

**Efficacy and Safety of Expanded Hemodialysis with the TheraNova 400 Dialyzer: A  
Randomized Controlled Trial**

**SUPPLEMENTAL MATERIAL**

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**Supplemental Table 1. Reduction Ratio of  $\lambda$  FLC at 24 Weeks– Multiple Imputation \***

| Parameter                            | Dialyzer  | n  | Mean             | Median | Min, Max         | Two-Sided 95% Confidence Interval** |
|--------------------------------------|-----------|----|------------------|--------|------------------|-------------------------------------|
| Reduction Ratio of $\lambda$ FLC (%) | Theranova | 82 | 32.16<br>(12.60) | 32.61  | -33.59,<br>64.40 | <b>10.501, 19.156</b>               |
|                                      | Control   | 79 | 17.51<br>(12.72) | 16.25  | -22.55,<br>74.2  |                                     |

\* Multiple imputations using SAS Proc MI were implemented to impute missing data under the missing at random assumption and 20 datasets generated were analyzed using SAS Proc MIANALYZE.

\*\* If the lower bound of the two-sided 95% confidence interval around the difference between Theranova 400 and the control dialyzer is > 0 then superiority will be demonstrated.

**Supplemental Table 2. Pre-dialysis Serum Albumin Assessment After 24 Weeks – Multiple Imputation\***

| Parameter                         | Dialyzer  | n  | Mean           | Median | Min, Max      | Two-Sided 95% Confidence Interval** |
|-----------------------------------|-----------|----|----------------|--------|---------------|-------------------------------------|
| Pre-dialysis serum albumin (g/dL) | Theranova | 84 | 4.03<br>(0.28) | 4.00   | 3.16,<br>4.84 | <b>-0.098, 0.069</b>                |
|                                   | Control   | 83 | 4.02<br>(0.39) | 4.00   | 2.39,<br>4.95 |                                     |

\* Multiple imputations using SAS Proc MI were implemented to impute missing data under the missing at random assumption and 20 datasets generated were analyzed using SAS Proc MIANALYZE.

\*\* If the lower bound of the two-sided 95% confidence interval around the mean estimated treatment difference between Theranova 400 and the control is > -0.1765 then non-inferiority can be claimed. If the lower bound of the two-sided 95% confidence interval is > 0, then superiority may be concluded.

| Supplemental Table 3. Dialysis Treatment Parameters |            |                         |                         |                          |
|-----------------------------------------------------|------------|-------------------------|-------------------------|--------------------------|
|                                                     |            | Theranova 400           | Elisio-17H              | Total<br>(N=172)         |
| Parameter                                           | Visit Week | n<br>Mean (SD)          | n<br>Mean (SD)          | n<br>Mean (SD)           |
| Ultrafiltration Volume<br>(mL)                      | Week 1     | 86<br>2427.71 (1137.14) | 84<br>2559.32 (1076.38) | 170<br>2492.74 (1106.22) |
|                                                     | Week 4     | 83<br>2323.86 (1087.68) | 80<br>2575.55 (1215.35) | 163<br>2447.39 (1155.45) |
|                                                     | Week 8     | 80<br>2303.93 (1079.03) | 77<br>2673.53 (1249.02) | 157<br>2485.20 (1176.43) |
|                                                     | Week 12    | 78<br>2420.67 (1043.10) | 75<br>2508.71 (1097.85) | 153<br>2463.82 (1067.67) |
|                                                     | Week 16    | 74<br>2440.51 (1072.12) | 72<br>2579.78 (1047.65) | 146<br>2509.19 (1058.77) |
|                                                     | Week 20    | 68<br>2693.57 (1019.25) | 70<br>2617.76 (1220.30) | 138<br>2655.12 (1122.28) |
|                                                     | Week 24    | 64<br>2395.38 (1134.41) | 66<br>2595.56 (1136.94) | 130<br>2497.01 (1135.74) |
| Blood Flow Rate<br>(mL/min)                         | Week 1     | 86<br>398.90 (52.13)    | 84<br>401.90 (61.40)    | 170<br>400.38 (56.75)    |
|                                                     | Week 4     | 83<br>393.35 (49.70)    | 80<br>407.46 (60.53)    | 163<br>400.28 (55.56)    |
|                                                     | Week 8     | 81<br>393.96 (41.92)    | 78<br>412.81 (63.55)    | 159<br>403.20 (54.29)    |
|                                                     | Week 12    | 78<br>387.18 (41.60)    | 75<br>406.58 (59.76)    | 153<br>396.69 (52.06)    |

