.2 | 4.0 | -14.0 |
| Q1 | 6.80 | -4.50 | 8.70 | -2.50 |
| Median | 10.30 | -1.00 | 11.00 | -0.30 |
| Q3 | 13.30 | 1.10 | 14.10 | 2.00 |
| Maximum | 25.2 | 6.0 | 29.1 | 15.1 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（19/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 73 | 73 | 83 | 83 |
| Mean | 10.73 | -1.51 | 11.57 | -0.23 |
| SD | 4.274 | 4.927 | 5.412 | 5.337 |
| Minimum | 2.9 | -24.6 | 3.7 | -11.2 |
| Q1 | 7.60 | -3.80 | 8.30 | -3.50 |
| Median | 10.20 | -1.20 | 10.20 | -1.00 |
| Q3 | 13.80 | 1.80 | 14.10 | 2.20 |
| Maximum | 22.0 | 6.5 | 37.0 | 23.6 |
| Week 16 | | | | |
| N | 71 | 71 | 77 | 77 |
| Mean | 10.38 | -2.06 | 11.40 | -0.22 |
| SD | 4.564 | 4.888 | 4.277 | 5.126 |
| Minimum | 3.4 | -23.1 | 3.3 | -20.6 |
| Q1 | 6.40 | -4.30 | 8.10 | -2.90 |
| Median | 9.70 | -1.50 | 11.60 | 0.10 |
| Q3 | 13.60 | 0.70 | 13.80 | 2.80 |
| Maximum | 22.2 | 7.7 | 26.0 | 18.2 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（20/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 70 | 70 | 76 | 76 |
| Mean | 11.02 | -1.35 | 10.98 | -0.68 |
| SD | 4.054 | 5.343 | 4.034 | 4.771 |
| Minimum | 2.7 | -23.4 | 3.4 | -17.1 |
| Q1 | 8.20 | -4.10 | 8.10 | -3.35 |
| Median | 10.80 | -0.45 | 10.40 | -0.60 |
| Q3 | 12.80 | 2.30 | 13.75 | 1.90 |
| Maximum | 22.5 | 7.1 | 22.6 | 12.7 |
| Week 24 | | | | |
| N | 69 | 69 | 76 | 76 |
| Mean | 11.60 | -0.81 | 11.37 | -0.29 |
| SD | 5.467 | 5.674 | 3.864 | 4.526 |
| Minimum | 2.3 | -23.4 | 5.1 | -15.4 |
| Q1 | 7.80 | -3.60 | 8.80 | -2.85 |
| Median | 10.80 | -0.50 | 10.75 | 0.05 |
| Q3 | 13.50 | 1.80 | 13.75 | 2.45 |
| Maximum | 31.0 | 14.6 | 22.9 | 13.0 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（21/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 69 | 69 | 75 | 75 |
| Mean | 11.07 | -1.34 | 11.59 | -0.15 |
| SD | 4.660 | 3.927 | 4.267 | 5.183 |
| Minimum | 2.6 | -16.1 | 6.0 | -19.3 |
| Q1 | 8.20 | -3.60 | 8.60 | -2.40 |
| Median | 10.60 | -0.70 | 10.30 | 0.20 |
| Q3 | 13.30 | 0.50 | 13.50 | 2.10 |
| Maximum | 28.0 | 5.4 | 28.9 | 15.6 |
| Week 32 | | | | |
| N | 69 | 69 | 72 | 72 |
| Mean | 10.73 | -1.68 | 11.34 | -0.45 |
| SD | 4.113 | 4.754 | 4.380 | 5.379 |
| Minimum | 3.0 | -22.9 | 4.5 | -13.7 |
| Q1 | 7.80 | -4.10 | 8.15 | -2.70 |
| Median | 10.50 | -1.40 | 10.90 | -0.40 |
| Q3 | 13.50 | 1.20 | 14.50 | 2.30 |
| Maximum | 20.7 | 9.7 | 27.0 | 17.2 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（22/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 69 | 69 | 72 | 72 |
| Mean | 11.61 | -0.80 | 11.58 | -0.22 |
| SD | 4.887 | 4.788 | 3.853 | 4.552 |
| Minimum | 2.7 | -23.2 | 3.1 | -13.1 |
| Q1 | 8.20 | -2.70 | 8.65 | -2.65 |
| Median | 11.60 | -0.30 | 11.25 | 0.80 |
| Q3 | 13.80 | 1.50 | 13.65 | 2.85 |
| Maximum | 30.2 | 10.1 | 20.2 | 7.7 |
| Week 40 | | | | |
| N | 67 | 67 | 72 | 72 |
| Mean | 11.77 | -0.87 | 11.71 | -0.09 |
| SD | 6.551 | 5.781 | 4.390 | 4.246 |
| Minimum | 2.9 | -16.7 | 4.2 | -10.8 |
| Q1 | 8.10 | -4.00 | 8.55 | -2.00 |
| Median | 10.90 | -1.00 | 11.05 | 0.40 |
| Q3 | 14.30 | 2.40 | 14.25 | 2.95 |
| Maximum | 53.7 | 24.9 | 26.7 | 10.0 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（23/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 36 | 36 | 48 | 48 |
| Mean | 11.05 | -1.54 | 9.93 | -0.97 |
| SD | 4.295 | 4.024 | 3.632 | 3.923 |
| Minimum | 3.4 | -12.9 | 4.8 | -11.0 |
| Q1 | 8.65 | -3.75 | 6.65 | -3.05 |
| Median | 10.30 | -1.70 | 9.75 | -0.80 |
| Q3 | 12.45 | 0.80 | 11.85 | 1.70 |
| Maximum | 20.9 | 8.0 | 19.3 | 7.2 |
| Week 48 | | | | |
| N | 36 | 36 | 48 | 48 |
| Mean | 11.63 | -0.97 | 10.31 | -0.59 |
| SD | 4.482 | 4.120 | 4.262 | 4.831 |
| Minimum | 3.6 | -13.8 | 3.3 | -12.0 |
| Q1 | 8.15 | -3.60 | 7.20 | -3.45 |
| Median | 11.50 | -0.60 | 10.20 | -0.30 |
| Q3 | 14.05 | 2.25 | 12.35 | 2.60 |
| Maximum | 22.8 | 6.4 | 22.9 | 15.1 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（24/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 35 | 35 | 48 | 48 |
| Mean | 10.37 | -2.11 | 9.96 | -0.94 |
| SD | 4.425 | 4.456 | 4.069 | 4.460 |
| Minimum | 4.3 | -12.3 | 3.0 | -15.3 |
| Q1 | 7.30 | -5.60 | 6.85 | -3.30 |
| Median | 9.30 | -2.00 | 9.45 | -0.85 |
| Q3 | 12.00 | 1.60 | 12.85 | 1.65 |
| Maximum | 24.9 | 7.7 | 20.6 | 9.2 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（25/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 73 | | 84 | |
| Mean | 0.642 | | 0.655 | |
| SD | 0.2855 | | 0.3109 | |
| Minimum | 0.22 | | 0.12 | |
| Q1 | 0.410 | | 0.415 | |
| Median | 0.580 | | 0.595 | |
| Q3 | 0.790 | | 0.855 | |
| Maximum | 1.59 | | 1.66 | |
| Week 2 | | | | |
| N | 48 | 48 | 61 | 61 |
| Mean | 0.595 | -0.040 | 0.598 | -0.065 |
| SD | 0.2936 | 0.2336 | 0.2347 | 0.2517 |
| Minimum | 0.16 | -0.70 | 0.15 | -0.77 |
| Q1 | 0.410 | -0.200 | 0.430 | -0.180 |
| Median | 0.540 | -0.025 | 0.560 | -0.070 |
| Q3 | 0.675 | 0.160 | 0.730 | 0.090 |
| Maximum | 1.69 | 0.41 | 1.20 | 0.40 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（26/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 68 | 68 | 80 | 80 |
| Mean | 0.575 | -0.062 | 0.589 | -0.048 |
| SD | 0.2354 | 0.2626 | 0.2496 | 0.2896 |
| Minimum | 0.13 | -0.92 | 0.25 | -1.05 |
| Q1 | 0.420 | -0.215 | 0.410 | -0.235 |
| Median | 0.555 | -0.060 | 0.560 | -0.080 |
| Q3 | 0.725 | 0.150 | 0.710 | 0.115 |
| Maximum | 1.17 | 0.41 | 1.48 | 0.77 |
| Week 8 | | | | |
| N | 73 | 73 | 83 | 83 |
| Mean | 0.575 | -0.067 | 0.634 | -0.028 |
| SD | 0.2776 | 0.2536 | 0.2578 | 0.2493 |
| Minimum | 0.23 | -0.91 | 0.14 | -0.97 |
| Q1 | 0.410 | -0.210 | 0.420 | -0.170 |
| Median | 0.500 | -0.050 | 0.640 | -0.040 |
| Q3 | 0.690 | 0.060 | 0.800 | 0.130 |
| Maximum | 1.68 | 0.69 | 1.30 | 0.55 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（27/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 73 | 73 | 83 | 83 |
| Mean | 0.598 | -0.043 | 0.656 | -0.005 |
| SD | 0.2556 | 0.2246 | 0.2832 | 0.2870 |
| Minimum | 0.17 | -0.61 | 0.12 | -0.89 |
| Q1 | 0.420 | -0.200 | 0.460 | -0.160 |
| Median | 0.540 | 0.000 | 0.570 | 0.010 |
| Q3 | 0.730 | 0.090 | 0.860 | 0.150 |
| Maximum | 1.43 | 0.61 | 1.41 | 0.74 |
| Week 16 | | | | |
| N | 71 | 71 | 77 | 77 |
| Mean | 0.544 | -0.105 | 0.633 | -0.016 |
| SD | 0.2501 | 0.2502 | 0.2984 | 0.2631 |
| Minimum | 0.14 | -0.89 | 0.00 | -0.55 |
| Q1 | 0.340 | -0.220 | 0.460 | -0.160 |
| Median | 0.500 | -0.080 | 0.570 | -0.040 |
| Q3 | 0.720 | 0.040 | 0.780 | 0.150 |
| Maximum | 1.30 | 0.52 | 1.58 | 0.77 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（28/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 70 | 70 | 76 | 76 |
| Mean | 0.596 | -0.051 | 0.607 | -0.044 |
| SD | 0.2846 | 0.3069 | 0.2443 | 0.3181 |
| Minimum | 0.19 | -1.22 | 0.13 | -1.31 |
| Q1 | 0.370 | -0.170 | 0.420 | -0.215 |
| Median | 0.535 | -0.040 | 0.570 | -0.025 |
| Q3 | 0.730 | 0.100 | 0.820 | 0.145 |
| Maximum | 1.69 | 0.68 | 1.19 | 0.68 |
| Week 24 | | | | |
| N | 69 | 69 | 76 | 76 |
| Mean | 0.592 | -0.063 | 0.604 | -0.048 |
| SD | 0.3187 | 0.2643 | 0.2402 | 0.2844 |
| Minimum | 0.19 | -0.74 | 0.00 | -1.23 |
| Q1 | 0.360 | -0.230 | 0.425 | -0.160 |
| Median | 0.550 | -0.060 | 0.580 | -0.030 |
| Q3 | 0.780 | 0.130 | 0.755 | 0.065 |
| Maximum | 1.75 | 0.48 | 1.49 | 0.86 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（29/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 69 | 69 | 75 | 75 |
| Mean | 0.568 | -0.087 | 0.603 | -0.051 |
| SD | 0.2567 | 0.2683 | 0.2454 | 0.3052 |
| Minimum | 0.20 | -0.85 | 0.16 | -1.31 |
| Q1 | 0.390 | -0.250 | 0.430 | -0.150 |
| Median | 0.550 | -0.080 | 0.550 | -0.030 |
| Q3 | 0.670 | 0.080 | 0.760 | 0.090 |
| Maximum | 1.58 | 0.70 | 1.36 | 0.72 |
| Week 32 | | | | |
| N | 69 | 69 | 72 | 72 |
| Mean | 0.560 | -0.096 | 0.621 | -0.048 |
| SD | 0.2660 | 0.2530 | 0.2715 | 0.2988 |
| Minimum | 0.17 | -0.76 | 0.00 | -1.10 |
| Q1 | 0.360 | -0.230 | 0.410 | -0.210 |
| Median | 0.500 | -0.050 | 0.645 | -0.020 |
| Q3 | 0.690 | 0.070 | 0.760 | 0.160 |
| Maximum | 1.46 | 0.40 | 1.37 | 0.66 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（30/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 69 | 69 | 72 | 72 |
| Mean | 0.586 | -0.070 | 0.583 | -0.080 |
| SD | 0.2802 | 0.2807 | 0.2543 | 0.3090 |
| Minimum | 0.00 | -1.27 | 0.00 | -1.14 |
| Q1 | 0.380 | -0.170 | 0.385 | -0.260 |
| Median | 0.540 | -0.050 | 0.570 | -0.010 |
| Q3 | 0.700 | 0.080 | 0.695 | 0.115 |
| Maximum | 1.41 | 0.47 | 1.25 | 0.50 |
| Week 40 | | | | |
| N | 67 | 67 | 72 | 72 |
| Mean | 0.592 | -0.072 | 0.611 | -0.052 |
| SD | 0.3075 | 0.2863 | 0.3141 | 0.2829 |
| Minimum | 0.14 | -0.58 | 0.00 | -0.78 |
| Q1 | 0.430 | -0.270 | 0.380 | -0.210 |
| Median | 0.510 | -0.090 | 0.565 | -0.030 |
| Q3 | 0.640 | 0.140 | 0.770 | 0.140 |
| Maximum | 1.92 | 0.70 | 1.67 | 0.73 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（31/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 36 | 36 | 48 | 48 |
| Mean | 0.595 | -0.077 | 0.550 | -0.079 |
| SD | 0.2286 | 0.2236 | 0.2706 | 0.2677 |
| Minimum | 0.14 | -0.57 | 0.00 | -0.50 |
| Q1 | 0.475 | -0.220 | 0.355 | -0.265 |
| Median | 0.570 | -0.115 | 0.495 | -0.095 |
| Q3 | 0.680 | 0.090 | 0.660 | 0.045 |
| Maximum | 1.20 | 0.43 | 1.48 | 0.68 |
| Week 48 | | | | |
| N | 36 | 36 | 48 | 48 |
| Mean | 0.583 | -0.089 | 0.533 | -0.095 |
| SD | 0.2705 | 0.2487 | 0.2432 | 0.2477 |
| Minimum | 0.15 | -0.64 | 0.14 | -0.89 |
| Q1 | 0.430 | -0.230 | 0.370 | -0.185 |
| Median | 0.585 | -0.100 | 0.515 | -0.120 |
| Q3 | 0.730 | 0.080 | 0.695 | -0.015 |
| Maximum | 1.36 | 0.37 | 1.24 | 0.54 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-23　eGFR 別〔観察期終了時（0 週）〕の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（32/32）