| Supplemental Table 3. Dialysis Treatment Parameters |            |                      |                      |                       |
|-----------------------------------------------------|------------|----------------------|----------------------|-----------------------|
|                                                     |            | Theranova 400        | Elisio-17H           | Total<br>(N=172)      |
| Parameter                                           | Visit Week | n<br>Mean (SD)       | n<br>Mean (SD)       | n<br>Mean (SD)        |
|                                                     | Week 16    | 74<br>395.16 (44.13) | 72<br>399.43 (60.17) | 146<br>397.26 (52.51) |
|                                                     | Week 20    | 68<br>392.04 (48.08) | 70<br>406.92 (67.78) | 138<br>399.59 (59.16) |
|                                                     | Week 24    | 64<br>389.31 (50.59) | 66<br>397.81 (57.27) | 130<br>393.63 (54.04) |
| Dialysate Flow Rate<br>(mL/min)                     | Week 1     | 86<br>656.98 (88.84) | 84<br>659.52 (93.29) | 170<br>658.24 (90.80) |
|                                                     | Week 4     | 83<br>656.02 (89.85) | 80<br>651.88 (92.59) | 163<br>653.99 (90.95) |
|                                                     | Week 8     | 81<br>651.85 (83.83) | 78<br>653.85 (89.29) | 159<br>652.83 (86.28) |
|                                                     | Week 12    | 78<br>656.41 (90.58) | 75<br>644.00 (87.36) | 153<br>650.33 (88.94) |
|                                                     | Week 16    | 74<br>652.70 (87.93) | 72<br>652.78 (93.41) | 146<br>652.74 (90.36) |
|                                                     | Week 20    | 68<br>651.47 (95.41) | 70<br>645.93 (89.25) | 138<br>648.66 (92.04) |
|                                                     | Week 24    | 64<br>643.75 (90.19) | 66<br>639.39 (92.62) | 130<br>641.54 (91.10) |
| Treatment Time (h)                                  | Week 1     | 86<br>3.71 (0.56)    | 84<br>3.66 (0.57)    | 170<br>3.68 (0.56)    |

| Supplemental Table 3. Dialysis Treatment Parameters |            |                   |                   |                    |
|-----------------------------------------------------|------------|-------------------|-------------------|--------------------|
|                                                     |            | Theranova 400     | Elisio-17H        | Total<br>(N=172)   |
| Parameter                                           | Visit Week | n<br>Mean (SD)    | n<br>Mean (SD)    | n<br>Mean (SD)     |
|                                                     | Week 4     | 83<br>3.71 (0.52) | 80<br>3.72 (0.54) | 163<br>3.71 (0.53) |
|                                                     | Week 8     | 81<br>3.74 (0.53) | 78<br>3.62 (0.58) | 159<br>3.68 (0.56) |
|                                                     | Week 12    | 78<br>3.70 (0.44) | 75<br>3.63 (0.59) | 153<br>3.67 (0.52) |
|                                                     | Week 16    | 74<br>3.70 (0.41) | 72<br>3.73 (0.52) | 146<br>3.72 (0.47) |
|                                                     | Week 20    | 68<br>3.72 (0.48) | 70<br>3.66 (0.60) | 138<br>3.69 (0.54) |
|                                                     | Week 24    | 64<br>3.72 (0.48) | 66<br>3.72 (0.60) | 130<br>3.72 (0.55) |

**Supplemental Table 4. Sensitivity Analysis - Pre-Dialysis Serum Albumin Assessment After 24 Weeks  
Last Observation Carried Forward**

|                                                        | Teranova 400                         | Elisio-17H                           | Theranova 400 - Elisio-17H                         |                                                   |
|--------------------------------------------------------|--------------------------------------|--------------------------------------|----------------------------------------------------|---------------------------------------------------|
| Parameter                                              | n<br>Mean (SD)<br>Median<br>Min, Max | n<br>Mean (SD)<br>Median<br>Min, Max | Mean Estimated<br>Treatment Difference<br>(ANCOVA) | Two-Sided 95%<br>Confidence Interval <sup>1</sup> |
| Pre-dialysis Serum<br>Albumin (g/dL) After 24<br>Weeks | 86                                   | 86                                   |                                                    |                                                   |
|                                                        | 4.03 (0.29)                          | 4.00 (0.41)                          | 0.003                                              | [-0.078, 0.083]                                   |
|                                                        | 4.00                                 | 4.0                                  |                                                    |                                                   |
|                                                        | 3.3, 4.7                             | 2.4, 4.9                             |                                                    |                                                   |

1. If the lower bound of the two-sided 95% confidence interval around the mean estimated treatment difference between Theranova 400 and Elisio 17H is > -0.1765 then non-inferiority can be claimed. If the lower bound of the two-sided 95% confidence interval is > 0, then superiority may be concluded.

Supplemental Table 5. Shift Table of Pre-dialysis Serum Albumin by Visit

|                   |                      |                              | Theranova 400<br>Value at Baseline |            |            |            |             | Elisio-17H<br>Value at Baseline |            |            |          |             |
|-------------------|----------------------|------------------------------|------------------------------------|------------|------------|------------|-------------|---------------------------------|------------|------------|----------|-------------|
| Parameter         | Visit                | Post<br>Baseline<br>Category | < 3.5                              | 3.5-4.0    | 4.0-4.5    | ≥ 4.5      | Total       | < 3.5                           | 3.5-4.0    | 4.0-4.5    | ≥ 4.5    | Total       |
| Albumin<br>(g/dL) | Visit 2<br>(Week 4)  | <3.5                         | 0                                  | 3 (3.5%)   | 0          | 0          | 3 (3.5%)    | 0                               | 2 (2.3%)   | 0          | 0        | 2 (2.3%)    |
|                   |                      | 3.5-4.0                      | 0                                  | 24 (27.9%) | 10 (11.6%) | 2 (2.3%)   | 36 (41.9%)  | 1 (1.2%)                        | 21 (24.4%) | 6 (7.0%)   | 0        | 28 (32.6%)  |
|                   |                      | 4.0-4.5                      | 0                                  | 7 (8.1%)   | 23 (26.7%) | 5 (5.8%)   | 35 (40.7%)  | 0                               | 9 (10.5%)  | 35 (40.7%) | 0        | 44 (51.2%)  |
|                   |                      | ≥ 4.5                        | 0                                  | 0          | 1 (1.2%)   | 5 (5.8%)   | 6 (7.0%)    | 0                               | 0          | 1 (1.2%)   | 2 (2.3%) | 3 (3.5%)    |
|                   |                      | Missing                      | 1 (1.2%)                           | 2 (2.3%)   | 3 (3.5%)   | 0          | 6 (7.0%)    | 1 (1.2%)                        | 4 (4.7%)   | 3 (3.5%)   | 1 (1.2%) | 9 (10.5%)   |
|                   |                      | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |
|                   | Visit 3<br>(Week 8)  | <3.5                         | 1 (1.2%)                           | 5 (5.8%)   | 0          | 0          | 6 (7.0%)    | 0                               | 2 (2.3%)   | 0          | 0        | 2 (2.3%)    |
|                   |                      | 3.5-4.0                      | 0                                  | 21 (24.4%) | 11 (12.8%) | 1 (1.2%)   | 33 (38.4%)  | 1 (1.2%)                        | 18 (20.9%) | 4 (4.7%)   | 0        | 23 (26.7%)  |
|                   |                      | 4.0-4.5                      | 0                                  | 8 (9.3%)   | 20 (23.3%) | 9 (10.5%)  | 37 (43.0%)  | 0                               | 12 (14.0%) | 36 (41.9%) | 2 (2.3%) | 50 (58.1%)  |
|                   |                      | ≥ 4.5                        | 0                                  | 0          | 0          | 2 (2.3%)   | 2 (2.3%)    | 0                               | 0          | 2 (2.3%)   | 0        | 2 (2.3%)    |
|                   |                      | Missing                      | 0                                  | 2 (2.3%)   | 6 (7.0%)   | 0          | 8 (9.3%)    | 1 (1.2%)                        | 4 (4.7%)   | 3 (3.5%)   | 1 (1.2%) | 9 (10.5%)   |
|                   |                      | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |
|                   | Visit 4<br>(Week 12) | <3.5                         | 1 (1.2%)                           | 6 (7.0%)   | 0          | 1 (1.2%)   | 8 (9.3%)    | 1 (1.2%)                        | 3 (3.5%)   | 1 (1.2%)   | 0        | 5 (5.8%)    |
|                   |                      | 3.5-4.0                      | 0                                  | 21 (24.4%) | 12 (14.0%) | 1 (1.2%)   | 34 (39.5%)  | 0                               | 19 (22.1%) | 5 (5.8%)   | 0        | 24 (27.9%)  |
|                   |                      | 4.0-4.5                      | 0                                  | 7 (8.1%)   | 16 (18.6%) | 7 (8.1%)   | 30 (34.9%)  | 0                               | 7 (8.1%)   | 32 (37.2%) | 0        | 39 (45.3%)  |
|                   |                      | ≥ 4.5                        | 0                                  | 0          | 2 (2.3%)   | 3 (3.5%)   | 5 (5.8%)    | 0                               | 0          | 2 (2.3%)   | 2 (2.3%) | 4 (4.7%)    |