eGFR (mL/min/1.73m$^2$ ) at Baseline (Week 0): 90<= - <=Max
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=73) Observed Value at Visit | 12.5 mg (N=73) Change from Baseline | 25 mg (N=84) Observed Value at Visit | 25 mg (N=84) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 35 | 35 | 48 | 48 |
| Mean | 0.557 | -0.103 | 0.542 | -0.086 |
| SD | 0.2624 | 0.2136 | 0.2744 | 0.2754 |
| Minimum | 0.17 | -0.62 | 0.00 | -0.95 |
| Q1 | 0.350 | -0.260 | 0.355 | -0.190 |
| Median | 0.510 | -0.090 | 0.515 | -0.070 |
| Q3 | 0.600 | 0.040 | 0.640 | 0.060 |
| Maximum | 1.43 | 0.39 | 1.39 | 0.64 |

添付資料（5.3.5.3-2）Table 2.3.1.1

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（1/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 120 | | 115 | |
| Mean | 11.19 | | 10.82 | |
| SD | 5.048 | | 4.538 | |
| Minimum | 2.7 | | 3.7 | |
| Q1 | 7.70 | | 7.10 | |
| Median | 10.90 | | 10.50 | |
| Q3 | 13.50 | | 13.70 | |
| Maximum | 30.7 | | 27.9 | |
| Week 2 | | | | |
| N | 85 | 85 | 87 | 87 |
| Mean | 10.50 | -0.33 | 10.30 | -0.45 |
| SD | 6.578 | 4.367 | 3.926 | 4.108 |
| Minimum | 3.3 | -7.9 | 3.5 | -11.2 |
| Q1 | 6.80 | -3.30 | 7.60 | -2.20 |
| Median | 9.30 | -0.30 | 9.70 | -0.50 |
| Q3 | 11.80 | 1.60 | 12.30 | 1.70 |
| Maximum | 53.1 | 22.4 | 24.5 | 16.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（2/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 116 | 116 | 109 | 109 |
| Mean | 10.83 | -0.46 | 10.86 | 0.16 |
| SD | 6.859 | 5.919 | 4.997 | 5.232 |
| Minimum | 3.3 | -17.7 | 1.5 | -12.9 |
| Q1 | 6.70 | -3.00 | 7.50 | -2.80 |
| Median | 9.70 | -0.50 | 10.30 | 0.50 |
| Q3 | 12.85 | 1.90 | 13.30 | 2.70 |
| Maximum | 53.1 | 24.4 | 33.0 | 17.3 |
| Week 8 | | | | |
| N | 119 | 119 | 113 | 113 |
| Mean | 10.24 | -1.01 | 10.69 | -0.06 |
| SD | 4.791 | 4.175 | 4.297 | 4.235 |
| Minimum | 2.5 | -21.8 | 3.2 | -12.0 |
| Q1 | 6.80 | -3.30 | 8.10 | -2.40 |
| Median | 9.70 | -0.90 | 9.80 | -0.30 |
| Q3 | 12.90 | 1.60 | 12.40 | 2.60 |
| Maximum | 34.1 | 8.3 | 29.1 | 15.1 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（3/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 119 | 119 | 112 | 112 |
| Mean | 10.24 | -1.01 | 10.63 | -0.14 |
| SD | 4.146 | 4.375 | 4.599 | 4.330 |
| Minimum | 2.4 | -20.1 | 3.7 | -11.2 |
| Q1 | 7.20 | -3.30 | 7.40 | -3.05 |
| Median | 9.70 | -0.30 | 10.00 | -0.10 |
| Q3 | 13.10 | 1.70 | 12.70 | 1.95 |
| Maximum | 22.1 | 10.8 | 31.4 | 23.6 |
| Week 16 | | | | |
| N | 117 | 117 | 108 | 108 |
| Mean | 10.39 | -0.97 | 10.74 | 0.00 |
| SD | 4.568 | 4.582 | 4.514 | 4.675 |
| Minimum | 3.4 | -19.5 | 3.3 | -20.6 |
| Q1 | 6.90 | -2.90 | 7.80 | -2.35 |
| Median | 9.80 | -0.80 | 10.05 | 0.25 |
| Q3 | 12.30 | 2.00 | 13.15 | 2.60 |
| Maximum | 28.4 | 11.5 | 29.7 | 18.2 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（4/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 115 | 115 | 107 | 107 |
| Mean | 10.77 | -0.41 | 10.19 | -0.56 |
| SD | 4.909 | 4.346 | 3.474 | 3.840 |
| Minimum | 2.7 | -15.5 | 3.4 | -17.1 |
| Q1 | 7.30 | -3.00 | 7.70 | -3.20 |
| Median | 9.90 | -0.10 | 9.60 | -0.60 |
| Q3 | 12.70 | 2.60 | 12.40 | 1.80 |
| Maximum | 37.5 | 9.1 | 19.1 | 10.7 |
| Week 24 | | | | |
| N | 114 | 114 | 107 | 107 |
| Mean | 10.83 | -0.37 | 10.79 | 0.04 |
| SD | 4.665 | 4.814 | 3.601 | 4.117 |
| Minimum | 2.3 | -17.9 | 2.9 | -15.4 |
| Q1 | 7.60 | -3.30 | 8.30 | -2.10 |
| Median | 9.80 | -0.25 | 10.20 | 0.30 |
| Q3 | 12.80 | 2.30 | 12.70 | 2.60 |
| Maximum | 31.0 | 14.6 | 20.7 | 10.8 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（5/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 114 | 114 | 105 | 105 |
| Mean | 10.27 | -0.93 | 10.48 | -0.27 |
| SD | 4.176 | 4.175 | 3.766 | 4.258 |
| Minimum | 2.6 | -16.2 | 3.8 | -19.3 |
| Q1 | 7.20 | -2.90 | 7.40 | -2.20 |
| Median | 9.80 | -0.50 | 9.90 | 0.00 |
| Q3 | 12.70 | 1.50 | 12.70 | 1.80 |
| Maximum | 23.8 | 11.0 | 23.7 | 10.1 |
| Week 32 | | | | |
| N | 114 | 114 | 103 | 103 |
| Mean | 9.95 | -1.25 | 10.41 | -0.32 |
| SD | 3.849 | 4.835 | 4.066 | 4.833 |
| Minimum | 3.0 | -24.0 | 4.1 | -13.7 |
| Q1 | 6.70 | -3.20 | 7.40 | -3.00 |
| Median | 9.55 | -1.20 | 9.80 | -0.40 |
| Q3 | 12.60 | 1.80 | 12.50 | 2.70 |
| Maximum | 24.1 | 12.8 | 25.1 | 14.1 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（6/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 114 | 114 | 103 | 103 |
| Mean | 10.79 | -0.41 | 10.97 | 0.24 |
| SD | 4.581 | 4.588 | 4.154 | 4.401 |
| Minimum | 2.6 | -20.3 | 3.1 | -12.6 |
| Q1 | 7.40 | -2.60 | 8.10 | -2.50 |
| Median | 10.30 | -0.30 | 10.50 | 0.80 |
| Q3 | 13.20 | 1.60 | 13.20 | 3.10 |
| Maximum | 22.6 | 12.6 | 29.2 | 11.2 |
| Week 40 | | | | |
| N | 112 | 112 | 103 | 103 |
| Mean | 10.29 | -1.02 | 11.33 | 0.60 |
| SD | 4.429 | 5.267 | 4.539 | 4.122 |
| Minimum | 2.3 | -24.9 | 3.5 | -10.8 |
| Q1 | 6.80 | -3.55 | 8.20 | -2.30 |
| Median | 9.95 | -0.60 | 11.00 | 0.50 |
| Q3 | 12.60 | 2.15 | 14.40 | 3.30 |
| Maximum | 31.4 | 20.1 | 26.7 | 10.0 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（7/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 73 | 73 | 72 | 72 |
| Mean | 9.86 | -1.28 | 9.93 | -0.42 |
| SD | 3.784 | 4.327 | 3.504 | 3.940 |
| Minimum | 3.4 | -21.8 | 4.2 | -11.0 |
| Q1 | 7.40 | -3.40 | 6.90 | -3.20 |
| Median | 9.10 | -1.40 | 9.85 | -0.30 |
| Q3 | 11.80 | 1.10 | 11.90 | 2.10 |
| Maximum | 20.9 | 8.2 | 19.3 | 9.1 |
| Week 48 | | | | |
| N | 73 | 73 | 72 | 72 |
| Mean | 10.03 | -1.12 | 10.18 | -0.16 |
| SD | 4.042 | 4.421 | 4.203 | 4.617 |
| Minimum | 3.6 | -21.3 | 2.9 | -12.0 |
| Q1 | 7.00 | -3.10 | 7.50 | -2.80 |
| Median | 9.90 | -1.00 | 9.80 | -0.20 |
| Q3 | 12.00 | 1.80 | 12.40 | 2.45 |
| Maximum | 22.8 | 6.8 | 22.9 | 15.1 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（8/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 71 | 71 | 72 | 72 |
| Mean | 10.25 | -0.85 | 10.13 | -0.22 |
| SD | 4.180 | 4.046 | 4.189 | 4.316 |
| Minimum | 4.3 | -12.7 | 3.0 | -15.3 |
| Q1 | 7.10 | -3.20 | 7.10 | -2.85 |
| Median | 9.10 | -0.40 | 9.90 | 0.15 |
| Q3 | 12.20 | 2.10 | 12.85 | 2.30 |
| Maximum | 24.9 | 7.7 | 22.4 | 11.4 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（9/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 120 | | 115 | |
| Mean | 0.574 | | 0.579 | |
| SD | 0.2529 | | 0.2788 | |
| Minimum | 0.22 | | 0.12 | |
| Q1 | 0.390 | | 0.380 | |
| Median | 0.520 | | 0.530 | |
| Q3 | 0.735 | | 0.680 | |
| Maximum | 1.59 | | 1.66 | |
| Week 2 | | | | |
| N | 85 | 85 | 87 | 87 |
| Mean | 0.544 | -0.023 | 0.531 | -0.058 |
| SD | 0.2743 | 0.2237 | 0.2177 | 0.2318 |
| Minimum | 0.16 | -0.70 | 0.15 | -0.75 |
| Q1 | 0.360 | -0.150 | 0.350 | -0.190 |
| Median | 0.480 | -0.010 | 0.510 | -0.070 |
| Q3 | 0.620 | 0.120 | 0.660 | 0.100 |
| Maximum | 1.69 | 0.66 | 1.20 | 0.40 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（10/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 116 | 116 | 109 | 109 |
| Mean | 0.536 | -0.036 | 0.570 | 0.002 |
| SD | 0.2355 | 0.2247 | 0.2360 | 0.2582 |
| Minimum | 0.13 | -0.92 | 0.11 | -0.83 |
| Q1 | 0.360 | -0.170 | 0.410 | -0.140 |
| Median | 0.495 | -0.050 | 0.540 | 0.020 |
| Q3 | 0.675 | 0.115 | 0.670 | 0.140 |
| Maximum | 1.23 | 0.75 | 1.48 | 0.77 |
| Week 8 | | | | |
| N | 119 | 119 | 113 | 113 |
| Mean | 0.553 | -0.024 | 0.572 | -0.010 |
| SD | 0.2779 | 0.2398 | 0.2525 | 0.2343 |
| Minimum | 0.15 | -0.73 | 0.12 | -0.64 |
| Q1 | 0.370 | -0.170 | 0.380 | -0.170 |
| Median | 0.480 | -0.030 | 0.520 | -0.020 |
| Q3 | 0.620 | 0.120 | 0.710 | 0.130 |
| Maximum | 1.68 | 0.81 | 1.30 | 0.84 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（11/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 119 | 119 | 112 | 112 |
| Mean | 0.563 | -0.013 | 0.589 | 0.004 |
| SD | 0.2517 | 0.2266 | 0.2628 | 0.2365 |
| Minimum | 0.15 | -0.61 | 0.12 | -0.56 |
| Q1 | 0.400 | -0.160 | 0.420 | -0.160 |
| Median | 0.510 | 0.000 | 0.510 | 0.030 |
| Q3 | 0.680 | 0.110 | 0.700 | 0.140 |
| Maximum | 1.43 | 0.76 | 1.41 | 0.74 |
| Week 16 | | | | |
| N | 117 | 117 | 108 | 108 |
| Mean | 0.523 | -0.057 | 0.574 | -0.007 |
| SD | 0.2357 | 0.2026 | 0.2854 | 0.2475 |
| Minimum | 0.11 | -0.75 | 0.00 | -0.56 |
| Q1 | 0.340 | -0.180 | 0.385 | -0.155 |
| Median | 0.500 | -0.040 | 0.530 | -0.015 |
| Q3 | 0.640 | 0.070 | 0.685 | 0.155 |
| Maximum | 1.30 | 0.52 | 1.58 | 0.77 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（12/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 115 | 115 | 107 | 107 |
| Mean | 0.544 | -0.033 | 0.555 | -0.026 |
| SD | 0.2644 | 0.2557 | 0.2371 | 0.2810 |
| Minimum | 0.14 | -1.22 | 0.13 | -1.31 |
| Q1 | 0.360 | -0.160 | 0.390 | -0.170 |
| Median | 0.490 | -0.030 | 0.500 | 0.000 |
| Q3 | 0.640 | 0.090 | 0.680 | 0.150 |
| Maximum | 1.69 | 0.68 | 1.19 | 0.68 |
| Week 24 | | | | |
| N | 114 | 114 | 107 | 107 |
| Mean | 0.570 | -0.011 | 0.574 | -0.008 |
| SD | 0.2994 | 0.2288 | 0.2349 | 0.2351 |
| Minimum | 0.14 | -0.69 | 0.00 | -1.23 |
| Q1 | 0.350 | -0.170 | 0.410 | -0.130 |
| Median | 0.515 | -0.035 | 0.530 | -0.020 |
| Q3 | 0.720 | 0.140 | 0.700 | 0.100 |
| Maximum | 1.75 | 0.77 | 1.49 | 0.86 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（13/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 114 | 114 | 105 | 105 |
| Mean | 0.512 | -0.069 | 0.548 | -0.035 |
| SD | 0.2134 | 0.2260 | 0.2343 | 0.2680 |
| Minimum | 0.19 | -0.85 | 0.16 | -1.31 |
| Q1 | 0.360 | -0.210 | 0.360 | -0.140 |
| Median | 0.490 | -0.055 | 0.530 | -0.050 |
| Q3 | 0.630 | 0.080 | 0.700 | 0.090 |
| Maximum | 1.58 | 0.46 | 1.36 | 0.72 |
| Week 32 | | | | |
| N | 114 | 114 | 103 | 103 |
| Mean | 0.510 | -0.071 | 0.553 | -0.036 |
| SD | 0.2490 | 0.2286 | 0.2506 | 0.2775 |
| Minimum | 0.14 | -0.76 | 0.00 | -1.10 |
| Q1 | 0.320 | -0.200 | 0.380 | -0.180 |
| Median | 0.470 | -0.050 | 0.490 | 0.010 |
| Q3 | 0.640 | 0.070 | 0.690 | 0.160 |
| Maximum | 1.46 | 0.63 | 1.37 | 0.66 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（14/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 114 | 114 | 103 | 103 |
| Mean | 0.528 | -0.053 | 0.542 | -0.042 |
| SD | 0.2510 | 0.2622 | 0.2662 | 0.2496 |
| Minimum | 0.00 | -1.27 | 0.00 | -0.77 |
| Q1 | 0.350 | -0.150 | 0.350 | -0.190 |
| Median | 0.480 | -0.040 | 0.530 | -0.010 |
| Q3 | 0.660 | 0.080 | 0.670 | 0.160 |
| Maximum | 1.41 | 0.63 | 1.54 | 0.43 |
| Week 40 | | | | |
| N | 112 | 112 | 103 | 103 |
| Mean | 0.511 | -0.074 | 0.553 | -0.031 |
| SD | 0.2446 | 0.2425 | 0.2954 | 0.2607 |
| Minimum | 0.13 | -0.56 | 0.00 | -0.73 |
| Q1 | 0.380 | -0.245 | 0.370 | -0.170 |
| Median | 0.485 | -0.090 | 0.520 | -0.040 |
| Q3 | 0.595 | 0.095 | 0.660 | 0.120 |
| Maximum | 1.53 | 0.67 | 1.67 | 0.92 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（15/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 73 | 73 | 72 | 72 |
| Mean | 0.494 | -0.085 | 0.511 | -0.060 |
| SD | 0.2180 | 0.1915 | 0.2447 | 0.2701 |
| Minimum | 0.00 | -0.57 | 0.00 | -0.77 |
| Q1 | 0.320 | -0.190 | 0.355 | -0.220 |
| Median | 0.480 | -0.080 | 0.470 | -0.080 |
| Q3 | 0.580 | 0.030 | 0.595 | 0.100 |
| Maximum | 1.20 | 0.43 | 1.48 | 0.68 |
| Week 48 | | | | |
| N | 73 | 73 | 72 | 72 |
| Mean | 0.510 | -0.068 | 0.484 | -0.087 |
| SD | 0.2452 | 0.2037 | 0.2093 | 0.2056 |
| Minimum | 0.12 | -0.64 | 0.14 | -0.78 |
| Q1 | 0.330 | -0.180 | 0.310 | -0.185 |
| Median | 0.460 | -0.060 | 0.460 | -0.090 |
| Q3 | 0.640 | 0.040 | 0.645 | 0.010 |
| Maximum | 1.36 | 0.38 | 1.02 | 0.54 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（16/64）