**Supplemental Table 5. Shift Table of Pre-dialysis Serum Albumin by Visit**

|           |                      |                              | Theranova 400<br>Value at Baseline |            |            |            |             | Elisio-17H<br>Value at Baseline |            |            |          |             |
|-----------|----------------------|------------------------------|------------------------------------|------------|------------|------------|-------------|---------------------------------|------------|------------|----------|-------------|
| Parameter | Visit                | Post<br>Baseline<br>Category | < 3.5                              | 3.5-4.0    | 4.0-4.5    | ≥ 4.5      | Total       | < 3.5                           | 3.5-4.0    | 4.0-4.5    | ≥ 4.5    | Total       |
|           |                      | Missing                      | 0                                  | 2 (2.3%)   | 7 (8.1%)   | 0          | 9 (10.5%)   | 1 (1.2%)                        | 7 (8.1%)   | 5 (5.8%)   | 1 (1.2%) | 14 (16.3%)  |
|           |                      | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |
|           | Visit 5<br>(Week 16) | <3.5                         | 1 (1.2%)                           | 2 (2.3%)   | 0          | 0          | 3 (3.5%)    | 1 (1.2%)                        | 1 (1.2%)   | 1 (1.2%)   | 0        | 3 (3.5%)    |
|           |                      | 3.5-4.0                      | 0                                  | 24 (27.9%) | 9 (10.5%)  | 4 (4.7%)   | 37 (43.0%)  | 0                               | 19 (22.1%) | 5 (5.8%)   | 0        | 24 (27.9%)  |
|           |                      | 4.0-4.5                      | 0                                  | 4 (4.7%)   | 18 (20.9%) | 6 (7.0%)   | 28 (32.6%)  | 0                               | 9 (10.5%)  | 30 (34.9%) | 1 (1.2%) | 40 (46.5%)  |
|           |                      | ≥ 4.5                        | 0                                  | 0          | 2 (2.3%)   | 2 (2.3%)   | 4 (4.7%)    | 0                               | 0          | 3 (3.5%)   | 1 (1.2%) | 4 (4.7%)    |
|           |                      | Missing                      | 0                                  | 6 (7.0%)   | 8 (9.3%)   | 0          | 14 (16.3%)  | 1 (1.2%)                        | 7 (8.1%)   | 6 (7.0%)   | 1 (1.2%) | 15 (17.4%)  |
|           |                      | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |
|           | Visit 6<br>(Week 20) | <3.5                         | 1 (1.2%)                           | 4 (4.7%)   | 0          | 0          | 5 (5.8%)    | 0                               | 4 (4.7%)   | 0          | 0        | 4 (4.7%)    |
|           |                      | 3.5-4.0                      | 0                                  | 17 (19.8%) | 10 (11.6%) | 3 (3.5%)   | 30 (34.9%)  | 1 (1.2%)                        | 14 (16.3%) | 6 (7.0%)   | 0        | 21 (24.4%)  |
|           |                      | 4.0-4.5                      | 0                                  | 7 (8.1%)   | 16 (18.6%) | 4 (4.7%)   | 27 (31.4%)  | 0                               | 10 (11.6%) | 31 (36.0%) | 1 (1.2%) | 42 (48.8%)  |
|           |                      | ≥ 4.5                        | 0                                  | 0          | 1 (1.2%)   | 3 (3.5%)   | 4 (4.7%)    | 0                               | 0          | 1 (1.2%)   | 1 (1.2%) | 2 (2.3%)    |
|           |                      | Missing                      | 0                                  | 8 (9.3%)   | 10 (11.6%) | 2 (2.3%)   | 20 (23.3%)  | 1 (1.2%)                        | 8 (9.3%)   | 7 (8.1%)   | 1 (1.2%) | 17 (19.8%)  |
|           |                      | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |
|           | Visit 7<br>(Week 24) | <3.5                         | 0                                  | 0          | 0          | 0          | 0           | 0                               | 4 (4.7%)   | 0          | 0        | 4 (4.7%)    |
|           |                      | 3.5-4.0                      | 1 (1.2%)                           | 17 (19.8%) | 5 (5.8%)   | 1 (1.2%)   | 24 (27.9%)  | 1 (1.2%)                        | 14 (16.3%) | 3 (3.5%)   | 0        | 18 (20.9%)  |

**Supplemental Table 5. Shift Table of Pre-dialysis Serum Albumin by Visit**

|           |                 |                              | Theranova 400<br>Value at Baseline |            |            |            |             | Elisio-17H<br>Value at Baseline |            |            |          |             |
|-----------|-----------------|------------------------------|------------------------------------|------------|------------|------------|-------------|---------------------------------|------------|------------|----------|-------------|
| Parameter | Visit           | Post<br>Baseline<br>Category | < 3.5                              | 3.5-4.0    | 4.0-4.5    | ≥ 4.5      | Total       | < 3.5                           | 3.5-4.0    | 4.0-4.5    | ≥ 4.5    | Total       |
|           |                 | 4.0-4.5                      | 0                                  | 11 (12.8%) | 18 (20.9%) | 5 (5.8%)   | 34 (39.5%)  | 0                               | 9 (10.5%)  | 26 (30.2%) | 1 (1.2%) | 36 (41.9%)  |
|           |                 | ≥ 4.5                        | 0                                  | 0          | 2 (2.3%)   | 4 (4.7%)   | 6 (7.0%)    | 0                               | 0          | 6 (7.0%)   | 1 (1.2%) | 7 (8.1%)    |
|           |                 | Missing                      | 0                                  | 8 (9.3%)   | 12 (14.0%) | 2 (2.3%)   | 22 (25.6%)  | 1 (1.2%)                        | 9 (10.5%)  | 10 (11.6%) | 1 (1.2%) | 21 (24.4%)  |
|           |                 | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |
|           | End of<br>Study | <3.5                         | 0                                  | 1 (1.2%)   | 0          | 0          | 1 (1.2%)    | 1 (1.2%)                        | 4 (4.7%)   | 0          | 0        | 5 (5.8%)    |
|           |                 | 3.5-4.0                      | 1 (1.2%)                           | 17 (19.8%) | 12 (14.0%) | 2 (2.3%)   | 32 (37.2%)  | 1 (1.2%)                        | 13 (15.1%) | 7 (8.1%)   | 0        | 21 (24.4%)  |
|           |                 | 4.0-4.5                      | 0                                  | 12 (14.0%) | 16 (18.6%) | 4 (4.7%)   | 32 (37.2%)  | 0                               | 13 (15.1%) | 26 (30.2%) | 2 (2.3%) | 41 (47.7%)  |
|           |                 | ≥ 4.5                        | 0                                  | 0          | 5 (5.8%)   | 5 (5.8%)   | 10 (11.6%)  | 0                               | 1 (1.2%)   | 5 (5.8%)   | 1 (1.2%) | 7 (8.1%)    |
|           |                 | Missing                      | 0                                  | 6 (7.0%)   | 4 (4.7%)   | 1 (1.2%)   | 11 (12.8%)  | 0                               | 5 (5.8%)   | 7 (8.1%)   | 0        | 12 (14.0%)  |
|           |                 | Total                        | 1 (1.2%)                           | 36 (41.9%) | 37 (43.0%) | 12 (14.0%) | 86 (100.0%) | 2 (2.3%)                        | 36 (41.9%) | 45 (52.3%) | 3 (3.5%) | 86 (100.0%) |

| Supplemental Table 6. Pre-Dialysis Coagulation Factors Summary and Change from Baseline |          |                      |                                           |                      |                                           |                                                                              |         |
|-----------------------------------------------------------------------------------------|----------|----------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                                         |          | Theranova 400        |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>MMRM Model Results                             |         |
| Parameter (Unit)                                                                        | Visit    | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Factor VII<br>Activity (%)                                                              | Baseline | 85<br>114.00 (51.03) | N/A                                       | 83<br>120.81 (47.96) | N/A                                       | N/A                                                                          | N/A     |
|                                                                                         | Week 12  | 74<br>116.05 (44.51) | 73<br>3.59 (24.06)                        | 72<br>127.93 (53.16) | 70<br>7.79 (27.80)                        | -6.32 (4.34)                                                                 | 0.15    |
|                                                                                         | Week 24  | 61<br>109.52 (39.21) | 60<br>0.38 (34.57)                        | 64<br>133.33 (63.94) | 63<br>9.19 (48.58)                        | -11.18 (7.15)                                                                | 0.12    |
| Factor II (%)                                                                           | Baseline | 85<br>77.45 (22.85)  | N/A                                       | 83<br>79.20 (22.32)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                                         | Week 12  | 74<br>81.04 (22.33)  | 73<br>3.45 (11.51)                        | 72<br>82.25 (22.29)  | 70<br>3.19 (13.28)                        | -0.25 (2.01)                                                                 | 0.90    |
|                                                                                         | Week 24  | 61<br>80.30 (23.39)  | 60<br>3.85 (11.68)                        | 64<br>86.84 (23.57)  | 63<br>5.78 (15.39)                        | -2.33 (2.37)                                                                 | 0.33    |
| Protein C (%)                                                                           | Baseline | 86<br>84.24 (26.20)  | N/A                                       | 83<br>83.30 (24.16)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                                         | Week 12  | 75<br>85.04 (25.07)  | 75<br>1.12 (15.71)                        | 72<br>85.32 (23.87)  | 70<br>1.76 (16.38)                        | -0.07 (2.49)                                                                 | 0.98    |
|                                                                                         | Week 24  | 63<br>82.95 (22.86)  | 63<br>0.14 (19.38)                        | 64<br>82.78 (24.86)  | 63<br>-1.78 (18.78)                       | 1.72 (2.91)                                                                  | 0.55    |