Severity of Liver Function at Baseline (Week 0): None
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=120) Observed Value at Visit | 12.5 mg (N=120) Change from Baseline | 25 mg (N=115) Observed Value at Visit | 25 mg (N=115) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 71 | 71 | 72 | 72 |
| Mean | 0.522 | -0.052 | 0.506 | -0.066 |
| SD | 0.2390 | 0.1859 | 0.2497 | 0.1960 |
| Minimum | 0.11 | -0.50 | 0.00 | -0.67 |
| Q1 | 0.350 | -0.160 | 0.305 | -0.150 |
| Median | 0.470 | -0.030 | 0.475 | -0.060 |
| Q3 | 0.640 | 0.070 | 0.615 | 0.070 |
| Maximum | 1.43 | 0.37 | 1.25 | 0.62 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（17/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 12 | | 18 | |
| Mean | 13.98 | | 13.16 | |
| SD | 5.446 | | 3.795 | |
| Minimum | 9.1 | | 8.6 | |
| Q1 | 10.10 | | 10.20 | |
| Median | 12.55 | | 12.40 | |
| Q3 | 15.85 | | 14.50 | |
| Maximum | 28.8 | | 20.7 | |
| Week 2 | | | | |
| N | 5 | 5 | 8 | 8 |
| Mean | 12.88 | -1.22 | 10.75 | -1.03 |
| SD | 2.771 | 4.411 | 3.537 | 4.795 |
| Minimum | 9.1 | -8.7 | 6.5 | -6.5 |
| Q1 | 11.20 | -1.60 | 7.80 | -5.60 |
| Median | 13.30 | 0.70 | 9.95 | -1.20 |
| Q3 | 14.80 | 1.30 | 14.30 | 3.10 |
| Maximum | 16.0 | 2.2 | 15.4 | 5.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（18/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 11 | 11 | 18 | 18 |
| Mean | 12.85 | -1.38 | 9.98 | -3.18 |
| SD | 3.272 | 4.680 | 4.265 | 5.907 |
| Minimum | 7.6 | -10.8 | 5.5 | -14.8 |
| Q1 | 11.00 | -4.30 | 7.10 | -4.20 |
| Median | 13.00 | -0.90 | 9.05 | -2.80 |
| Q3 | 14.80 | 2.60 | 12.10 | -1.40 |
| Maximum | 18.1 | 4.9 | 21.4 | 7.9 |
| Week 8 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 12.69 | -1.28 | 10.49 | -2.67 |
| SD | 4.545 | 3.119 | 3.408 | 5.579 |
| Minimum | 6.6 | -5.3 | 6.6 | -14.0 |
| Q1 | 10.55 | -4.15 | 8.00 | -6.00 |
| Median | 11.80 | -1.25 | 9.70 | -2.00 |
| Q3 | 14.10 | 1.90 | 12.00 | 0.40 |
| Maximum | 23.5 | 2.5 | 19.8 | 10.0 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（19/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 12.28 | -1.69 | 11.02 | -2.14 |
| SD | 3.038 | 3.977 | 3.132 | 5.103 |
| Minimum | 8.0 | -10.1 | 6.2 | -11.6 |
| Q1 | 10.75 | -3.65 | 8.30 | -6.90 |
| Median | 12.00 | -2.10 | 10.80 | -1.20 |
| Q3 | 13.40 | 1.55 | 12.60 | 2.50 |
| Maximum | 18.7 | 3.2 | 17.2 | 7.0 |
| Week 16 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 11.58 | -2.40 | 11.81 | -1.36 |
| SD | 3.358 | 3.719 | 3.833 | 5.235 |
| Minimum | 7.4 | -9.1 | 6.3 | -13.6 |
| Q1 | 9.45 | -4.55 | 7.90 | -4.70 |
| Median | 11.20 | -1.70 | 11.95 | -1.10 |
| Q3 | 12.70 | 0.85 | 13.80 | 1.70 |
| Maximum | 20.5 | 2.5 | 21.1 | 7.6 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（20/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 12.01 | -1.97 | 11.07 | -2.09 |
| SD | 2.684 | 5.859 | 4.090 | 6.538 |
| Minimum | 7.3 | -17.9 | 6.1 | -14.6 |
| Q1 | 9.95 | -3.95 | 8.60 | -5.20 |
| Median | 12.25 | -1.50 | 9.60 | -0.85 |
| Q3 | 14.35 | 2.25 | 13.10 | 1.90 |
| Maximum | 15.7 | 5.0 | 22.5 | 12.7 |
| Week 24 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 13.45 | -0.53 | 12.08 | -1.08 |
| SD | 5.050 | 5.705 | 4.857 | 5.360 |
| Minimum | 7.2 | -8.1 | 5.1 | -11.6 |
| Q1 | 9.20 | -4.45 | 9.10 | -3.80 |
| Median | 12.85 | -2.55 | 11.15 | -1.70 |
| Q3 | 17.10 | 2.55 | 13.50 | 1.70 |
| Maximum | 22.1 | 12.1 | 22.9 | 13.0 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（21/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 12.03 | -1.95 | 12.54 | -0.62 |
| SD | 4.053 | 3.872 | 5.814 | 7.391 |
| Minimum | 6.3 | -9.6 | 5.0 | -11.5 |
| Q1 | 8.10 | -3.20 | 9.70 | -4.10 |
| Median | 12.70 | -1.80 | 12.05 | -1.10 |
| Q3 | 15.35 | -0.30 | 13.00 | 1.80 |
| Maximum | 19.2 | 4.9 | 28.9 | 15.6 |
| Week 32 | | | | |
| N | 12 | 12 | 17 | 17 |
| Mean | 10.80 | -3.18 | 12.30 | -1.13 |
| SD | 3.943 | 2.603 | 4.647 | 6.563 |
| Minimum | 5.7 | -8.1 | 7.2 | -12.3 |
| Q1 | 8.10 | -4.80 | 9.70 | -5.40 |
| Median | 10.40 | -3.65 | 11.40 | 0.00 |
| Q3 | 12.25 | -1.45 | 14.10 | 0.90 |
| Maximum | 20.7 | 1.5 | 27.0 | 17.2 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（22/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 12 | 12 | 17 | 17 |
| Mean | 11.33 | -2.65 | 12.21 | -1.22 |
| SD | 6.202 | 3.625 | 3.440 | 5.395 |
| Minimum | 7.0 | -9.5 | 6.4 | -13.1 |
| Q1 | 8.45 | -5.40 | 9.50 | -5.20 |
| Median | 9.35 | -2.25 | 12.60 | 1.00 |
| Q3 | 11.95 | 0.50 | 14.20 | 2.80 |
| Maximum | 30.2 | 1.6 | 19.9 | 6.6 |
| Week 40 | | | | |
| N | 12 | 12 | 17 | 17 |
| Mean | 17.17 | 3.19 | 11.75 | -1.68 |
| SD | 12.687 | 9.177 | 3.001 | 4.638 |
| Minimum | 7.0 | -4.8 | 7.5 | -10.7 |
| Q1 | 11.00 | -2.85 | 9.20 | -4.50 |
| Median | 13.50 | 0.80 | 11.70 | -1.80 |
| Q3 | 17.00 | 5.15 | 13.60 | 3.10 |
| Maximum | 53.7 | 24.9 | 17.4 | 4.3 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（23/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 4 | 4 | 8 | 8 |
| Mean | 11.15 | -3.70 | 10.41 | -1.36 |
| SD | 2.428 | 2.334 | 3.417 | 4.034 |
| Minimum | 9.2 | -6.0 | 6.4 | -7.2 |
| Q1 | 9.75 | -5.50 | 7.85 | -4.25 |
| Median | 10.35 | -4.05 | 9.85 | -1.30 |
| Q3 | 12.55 | -1.90 | 12.30 | 1.35 |
| Maximum | 14.7 | -0.7 | 16.9 | 4.7 |
| Week 48 | | | | |
| N | 4 | 4 | 8 | 8 |
| Mean | 13.73 | -1.13 | 9.71 | -2.06 |
| SD | 3.505 | 3.747 | 2.532 | 3.809 |
| Minimum | 11.3 | -5.1 | 6.4 | -7.2 |
| Q1 | 11.60 | -4.25 | 7.65 | -4.95 |
| Median | 12.35 | -1.15 | 9.30 | -2.85 |
| Q3 | 15.85 | 2.00 | 11.90 | 1.45 |
| Maximum | 18.9 | 2.9 | 13.6 | 3.4 |

添付資料（5.3.5.3-2）Table 2.3.1.2

表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（24/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 4 | 4 | 8 | 8 |
| Mean | 10.15 | -4.70 | 12.16 | 0.39 |
| SD | 3.122 | 5.998 | 5.214 | 5.541 |
| Minimum | 5.5 | -12.3 | 6.2 | -6.4 |
| Q1 | 8.40 | -8.70 | 7.75 | -3.45 |
| Median | 11.45 | -4.40 | 11.25 | -1.80 |
| Q3 | 11.90 | -0.70 | 16.40 | 5.45 |
| Maximum | 12.2 | 2.3 | 20.3 | 9.1 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（25/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 12 | | 18 | |
| Mean | 0.676 | | 0.729 | |
| SD | 0.2820 | | 0.2724 | |
| Minimum | 0.29 | | 0.36 | |
| Q1 | 0.440 | | 0.510 | |
| Median | 0.685 | | 0.705 | |
| Q3 | 0.890 | | 0.950 | |
| Maximum | 1.22 | | 1.30 | |
| Week 2 | | | | |
| N | 5 | 5 | 8 | 8 |
| Mean | 0.642 | -0.110 | 0.626 | -0.160 |
| SD | 0.2789 | 0.2499 | 0.2553 | 0.3480 |
| Minimum | 0.44 | -0.45 | 0.33 | -0.77 |
| Q1 | 0.490 | -0.270 | 0.465 | -0.370 |
| Median | 0.570 | -0.040 | 0.525 | -0.080 |
| Q3 | 0.580 | 0.030 | 0.810 | 0.040 |
| Maximum | 1.13 | 0.18 | 1.08 | 0.31 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（26/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 11 | 11 | 18 | 18 |
| Mean | 0.529 | -0.122 | 0.545 | -0.184 |
| SD | 0.1168 | 0.2993 | 0.1998 | 0.3440 |
| Minimum | 0.33 | -0.79 | 0.25 | -1.05 |
| Q1 | 0.430 | -0.200 | 0.420 | -0.350 |
| Median | 0.550 | -0.130 | 0.505 | -0.090 |
| Q3 | 0.600 | 0.040 | 0.620 | 0.030 |
| Maximum | 0.74 | 0.39 | 0.97 | 0.38 |
| Week 8 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 0.496 | -0.180 | 0.663 | -0.066 |
| SD | 0.1718 | 0.3147 | 0.2202 | 0.3092 |
| Minimum | 0.26 | -0.91 | 0.33 | -0.60 |
| Q1 | 0.370 | -0.340 | 0.460 | -0.200 |
| Median | 0.495 | -0.125 | 0.675 | -0.095 |
| Q3 | 0.530 | 0.020 | 0.740 | 0.140 |
| Maximum | 0.81 | 0.19 | 1.14 | 0.55 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（27/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 0.619 | -0.057 | 0.638 | -0.091 |
| SD | 0.1857 | 0.1769 | 0.2539 | 0.4047 |
| Minimum | 0.39 | -0.34 | 0.28 | -0.83 |
| Q1 | 0.445 | -0.225 | 0.490 | -0.420 |
| Median | 0.640 | -0.035 | 0.645 | 0.045 |
| Q3 | 0.735 | 0.115 | 0.720 | 0.210 |
| Maximum | 0.98 | 0.16 | 1.33 | 0.59 |
| Week 16 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 0.521 | -0.155 | 0.642 | -0.087 |
| SD | 0.1706 | 0.3094 | 0.2129 | 0.2648 |
| Minimum | 0.25 | -0.89 | 0.34 | -0.72 |
| Q1 | 0.395 | -0.275 | 0.520 | -0.160 |
| Median | 0.490 | -0.090 | 0.580 | -0.055 |
| Q3 | 0.660 | 0.035 | 0.760 | 0.070 |
| Maximum | 0.83 | 0.28 | 1.09 | 0.26 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（28/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 0.609 | -0.067 | 0.558 | -0.171 |
| SD | 0.1952 | 0.3367 | 0.1992 | 0.3152 |
| Minimum | 0.25 | -0.89 | 0.20 | -0.70 |
| Q1 | 0.445 | -0.190 | 0.380 | -0.450 |
| Median | 0.685 | -0.025 | 0.565 | -0.120 |
| Q3 | 0.735 | 0.165 | 0.670 | 0.040 |
| Maximum | 0.82 | 0.33 | 0.90 | 0.50 |
| Week 24 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 0.616 | -0.060 | 0.637 | -0.092 |
| SD | 0.1299 | 0.3240 | 0.1981 | 0.2637 |
| Minimum | 0.42 | -0.74 | 0.24 | -0.73 |
| Q1 | 0.510 | -0.280 | 0.520 | -0.270 |
| Median | 0.635 | -0.040 | 0.600 | -0.030 |
| Q3 | 0.715 | 0.210 | 0.750 | 0.050 |
| Maximum | 0.80 | 0.38 | 1.03 | 0.36 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（29/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 12 | 12 | 18 | 18 |
| Mean | 0.571 | -0.105 | 0.653 | -0.076 |
| SD | 0.1606 | 0.2895 | 0.2164 | 0.3522 |
| Minimum | 0.37 | -0.57 | 0.42 | -0.62 |
| Q1 | 0.440 | -0.280 | 0.460 | -0.320 |
| Median | 0.545 | -0.105 | 0.535 | -0.060 |
| Q3 | 0.665 | 0.120 | 0.900 | 0.160 |
| Maximum | 0.94 | 0.42 | 0.98 | 0.58 |
| Week 32 | | | | |
| N | 12 | 12 | 17 | 17 |
| Mean | 0.518 | -0.158 | 0.633 | -0.118 |
| SD | 0.1714 | 0.3086 | 0.2258 | 0.2868 |
| Minimum | 0.17 | -0.65 | 0.32 | -0.66 |
| Q1 | 0.440 | -0.440 | 0.410 | -0.260 |
| Median | 0.495 | -0.090 | 0.660 | -0.120 |
| Q3 | 0.690 | 0.040 | 0.730 | 0.130 |
| Maximum | 0.71 | 0.35 | 1.15 | 0.28 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（30/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 12 | 12 | 17 | 17 |
| Mean | 0.537 | -0.139 | 0.614 | -0.136 |
| SD | 0.2840 | 0.2663 | 0.2346 | 0.3436 |
| Minimum | 0.22 | -0.62 | 0.38 | -0.72 |
| Q1 | 0.350 | -0.270 | 0.490 | -0.380 |
| Median | 0.500 | -0.085 | 0.550 | -0.020 |
| Q3 | 0.670 | 0.065 | 0.680 | 0.100 |
| Maximum | 1.28 | 0.17 | 1.25 | 0.50 |
| Week 40 | | | | |
| N | 12 | 12 | 17 | 17 |
| Mean | 0.678 | 0.002 | 0.612 | -0.138 |
| SD | 0.4378 | 0.3223 | 0.2088 | 0.3258 |
| Minimum | 0.32 | -0.52 | 0.30 | -0.78 |
| Q1 | 0.390 | -0.180 | 0.490 | -0.430 |
| Median | 0.630 | 0.050 | 0.590 | -0.180 |
| Q3 | 0.745 | 0.175 | 0.690 | 0.130 |
| Maximum | 1.92 | 0.70 | 1.14 | 0.40 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（31/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 4 | 4 | 8 | 8 |
| Mean | 0.473 | -0.230 | 0.618 | -0.169 |
| SD | 0.0386 | 0.2434 | 0.2112 | 0.2216 |
| Minimum | 0.42 | -0.45 | 0.26 | -0.46 |
| Q1 | 0.445 | -0.410 | 0.495 | -0.350 |
| Median | 0.480 | -0.285 | 0.615 | -0.180 |
| Q3 | 0.500 | -0.050 | 0.780 | 0.010 |
| Maximum | 0.51 | 0.10 | 0.90 | 0.15 |
| Week 48 | | | | |
| N | 4 | 4 | 8 | 8 |
| Mean | 0.535 | -0.168 | 0.635 | -0.151 |
| SD | 0.2095 | 0.3753 | 0.2746 | 0.4165 |
| Minimum | 0.25 | -0.59 | 0.41 | -0.89 |
| Q1 | 0.380 | -0.435 | 0.450 | -0.395 |
| Median | 0.585 | -0.195 | 0.530 | -0.080 |
| Q3 | 0.690 | 0.100 | 0.735 | 0.070 |
| Maximum | 0.72 | 0.31 | 1.24 | 0.49 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（32/64）