| <b>Supplemental Table 7. Summary of Normalized Protein Equivalent of Nitrogen Appearance</b> |              |                        |                        |                                                            |                |
|----------------------------------------------------------------------------------------------|--------------|------------------------|------------------------|------------------------------------------------------------|----------------|
|                                                                                              |              | <b>Theranova 400</b>   | <b>Elisio-17H</b>      | <b>Theranova 400 - Elisio-17H<br/>MMRM Model Results</b>   |                |
| <b>Parameter (Unit)</b>                                                                      | <b>Visit</b> | <b>n<br/>Mean (SD)</b> | <b>n<br/>Mean (SD)</b> | <b>Estimated Treatment<br/>Difference<br/>in Mean (SE)</b> | <b>p-Value</b> |
| nPNA(nPCR) (g/kg/d)                                                                          | Week 4       | 78<br>0.98 (0.25)      | 76<br>1.06 (0.31)      | -0.079 (0.045)                                             | 0.08           |
|                                                                                              | Week 8       | 75<br>1.01 (0.24)      | 75<br>1.02 (0.29)      | -0.003 (0.043)                                             | 0.95           |
|                                                                                              | Week 12      | 77<br>0.97 (0.26)      | 70<br>1.03 (0.27)      | -0.062 (0.043)                                             | 0.15           |
|                                                                                              | Week 16      | 69<br>1.02 (0.29)      | 70<br>0.97 (0.29)      | 0.054 (0.047)                                              | 0.25           |
|                                                                                              | Week 20      | 66<br>0.99 (0.27)      | 69<br>1.02 (0.34)      | -0.035 (0.050)                                             | 0.49           |
|                                                                                              | Week 24      | 62<br>0.95 (0.25)      | 65<br>1.01 (0.29)      | -0.066 (0.046)                                             | 0.15           |

| Supplemental Table 8. Comprehensive Metabolic Panel Summary and Change from Baseline |              |                     |                                           |                     |                                           |                                                                              |         |
|--------------------------------------------------------------------------------------|--------------|---------------------|-------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                                      |              | Theranova 400       |                                           | Elisio-17H          |                                           | Theranova 400 - Elisio-17H ANCOVA Model Results                              |         |
| Parameter                                                                            | Visit Week   | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Sodium (mmol/L)                                                                      | Baseline     | 86<br>139.29 (3.05) | N/A                                       | 86<br>138.84 (3.40) | N/A                                       | N/A                                                                          | N/A     |
|                                                                                      | Week 12      | 77<br>138.75 (2.93) | 77<br>-0.49 (2.98)                        | 72<br>138.78 (2.73) | 72<br>0.04 (2.78)                         | N/A                                                                          | N/A     |
|                                                                                      | End of Study | 75<br>139.12 (2.93) | 75<br>-0.20 (3.19)                        | 74<br>138.68 (3.10) | 74<br>0.00 (3.67)                         | 0.20 (0.45)                                                                  | 0.66    |
| Potassium (mmol/L)                                                                   | Baseline     | 86<br>4.87 (0.57)   | N/A                                       | 86<br>4.84 (0.59)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                                      | Week 12      | 77<br>4.89 (0.65)   | 77<br>0.02 (0.69)                         | 72<br>4.87 (0.69)   | 72<br>-0.01 (0.62)                        | N/A                                                                          | N/A     |
|                                                                                      | End of Study | 75<br>4.95 (0.77)   | 75<br>0.08 (0.73)                         | 74<br>4.68 (0.61)   | 74<br>-0.23 (0.67)                        | 0.29 (0.10)                                                                  | 0.0058  |
| Calcium (mmol/L)                                                                     | Baseline     | 86<br>2.30 (0.16)   | N/A                                       | 86<br>2.30 (0.19)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                                      | Week 12      | 77<br>2.24 (0.19)   | 77<br>-0.06 (0.15)                        | 72<br>2.31 (0.21)   | 72<br>0.01 (0.20)                         | N/A                                                                          | N/A     |
|                                                                                      | End of Study | 75<br>2.24 (0.18)   | 75<br>-0.06 (0.15)                        | 74<br>2.29 (0.19)   | 74<br>-0.02 (0.15)                        | -0.05 (0.023)                                                                | 0.034   |
| Phosphate (mmol/L)                                                                   | Baseline     | 86<br>1.78 (0.47)   | N/A                                       | 86<br>1.82 (0.53)   | N/A                                       | N/A                                                                          | N/A     |