Severity of Liver Function at Baseline (Week 0): 1xULN<AST<=1.5xULN or 1xULN<ALT<=1.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=12) Observed Value at Visit | 12.5 mg (N=12) Change from Baseline | 25 mg (N=18) Observed Value at Visit | 25 mg (N=18) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 4 | 4 | 8 | 8 |
| Mean | 0.485 | -0.218 | 0.616 | -0.170 |
| SD | 0.2144 | 0.4367 | 0.3319 | 0.4587 |
| Minimum | 0.32 | -0.62 | 0.35 | -0.95 |
| Q1 | 0.360 | -0.520 | 0.425 | -0.415 |
| Median | 0.410 | -0.320 | 0.525 | -0.120 |
| Q3 | 0.610 | 0.085 | 0.645 | 0.010 |
| Maximum | 0.80 | 0.39 | 1.39 | 0.64 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（33/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 9 | | 11 | |
| Mean | 15.68 | | 14.56 | |
| SD | 7.014 | | 3.282 | |
| Minimum | 8.2 | | 6.3 | |
| Q1 | 13.00 | | 13.40 | |
| Median | 13.20 | | 15.50 | |
| Q3 | 16.70 | | 17.30 | |
| Maximum | 32.0 | | 17.6 | |
| Week 2 | | | | |
| N | 6 | 6 | 7 | 7 |
| Mean | 11.12 | -6.05 | 10.53 | -3.70 |
| SD | 2.328 | 7.021 | 3.487 | 4.000 |
| Minimum | 7.9 | -18.6 | 6.4 | -10.3 |
| Q1 | 8.80 | -7.90 | 7.30 | -6.60 |
| Median | 11.65 | -5.35 | 9.80 | -3.70 |
| Q3 | 13.30 | 0.30 | 14.30 | 0.10 |
| Maximum | 13.4 | 0.6 | 16.0 | 1.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（34/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 7 | 7 | 10 | 10 |
| Mean | 11.59 | -2.13 | 12.20 | -2.48 |
| SD | 2.663 | 4.636 | 5.265 | 5.091 |
| Minimum | 7.3 | -5.8 | 6.2 | -10.3 |
| Q1 | 9.90 | -5.70 | 7.40 | -5.50 |
| Median | 11.40 | -4.40 | 10.55 | -1.95 |
| Q3 | 14.80 | 1.00 | 16.60 | 0.20 |
| Maximum | 14.8 | 6.6 | 21.2 | 5.7 |
| Week 8 | | | | |
| N | 9 | 9 | 11 | 11 |
| Mean | 10.34 | -5.33 | 12.07 | -2.49 |
| SD | 3.225 | 8.621 | 3.909 | 4.176 |
| Minimum | 5.9 | -22.2 | 6.9 | -8.6 |
| Q1 | 7.90 | -7.10 | 8.70 | -7.20 |
| Median | 9.80 | -5.20 | 11.30 | -0.40 |
| Q3 | 12.80 | -0.40 | 15.80 | 0.60 |
| Maximum | 15.3 | 7.1 | 19.2 | 2.4 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（35/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 8 | 8 | 11 | 11 |
| Mean | 10.60 | -5.39 | 14.73 | 0.16 |
| SD | 3.774 | 8.411 | 8.883 | 7.823 |
| Minimum | 6.8 | -24.6 | 6.0 | -8.3 |
| Q1 | 7.45 | -5.90 | 8.10 | -5.40 |
| Median | 9.95 | -3.75 | 12.80 | -0.30 |
| Q3 | 12.80 | -1.65 | 18.70 | 1.40 |
| Maximum | 17.6 | 4.1 | 37.0 | 19.6 |
| Week 16 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 9.24 | -6.75 | 12.21 | -2.08 |
| SD | 2.642 | 8.048 | 5.454 | 5.187 |
| Minimum | 5.2 | -23.1 | 5.8 | -9.1 |
| Q1 | 7.20 | -8.60 | 8.00 | -6.35 |
| Median | 9.75 | -7.70 | 10.40 | -2.60 |
| Q3 | 11.45 | -1.00 | 17.30 | 3.10 |
| Maximum | 11.9 | 3.7 | 20.5 | 4.2 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（36/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 11.28 | -4.71 | 13.38 | -0.91 |
| SD | 3.269 | 8.232 | 5.228 | 4.344 |
| Minimum | 7.8 | -23.4 | 6.0 | -7.2 |
| Q1 | 8.70 | -6.55 | 10.40 | -4.30 |
| Median | 10.35 | -1.95 | 12.40 | -1.10 |
| Q3 | 13.80 | 0.75 | 16.40 | 2.70 |
| Maximum | 16.7 | 1.2 | 22.6 | 5.3 |
| Week 24 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 10.99 | -5.00 | 12.16 | -2.13 |
| SD | 3.907 | 8.569 | 4.115 | 5.499 |
| Minimum | 4.4 | -23.4 | 6.8 | -9.6 |
| Q1 | 8.20 | -7.55 | 8.40 | -6.60 |
| Median | 11.85 | -4.05 | 12.65 | -1.60 |
| Q3 | 13.35 | 1.60 | 14.75 | 1.00 |
| Maximum | 16.7 | 3.4 | 18.9 | 7.0 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（37/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 14.40 | -1.59 | 12.34 | -1.95 |
| SD | 5.825 | 3.182 | 3.487 | 3.970 |
| Minimum | 9.7 | -4.8 | 8.7 | -7.1 |
| Q1 | 11.10 | -4.15 | 9.25 | -5.25 |
| Median | 12.90 | -2.00 | 12.10 | -2.55 |
| Q3 | 14.75 | -0.15 | 14.35 | 2.00 |
| Maximum | 28.0 | 4.7 | 18.6 | 3.1 |
| Week 32 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 11.65 | -4.34 | 11.28 | -3.01 |
| SD | 3.606 | 9.390 | 4.173 | 5.006 |
| Minimum | 6.1 | -22.9 | 5.6 | -12.0 |
| Q1 | 9.35 | -7.00 | 7.55 | -6.75 |
| Median | 11.45 | -5.05 | 12.15 | -1.15 |
| Q3 | 14.30 | 2.75 | 14.80 | 0.50 |
| Maximum | 16.9 | 6.8 | 15.6 | 2.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（38/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 7 | 7 | 8 | 8 |
| Mean | 11.63 | -3.76 | 12.73 | -1.56 |
| SD | 3.694 | 10.369 | 5.363 | 5.626 |
| Minimum | 5.6 | -23.2 | 6.7 | -9.7 |
| Q1 | 8.80 | -11.10 | 8.25 | -6.25 |
| Median | 12.80 | -0.30 | 12.30 | -1.25 |
| Q3 | 14.70 | 5.40 | 16.00 | 2.85 |
| Maximum | 15.8 | 6.5 | 22.0 | 6.5 |
| Week 40 | | | | |
| N | 7 | 7 | 8 | 8 |
| Mean | 11.81 | -3.57 | 10.38 | -3.91 |
| SD | 2.630 | 6.295 | 3.531 | 3.508 |
| Minimum | 7.9 | -16.7 | 5.4 | -10.2 |
| Q1 | 9.10 | -5.10 | 8.00 | -6.65 |
| Median | 12.70 | -2.20 | 10.45 | -2.40 |
| Q3 | 13.50 | 0.90 | 12.05 | -1.15 |
| Maximum | 15.3 | 2.3 | 16.6 | -0.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（39/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 3 | 3 | 3 | 3 |
| Mean | 8.30 | -4.27 | 9.07 | -4.37 |
| SD | 1.353 | 3.004 | 2.695 | 6.045 |
| Minimum | 6.9 | -6.1 | 6.7 | -9.7 |
| Q1 | 6.90 | -6.10 | 6.70 | -9.70 |
| Median | 8.40 | -5.90 | 8.50 | -5.60 |
| Q3 | 9.60 | -0.80 | 12.00 | 2.20 |
| Maximum | 9.6 | -0.8 | 12.0 | 2.2 |
| Week 48 | | | | |
| N | 3 | 3 | 3 | 3 |
| Mean | 9.43 | -3.13 | 9.23 | -4.20 |
| SD | 3.293 | 5.142 | 2.479 | 4.349 |
| Minimum | 7.1 | -6.3 | 7.0 | -7.6 |
| Q1 | 7.10 | -6.30 | 7.00 | -7.60 |
| Median | 8.00 | -5.90 | 8.80 | -5.70 |
| Q3 | 13.20 | 2.80 | 11.90 | 0.70 |
| Maximum | 13.2 | 2.8 | 11.9 | 0.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（40/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 3 | 3 | 3 | 3 |
| Mean | 10.17 | -2.40 | 9.27 | -4.17 |
| SD | 2.053 | 3.460 | 2.515 | 5.718 |
| Minimum | 7.9 | -5.1 | 7.3 | -9.1 |
| Q1 | 7.90 | -5.10 | 7.30 | -9.10 |
| Median | 10.70 | -3.60 | 8.40 | -5.50 |
| Q3 | 11.90 | 1.50 | 12.10 | 2.10 |
| Maximum | 11.9 | 1.5 | 12.1 | 2.1 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（41/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 9 | | 11 | |
| Mean | 0.728 | | 0.841 | |
| SD | 0.1738 | | 0.3187 | |
| Minimum | 0.48 | | 0.36 | |
| Q1 | 0.600 | | 0.680 | |
| Median | 0.740 | | 0.790 | |
| Q3 | 0.850 | | 1.010 | |
| Maximum | 0.94 | | 1.56 | |
| Week 2 | | | | |
| N | 6 | 6 | 7 | 7 |
| Mean | 0.660 | -0.128 | 0.621 | -0.177 |
| SD | 0.1386 | 0.2660 | 0.2973 | 0.3642 |
| Minimum | 0.57 | -0.37 | 0.25 | -0.76 |
| Q1 | 0.570 | -0.280 | 0.290 | -0.500 |
| Median | 0.610 | -0.270 | 0.690 | -0.050 |
| Q3 | 0.670 | 0.170 | 0.870 | 0.070 |
| Maximum | 0.93 | 0.25 | 0.99 | 0.31 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（42/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 7 | 7 | 10 | 10 |
| Mean | 0.616 | -0.129 | 0.635 | -0.222 |
| SD | 0.1449 | 0.2281 | 0.3009 | 0.1592 |
| Minimum | 0.45 | -0.38 | 0.29 | -0.45 |
| Q1 | 0.520 | -0.330 | 0.430 | -0.340 |
| Median | 0.580 | -0.150 | 0.600 | -0.225 |
| Q3 | 0.680 | 0.100 | 0.690 | -0.170 |
| Maximum | 0.90 | 0.22 | 1.32 | 0.10 |
| Week 8 | | | | |
| N | 9 | 9 | 11 | 11 |
| Mean | 0.640 | -0.088 | 0.681 | -0.160 |
| SD | 0.1979 | 0.3102 | 0.2826 | 0.3475 |
| Minimum | 0.41 | -0.53 | 0.12 | -0.97 |
| Q1 | 0.480 | -0.410 | 0.430 | -0.380 |
| Median | 0.570 | -0.060 | 0.700 | -0.130 |
| Q3 | 0.830 | 0.090 | 0.980 | 0.070 |
| Maximum | 0.92 | 0.33 | 1.03 | 0.30 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（43/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 8 | 8 | 11 | 11 |
| Mean | 0.633 | -0.094 | 0.733 | -0.108 |
| SD | 0.2004 | 0.2083 | 0.3028 | 0.4146 |
| Minimum | 0.49 | -0.41 | 0.20 | -0.89 |
| Q1 | 0.515 | -0.280 | 0.510 | -0.480 |
| Median | 0.545 | -0.025 | 0.700 | -0.060 |
| Q3 | 0.680 | 0.050 | 0.950 | 0.150 |
| Maximum | 1.09 | 0.17 | 1.26 | 0.55 |
| Week 16 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 0.565 | -0.161 | 0.635 | -0.191 |
| SD | 0.2558 | 0.3033 | 0.2627 | 0.2441 |
| Minimum | 0.23 | -0.52 | 0.30 | -0.53 |
| Q1 | 0.410 | -0.425 | 0.375 | -0.410 |
| Median | 0.495 | -0.180 | 0.695 | -0.140 |
| Q3 | 0.725 | 0.045 | 0.805 | -0.040 |
| Maximum | 1.03 | 0.35 | 1.03 | 0.18 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（44/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 0.664 | -0.063 | 0.685 | -0.141 |
| SD | 0.2220 | 0.2136 | 0.2429 | 0.3078 |
| Minimum | 0.34 | -0.42 | 0.28 | -0.75 |
| Q1 | 0.510 | -0.140 | 0.470 | -0.290 |
| Median | 0.655 | -0.090 | 0.790 | -0.065 |
| Q3 | 0.815 | 0.025 | 0.870 | 0.035 |
| Maximum | 1.01 | 0.33 | 0.94 | 0.26 |
| Week 24 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 0.668 | -0.059 | 0.713 | -0.114 |
| SD | 0.3291 | 0.4102 | 0.3021 | 0.4566 |
| Minimum | 0.26 | -0.58 | 0.38 | -0.86 |
| Q1 | 0.415 | -0.480 | 0.475 | -0.425 |
| Median | 0.655 | 0.025 | 0.685 | -0.075 |
| Q3 | 0.825 | 0.285 | 0.850 | 0.165 |
| Maximum | 1.29 | 0.45 | 1.30 | 0.62 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（45/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 0.748 | 0.021 | 0.606 | -0.220 |
| SD | 0.3856 | 0.3524 | 0.2377 | 0.4323 |
| Minimum | 0.36 | -0.38 | 0.32 | -1.13 |
| Q1 | 0.450 | -0.190 | 0.395 | -0.360 |
| Median | 0.700 | -0.100 | 0.580 | -0.155 |
| Q3 | 0.890 | 0.215 | 0.820 | 0.070 |
| Maximum | 1.54 | 0.70 | 0.94 | 0.26 |
| Week 32 | | | | |
| N | 8 | 8 | 8 | 8 |
| Mean | 0.648 | -0.079 | 0.656 | -0.170 |
| SD | 0.1738 | 0.2158 | 0.3471 | 0.4122 |
| Minimum | 0.41 | -0.48 | 0.25 | -0.74 |
| Q1 | 0.480 | -0.175 | 0.320 | -0.470 |
| Median | 0.670 | -0.085 | 0.685 | -0.185 |
| Q3 | 0.800 | 0.090 | 0.870 | 0.060 |
| Maximum | 0.87 | 0.19 | 1.25 | 0.57 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（46/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 7 | 7 | 8 | 8 |
| Mean | 0.561 | -0.137 | 0.596 | -0.230 |
| SD | 0.1561 | 0.1982 | 0.3922 | 0.5543 |
| Minimum | 0.31 | -0.50 | 0.35 | -1.14 |
| Q1 | 0.440 | -0.200 | 0.390 | -0.410 |
| Median | 0.540 | -0.150 | 0.480 | -0.285 |
| Q3 | 0.720 | 0.040 | 0.570 | -0.085 |
| Maximum | 0.75 | 0.12 | 1.54 | 0.86 |
| Week 40 | | | | |
| N | 7 | 7 | 8 | 8 |
| Mean | 0.500 | -0.199 | 0.581 | -0.245 |
| SD | 0.1344 | 0.2137 | 0.2462 | 0.2835 |
| Minimum | 0.36 | -0.58 | 0.30 | -0.68 |
| Q1 | 0.360 | -0.360 | 0.395 | -0.460 |
| Median | 0.490 | -0.120 | 0.525 | -0.210 |
| Q3 | 0.570 | -0.090 | 0.760 | -0.060 |
| Maximum | 0.75 | 0.07 | 0.99 | 0.18 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（47/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=9) Observed Value at Visit | 12.5 mg (N=9) Change from Baseline | 25 mg (N=11) Observed Value at Visit | 25 mg (N=11) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 3 | 3 | 3 | 3 |
| Mean | 0.533 | -0.290 | 0.477 | -0.280 |
| SD | 0.1079 | 0.0346 | 0.1320 | 0.3223 |
| Minimum | 0.41 | -0.33 | 0.36 | -0.50 |
| Q1 | 0.410 | -0.330 | 0.360 | -0.500 |
| Median | 0.580 | -0.270 | 0.450 | -0.430 |
| Q3 | 0.610 | -0.270 | 0.620 | 0.090 |
| Maximum | 0.61 | -0.27 | 0.62 | 0.09 |
| Week 48 | | | | |
| N | 3 | 3 | 3 | 3 |
| Mean | 0.463 | -0.360 | 0.520 | -0.237 |
| SD | 0.0153 | 0.1179 | 0.1039 | 0.3011 |
| Minimum | 0.45 | -0.46 | 0.46 | -0.48 |
| Q1 | 0.450 | -0.460 | 0.460 | -0.480 |
| Median | 0.460 | -0.390 | 0.460 | -0.330 |
| Q3 | 0.480 | -0.230 | 0.640 | 0.100 |
| Maximum | 0.48 | -0.23 | 0.64 | 0.10 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（48/64）

Severity of Liver Function at Baseline (Week 0): 1.5xULN<AST<=2.5xULN or 1.5xULN<ALT<=2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| | 12.5 mg (N=9) | | 25 mg (N=11) | |
|---|---|---|---|---|
| Visit / Statistics | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 52 | | | | |
| N | 3 | 3 | 3 | 3 |
| Mean | 0.517 | -0.307 | 0.413 | -0.343 |
| SD | 0.0751 | 0.0987 | 0.1762 | 0.2230 |
| Minimum | 0.44 | -0.42 | 0.27 | -0.51 |
| Q1 | 0.440 | -0.420 | 0.270 | -0.510 |
| Median | 0.520 | -0.260 | 0.360 | -0.430 |
| Q3 | 0.590 | -0.240 | 0.610 | -0.090 |
| Maximum | 0.59 | -0.24 | 0.61 | -0.09 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（49/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 1 | | 1 | |
| Mean | 21.90 | | 12.70 | |
| SD | | | | |
| Minimum | 21.9 | | 12.7 | |
| Q1 | 21.90 | | 12.70 | |
| Median | 21.90 | | 12.70 | |
| Q3 | 21.90 | | 12.70 | |
| Maximum | 21.9 | | 12.7 | |
| Week 2 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 13.70 | -8.20 | | |
| SD | | | | |
| Minimum | 13.7 | -8.2 | | |
| Q1 | 13.70 | -8.20 | | |
| Median | 13.70 | -8.20 | | |
| Q3 | 13.70 | -8.20 | | |
| Maximum | 13.7 | -8.2 | | |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（50/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 15.30 | -6.60 | 13.80 | 1.10 |
| SD | | | | |
| Minimum | 15.3 | -6.6 | 13.8 | 1.1 |
| Q1 | 15.30 | -6.60 | 13.80 | 1.10 |
| Median | 15.30 | -6.60 | 13.80 | 1.10 |
| Q3 | 15.30 | -6.60 | 13.80 | 1.10 |
| Maximum | 15.3 | -6.6 | 13.8 | 1.1 |
| Week 8 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 22.00 | 0.10 | 6.00 | -6.70 |
| SD | | | | |
| Minimum | 22.0 | 0.1 | 6.0 | -6.7 |
| Q1 | 22.00 | 0.10 | 6.00 | -6.70 |
| Median | 22.00 | 0.10 | 6.00 | -6.70 |
| Q3 | 22.00 | 0.10 | 6.00 | -6.70 |
| Maximum | 22.0 | 0.1 | 6.0 | -6.7 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（51/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 10.60 | -11.30 | 5.80 | -6.90 |
| SD | | | | |
| Minimum | 10.6 | -11.3 | 5.8 | -6.9 |
| Q1 | 10.60 | -11.30 | 5.80 | -6.90 |
| Median | 10.60 | -11.30 | 5.80 | -6.90 |
| Q3 | 10.60 | -11.30 | 5.80 | -6.90 |
| Maximum | 10.6 | -11.3 | 5.8 | -6.9 |
| Week 16 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 13.60 | -8.30 | 6.30 | -6.40 |
| SD | | | | |
| Minimum | 13.6 | -8.3 | 6.3 | -6.4 |
| Q1 | 13.60 | -8.30 | 6.30 | -6.40 |
| Median | 13.60 | -8.30 | 6.30 | -6.40 |
| Q3 | 13.60 | -8.30 | 6.30 | -6.40 |
| Maximum | 13.6 | -8.3 | 6.3 | -6.4 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（52/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 16.20 | -5.70 | 9.10 | -3.60 |
| SD | | | | |
| Minimum | 16.2 | -5.7 | 9.1 | -3.6 |
| Q1 | 16.20 | -5.70 | 9.10 | -3.60 |
| Median | 16.20 | -5.70 | 9.10 | -3.60 |
| Q3 | 16.20 | -5.70 | 9.10 | -3.60 |
| Maximum | 16.2 | -5.7 | 9.1 | -3.6 |
| Week 24 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 11.50 | -10.40 | 5.40 | -7.30 |
| SD | | | | |
| Minimum | 11.5 | -10.4 | 5.4 | -7.3 |
| Q1 | 11.50 | -10.40 | 5.40 | -7.30 |
| Median | 11.50 | -10.40 | 5.40 | -7.30 |
| Q3 | 11.50 | -10.40 | 5.40 | -7.30 |
| Maximum | 11.5 | -10.4 | 5.4 | -7.3 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（53/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 14.10 | -7.80 | 6.90 | -5.80 |
| SD | | | | |
| Minimum | 14.1 | -7.8 | 6.9 | -5.8 |
| Q1 | 14.10 | -7.80 | 6.90 | -5.80 |
| Median | 14.10 | -7.80 | 6.90 | -5.80 |
| Q3 | 14.10 | -7.80 | 6.90 | -5.80 |
| Maximum | 14.1 | -7.8 | 6.9 | -5.8 |
| Week 32 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 19.10 | -2.80 | 4.70 | -8.00 |
| SD | | | | |
| Minimum | 19.1 | -2.8 | 4.7 | -8.0 |
| Q1 | 19.10 | -2.80 | 4.70 | -8.00 |
| Median | 19.10 | -2.80 | 4.70 | -8.00 |
| Q3 | 19.10 | -2.80 | 4.70 | -8.00 |
| Maximum | 19.1 | -2.8 | 4.7 | -8.0 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（54/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 12.70 | -9.20 | 7.40 | -5.30 |
| SD | | | | |
| Minimum | 12.7 | -9.2 | 7.4 | -5.3 |
| Q1 | 12.70 | -9.20 | 7.40 | -5.30 |
| Median | 12.70 | -9.20 | 7.40 | -5.30 |
| Q3 | 12.70 | -9.20 | 7.40 | -5.30 |
| Maximum | 12.7 | -9.2 | 7.4 | -5.3 |
| Week 40 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 16.30 | -5.60 | 5.80 | -6.90 |
| SD | | | | |
| Minimum | 16.3 | -5.6 | 5.8 | -6.9 |
| Q1 | 16.30 | -5.60 | 5.80 | -6.90 |
| Median | 16.30 | -5.60 | 5.80 | -6.90 |
| Q3 | 16.30 | -5.60 | 5.80 | -6.90 |
| Maximum | 16.3 | -5.6 | 5.8 | -6.9 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（55/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 20.30 | -1.60 | | |
| SD | | | | |
| Minimum | 20.3 | -1.6 | | |
| Q1 | 20.30 | -1.60 | | |
| Median | 20.30 | -1.60 | | |
| Q3 | 20.30 | -1.60 | | |
| Maximum | 20.3 | -1.6 | | |
| Week 48 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 18.90 | -3.00 | | |
| SD | | | | |
| Minimum | 18.9 | -3.0 | | |
| Q1 | 18.90 | -3.00 | | |
| Median | 18.90 | -3.00 | | |
| Q3 | 18.90 | -3.00 | | |
| Maximum | 18.9 | -3.0 | | |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（56/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Lactic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 17.00 | -4.90 | | |
| SD | | | | |
| Minimum | 17.0 | -4.9 | | |
| Q1 | 17.00 | -4.90 | | |
| Median | 17.00 | -4.90 | | |
| Q3 | 17.00 | -4.90 | | |
| Maximum | 17.0 | -4.9 | | |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（57/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 0 | | | | |
| N | 1 | | 1 | |
| Mean | 0.890 | | 0.620 | |
| SD | | | | |
| Minimum | 0.89 | | 0.62 | |
| Q1 | 0.890 | | 0.620 | |
| Median | 0.890 | | 0.620 | |
| Q3 | 0.890 | | 0.620 | |
| Maximum | 0.89 | | 0.62 | |
| Week 2 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 0.580 | -0.310 | | |
| SD | | | | |
| Minimum | 0.58 | -0.31 | | |
| Q1 | 0.580 | -0.310 | | |
| Median | 0.580 | -0.310 | | |
| Q3 | 0.580 | -0.310 | | |
| Maximum | 0.58 | -0.31 | | |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（58/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 4 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.620 | -0.270 | 0.510 | -0.110 |
| SD | | | | |
| Minimum | 0.62 | -0.27 | 0.51 | -0.11 |
| Q1 | 0.620 | -0.270 | 0.510 | -0.110 |
| Median | 0.620 | -0.270 | 0.510 | -0.110 |
| Q3 | 0.620 | -0.270 | 0.510 | -0.110 |
| Maximum | 0.62 | -0.27 | 0.51 | -0.11 |
| Week 8 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.590 | -0.300 | 0.430 | -0.190 |
| SD | | | | |
| Minimum | 0.59 | -0.30 | 0.43 | -0.19 |
| Q1 | 0.590 | -0.300 | 0.430 | -0.190 |
| Median | 0.590 | -0.300 | 0.430 | -0.190 |
| Q3 | 0.590 | -0.300 | 0.430 | -0.190 |
| Maximum | 0.59 | -0.30 | 0.43 | -0.19 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（59/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 12 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.520 | -0.370 | 0.370 | -0.250 |
| SD | | | | |
| Minimum | 0.52 | -0.37 | 0.37 | -0.25 |
| Q1 | 0.520 | -0.370 | 0.370 | -0.250 |
| Median | 0.520 | -0.370 | 0.370 | -0.250 |
| Q3 | 0.520 | -0.370 | 0.370 | -0.250 |
| Maximum | 0.52 | -0.37 | 0.37 | -0.25 |
| Week 16 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.340 | -0.550 | 0.480 | -0.140 |
| SD | | | | |
| Minimum | 0.34 | -0.55 | 0.48 | -0.14 |
| Q1 | 0.340 | -0.550 | 0.480 | -0.140 |
| Median | 0.340 | -0.550 | 0.480 | -0.140 |
| Q3 | 0.340 | -0.550 | 0.480 | -0.140 |
| Maximum | 0.34 | -0.55 | 0.48 | -0.14 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（60/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 20 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.790 | -0.100 | 0.580 | -0.040 |
| SD | | | | |
| Minimum | 0.79 | -0.10 | 0.58 | -0.04 |
| Q1 | 0.790 | -0.100 | 0.580 | -0.040 |
| Median | 0.790 | -0.100 | 0.580 | -0.040 |
| Q3 | 0.790 | -0.100 | 0.580 | -0.040 |
| Maximum | 0.79 | -0.10 | 0.58 | -0.04 |
| Week 24 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.400 | -0.490 | 0.340 | -0.280 |
| SD | | | | |
| Minimum | 0.40 | -0.49 | 0.34 | -0.28 |
| Q1 | 0.400 | -0.490 | 0.340 | -0.280 |
| Median | 0.400 | -0.490 | 0.340 | -0.280 |
| Q3 | 0.400 | -0.490 | 0.340 | -0.280 |
| Maximum | 0.40 | -0.49 | 0.34 | -0.28 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（61/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 28 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.580 | -0.310 | 0.130 | -0.490 |
| SD | | | | |
| Minimum | 0.58 | -0.31 | 0.13 | -0.49 |
| Q1 | 0.580 | -0.310 | 0.130 | -0.490 |
| Median | 0.580 | -0.310 | 0.130 | -0.490 |
| Q3 | 0.580 | -0.310 | 0.130 | -0.490 |
| Maximum | 0.58 | -0.31 | 0.13 | -0.49 |
| Week 32 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.470 | -0.420 | 0.380 | -0.240 |
| SD | | | | |
| Minimum | 0.47 | -0.42 | 0.38 | -0.24 |
| Q1 | 0.470 | -0.420 | 0.380 | -0.240 |
| Median | 0.470 | -0.420 | 0.380 | -0.240 |
| Q3 | 0.470 | -0.420 | 0.380 | -0.240 |
| Maximum | 0.47 | -0.42 | 0.38 | -0.24 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（62/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 36 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.330 | -0.560 | 0.570 | -0.050 |
| SD | | | | |
| Minimum | 0.33 | -0.56 | 0.57 | -0.05 |
| Q1 | 0.330 | -0.560 | 0.570 | -0.050 |
| Median | 0.330 | -0.560 | 0.570 | -0.050 |
| Q3 | 0.330 | -0.560 | 0.570 | -0.050 |
| Maximum | 0.33 | -0.56 | 0.57 | -0.05 |
| Week 40 | | | | |
| N | 1 | 1 | 1 | 1 |
| Mean | 0.540 | -0.350 | 0.410 | -0.210 |
| SD | | | | |
| Minimum | 0.54 | -0.35 | 0.41 | -0.21 |
| Q1 | 0.540 | -0.350 | 0.410 | -0.210 |
| Median | 0.540 | -0.350 | 0.410 | -0.210 |
| Q3 | 0.540 | -0.350 | 0.410 | -0.210 |
| Maximum | 0.54 | -0.35 | 0.41 | -0.21 |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（63/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 44 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 0.620 | -0.270 | | |
| SD | | | | |
| Minimum | 0.62 | -0.27 | | |
| Q1 | 0.620 | -0.270 | | |
| Median | 0.620 | -0.270 | | |
| Q3 | 0.620 | -0.270 | | |
| Maximum | 0.62 | -0.27 | | |
| Week 48 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 0.290 | -0.600 | | |
| SD | | | | |
| Minimum | 0.29 | -0.60 | | |
| Q1 | 0.290 | -0.600 | | |
| Median | 0.290 | -0.600 | | |
| Q3 | 0.290 | -0.600 | | |
| Maximum | 0.29 | -0.60 | | |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-24　肝機能低下の程度〔観察期終了時（0 週）〕別の乳酸及びピルビン酸の評価時点別変化量（SYR-322/OCT-005 試験）（64/64）