| Supplemental Table 8. Comprehensive Metabolic Panel Summary and Change from Baseline |              |                    |                                           |                     |                                           |                                                                              |         |
|--------------------------------------------------------------------------------------|--------------|--------------------|-------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                                      |              | Theranova 400      |                                           | Elisio-17H          |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                            | Visit Week   | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                                      | Week 12      | 77<br>1.71 (0.55)  | 77<br>-0.11 (0.48)                        | 72<br>1.76 (0.52)   | 72<br>-0.05 (0.48)                        | N/A                                                                          | N/A     |
|                                                                                      | End of Study | 75<br>1.80 (0.51)  | 75<br>-0.03 (0.44)                        | 74<br>1.65 (0.57)   | 74<br>-0.19 (0.50)                        | 0.16 (0.071)                                                                 | 0.029   |
| Chloride<br>(mmol/L)                                                                 | Baseline     | 86<br>96.44 (3.50) | N/A                                       | 86<br>96.06 (4.140) | N/A                                       | N/A                                                                          | N/A     |
|                                                                                      | Week 12      | 77<br>96.44 (3.88) | 77<br>-0.01 (3.071)                       | 72<br>96.56 (3.451) | 72<br>0.60 (3.29)                         | N/A                                                                          | N/A     |
|                                                                                      | End of Study | 75<br>96.60 (3.60) | 75<br>0.09 (3.49)                         | 74<br>96.45 (3.480) | 74<br>0.43 (4.11)                         | -0.06 (0.51)                                                                 | 0.907   |
| Bicarbonate<br>(mmol/L)                                                              | Baseline     | 86<br>20.41 (2.66) | N/A                                       | 86<br>19.99 (2.85)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                                      | Week 12      | 77<br>21.57 (2.49) | 77<br>1.26 (2.49)                         | 72<br>21.07 (2.89)  | 72<br>1.08 (2.83)                         | N/A                                                                          | N/A     |
|                                                                                      | End of Study | 75<br>21.60 (2.93) | 75<br>1.31 (3.05)                         | 73<br>21.38 (2.99)  | 73<br>1.37 (3.08)                         | 0.09 (0.44)                                                                  | 0.84    |
| Glucose<br>(mmol/L)                                                                  | Baseline     | 86<br>7.36 (3.17)  | N/A                                       | 86<br>8.39 (4.47)   | N/A                                       | N/A                                                                          | N/A     |

| <b>Supplemental Table 8. Comprehensive Metabolic Panel Summary and Change from Baseline</b> |                   |                        |                                                     |                        |                                                     |                                                                                         |                |
|---------------------------------------------------------------------------------------------|-------------------|------------------------|-----------------------------------------------------|------------------------|-----------------------------------------------------|-----------------------------------------------------------------------------------------|----------------|
|                                                                                             |                   | <b>Theranova 400</b>   |                                                     | <b>Elisio-17H</b>      |                                                     | <b>Theranova 400 - Elisio-17H<br/>ANCOVA Model Results</b>                              |                |
| <b>Parameter</b>                                                                            | <b>Visit Week</b> | <b>n<br/>Mean (SD)</b> | <b>Change from<br/>Baseline<br/>n<br/>Mean (SD)</b> | <b>n<br/>Mean (SD)</b> | <b>Change from<br/>Baseline<br/>n<br/>Mean (SD)</b> | <b>Estimated<br/>Treatment<br/>Difference<br/>in Change from<br/>Baseline Mean (SE)</b> | <b>p-Value</b> |
|                                                                                             | Week 12           | 77<br>7.56 (4.013)     | 77<br>0.18 (2.678)                                  | 72<br>8.50 (4.17)      | 72<br>0.37 (3.65)                                   | N/A                                                                                     | N/A            |
|                                                                                             | End of Study      | 76<br>7.01 (2.80)      | 76<br>-0.20 (2.20)                                  | 75<br>8.85 (4.51)      | 75<br>0.47 (2.86)                                   | -0.97 (0.38)                                                                            | 0.013          |