Severity of Liver Function at Baseline (Week 0): AST>2.5xULN or ALT>2.5xULN
Laboratory Test: Pyruvic Acid (mg/dL)

| Visit / Statistics | 12.5 mg (N=1) Observed Value at Visit | 12.5 mg (N=1) Change from Baseline | 25 mg (N=1) Observed Value at Visit | 25 mg (N=1) Change from Baseline |
|---|---|---|---|---|
| Week 52 | | | | |
| N | 1 | 1 | 0 | 0 |
| Mean | 0.590 | -0.300 | | |
| SD | | | | |
| Minimum | 0.59 | -0.30 | | |
| Q1 | 0.590 | -0.300 | | |
| Median | 0.590 | -0.300 | | |
| Q3 | 0.590 | -0.300 | | |
| Maximum | 0.59 | -0.30 | | |

添付資料（5.3.5.3-2）Table 2.3.1.2

## 表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（1/50）

Laboratory Test: RBC ($10^4$ /μL)

| Visit / Statistics | Placebo (N=71) | | QD (N=152) | | BID (N=151) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week -12 | | | | | | |
| N | 71 | | 152 | | 151 | |
| Mean | 468.5 | | 474.9 | | 469.4 | |
| SD | 43.35 | | 38.88 | | 41.28 | |
| Minimum | 332 | | 378 | | 359 | |
| Q1 | 449.0 | | 446.5 | | 443.0 | |
| Median | 467.0 | | 474.0 | | 467.0 | |
| Q3 | 501.0 | | 507.0 | | 495.0 | |
| Maximum | 569 | | 599 | | 584 | |
| Week -4 | | | | | | |
| N | 71 | | 152 | | 151 | |
| Mean | 464.7 | | 470.0 | | 467.2 | |
| SD | 45.96 | | 40.33 | | 41.59 | |
| Minimum | 348 | | 360 | | 360 | |
| Q1 | 434.0 | | 442.0 | | 437.0 | |
| Median | 468.0 | | 470.0 | | 466.0 | |
| Q3 | 498.0 | | 496.5 | | 501.0 | |
| Maximum | 573 | | 613 | | 578 | |

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

## 表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（2/50）

Laboratory Test: RBC ($10^4$ /μL)

| Visit / Statistics | Placebo (N=71) | | QD (N=152) | | BID (N=151) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 0 | | | | | | |
| N | 71 | | 151 | | 151 | |
| Mean | 462.4 | | 466.8 | | 464.6 | |
| SD | 44.62 | | 38.51 | | 44.06 | |
| Minimum | 320 | | 361 | | 333 | |
| Q1 | 434.0 | | 441.0 | | 432.0 | |
| Median | 465.0 | | 471.0 | | 462.0 | |
| Q3 | 492.0 | | 487.0 | | 496.0 | |
| Maximum | 581 | | 575 | | 586 | |
| Week 2 | | | | | | |
| N | 71 | 71 | 152 | 151 | 151 | 151 |
| Mean | 457.9 | -4.4 | 464.2 | -2.4 | 459.4 | -5.2 |
| SD | 45.31 | 15.87 | 39.40 | 18.10 | 41.15 | 17.83 |
| Minimum | 331 | -44 | 368 | -50 | 344 | -49 |
| Q1 | 439.0 | -14.0 | 438.0 | -15.0 | 429.0 | -18.0 |
| Median | 462.0 | -3.0 | 465.5 | -2.0 | 458.0 | -6.0 |
| Q3 | 491.0 | 5.0 | 485.0 | 11.0 | 486.0 | 7.0 |
| Maximum | 552 | 30 | 579 | 45 | 602 | 46 |

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

## 表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（3/50）

Laboratory Test: RBC ($10^4$ /μL)

| Visit / Statistics | Placebo (N=71) | | QD (N=152) | | BID (N=151) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 4 | | | | | | |
| N | 70 | 70 | 150 | 149 | 150 | 150 |
| Mean | 461.7 | -0.6 | 463.7 | -3.4 | 457.3 | -7.7 |
| SD | 48.78 | 19.80 | 39.47 | 16.92 | 41.95 | 16.64 |
| Minimum | 324 | -47 | 367 | -50 | 346 | -43 |
| Q1 | 439.0 | -14.0 | 439.0 | -14.0 | 428.0 | -19.0 |
| Median | 464.0 | 2.5 | 463.5 | -4.0 | 455.0 | -8.0 |
| Q3 | 493.0 | 13.0 | 487.0 | 9.0 | 486.0 | 2.0 |
| Maximum | 557 | 50 | 605 | 33 | 578 | 42 |
| Week 8 | | | | | | |
| N | 68 | 68 | 149 | 148 | 149 | 149 |
| Mean | 460.2 | -1.4 | 461.7 | -4.4 | 455.6 | -9.1 |
| SD | 43.68 | 18.47 | 39.86 | 18.71 | 43.13 | 18.13 |
| Minimum | 353 | -37 | 357 | -54 | 335 | -62 |
| Q1 | 439.5 | -16.5 | 438.0 | -17.0 | 423.0 | -20.0 |
| Median | 461.0 | 0.5 | 461.0 | -6.0 | 451.0 | -8.0 |
| Q3 | 489.0 | 10.0 | 484.0 | 10.0 | 488.0 | 4.0 |
| Maximum | 557 | 38 | 557 | 40 | 579 | 36 |

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1

## 表 2.7.4.7-付録-25　血液学的検査の評価時点別変化量（SYR-322-MET/CCT-001 試験）（4/50）

Laboratory Test: RBC ($10^4$ /μL)

| Visit / Statistics | Placebo (N=71) | | QD (N=152) | | BID (N=151) | |
|---|---|---|---|---|---|---|
| | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline | Observed Value at Visit | Change from Baseline |
| Week 12 | | | | | | |
| N | 67 | 67 | 148 | 147 | 148 | 148 |
| Mean | 462.0 | 0.7 | 460.4 | -5.9 | 457.9 | -7.3 |
| SD | 49.04 | 19.41 | 39.70 | 17.83 | 42.10 | 20.43 |
| Minimum | 348 | -39 | 356 | -48 | 343 | -68 |
| Q1 | 434.0 | -16.0 | 435.5 | -16.0 | 429.5 | -20.5 |
| Median | 465.0 | 1.0 | 464.0 | -6.0 | 453.5 | -7.0 |
| Q3 | 500.0 | 15.0 | 483.0 | 6.0 | 485.0 | 6.0 |
| Maximum | 589 | 44 | 589 | 37 | 582 | 65 |
| Week 16 | | | | | | |
| N | 66 | 66 | 148 | 147 | 147 | 147 |
| Mean | 464.8 | 5.3 | 466.4 | 0.1 | 459.5 | -6.0 |
| SD | 44.89 | 18.60 | 40.67 | 21.44 | 42.61 | 21.85 |
| Minimum | 359 | -39 | 353 | -56 | 329 | -60 |
| Q1 | 434.0 | -9.0 | 439.0 | -17.0 | 434.0 | -21.0 |
| Median | 468.0 | 6.5 | 465.5 | 1.0 | 457.0 | -4.0 |
| Q3 | 494.0 | 18.0 | 491.5 | 15.0 | 486.0 | 3.0 |
| Maximum | 556 | 58 | 574 | 57 | 579 | 57 |

総括報告書（5.3.5.1-1）15.1 Table 3.3.1.1.1