| Supplemental Table 9. Coagulation Summary and Change from Screening |              |                     |                                           |                     |                                           |                                                                              |         |
|---------------------------------------------------------------------|--------------|---------------------|-------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                     |              | Theranova 400       |                                           | Elisio-17H          |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                           | Visit Week   | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Prothrombin<br>Time (Sec)                                           | Screening    | 83<br>13.89 (6.31)  | N/A                                       | 85<br>13.26 (5.20)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                     | Week 12      | 67<br>13.16 (4.34)  | 66<br>-0.45 (3.59)                        | 70<br>13.18 (6.09)  | 70<br>-0.96 (4.74)                        | N/A                                                                          | N/A     |
|                                                                     | End of Study | 74<br>13.32 (3.75)  | 72<br>-0.04 (4.02)                        | 73<br>13.24 (4.12)  | 73<br>-0.49 (6.31)                        | 0.22 (0.56)                                                                  | 0.69    |
| Prothrombin Intl.<br>Normalized Ratio                               | Screening    | 83<br>1.22 (0.54)   | N/A                                       | 85<br>1.17 (0.44)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                     | Week 12      | 75<br>1.26 (1.15)   | 74<br>0.08 (1.12)                         | 72<br>1.15 (0.52)   | 72<br>-0.08 (0.40)                        | N/A                                                                          | N/A     |
|                                                                     | End of Study | 75<br>1.17 (0.32)   | 73<br>-0.01 (0.34)                        | 76<br>1.16 (0.35)   | 76<br>-0.05 (0.53)                        | 0.02 (0.047)                                                                 | 0.60    |
| Activated Partial<br>Thromboplastin<br>Time (Sec)                   | Screening    | 82<br>39.97 (13.73) | N/A                                       | 84<br>37.56 (9.77)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                     | Week 12      | 72<br>38.27 (17.70) | 70<br>-1.38 (20.42)                       | 69<br>35.34 (7.076) | 68<br>-3.89 (11.37)                       | N/A                                                                          | N/A     |
|                                                                     | End of Study | 72<br>39.55 (14.72) | 69<br>-0.82 (16.68)                       | 73<br>37.32 (11.15) | 72<br>-0.96 (15.42)                       | 1.39 (2.080)                                                                 | 0.51    |

| <b>Supplemental Table 10. Hematology Laboratory Summary and Change from Baseline</b> |                   |                        |                                                     |                        |                                                     |                                                                                         |                |
|--------------------------------------------------------------------------------------|-------------------|------------------------|-----------------------------------------------------|------------------------|-----------------------------------------------------|-----------------------------------------------------------------------------------------|----------------|
|                                                                                      |                   | <b>Theranova 400</b>   |                                                     | <b>Elisio-17H</b>      |                                                     | <b>Theranova 400 - Elisio-17H<br/>ANCOVA Model Results</b>                              |                |
| <b>Parameter</b>                                                                     | <b>Visit Week</b> | <b>n<br/>Mean (SD)</b> | <b>Change from<br/>Baseline<br/>n<br/>Mean (SD)</b> | <b>n<br/>Mean (SD)</b> | <b>Change from<br/>Baseline<br/>n<br/>Mean (SD)</b> | <b>Estimated<br/>Treatment<br/>Difference<br/>in Change from<br/>Baseline Mean (SE)</b> | <b>p-Value</b> |
| Hematocrit (L/L)                                                                     | Baseline          | 86<br>0.36 (0.048)     | N/A                                                 | 86<br>0.36 (0.036)     | N/A                                                 | N/A                                                                                     | N/A            |
|                                                                                      | Week 12           | 75<br>0.38 (0.050)     | 75<br>0.02 (0.043)                                  | 67<br>0.36 (0.038)     | 67<br>0.01 (0.037)                                  | N/A                                                                                     | N/A            |
|                                                                                      | End of Study      | 60<br>0.38 (0.064)     | 60<br>0.03 (0.055)                                  | 54<br>0.37 (0.039)     | 54<br>0.01 (0.042)                                  | 0.02 (0.009)                                                                            | 0.030          |
| Hemoglobin (g/L)                                                                     | Baseline          | 86<br>112.93 (14.83)   | N/A                                                 | 86<br>111.33 (10.98)   | N/A                                                 | N/A                                                                                     | N/A            |
|                                                                                      | Week 12           | 76<br>115.66 (15.62)   | 76<br>2.64 (12.62)                                  | 70<br>111.34 (10.59)   | 70<br>-0.24 (10.68)                                 | N/A                                                                                     | N/A            |
|                                                                                      | End of Study      | 73<br>115.05 (18.51)   | 73<br>2.74 (15.57)                                  | 72<br>111.11 (10.79)   | 72<br>-0.11 (11.22)                                 | 3.24 (2.14)                                                                             | 0.13           |
| Ery. Mean<br>Corpuscular<br>Hemoglobin (pg)                                          | Baseline          | 86<br>30.56 (2.70)     | N/A                                                 | 86<br>30.95 (2.25)     | N/A                                                 | N/A                                                                                     | N/A            |
|                                                                                      | Week 12           | 76<br>30.33 (2.76)     | 76<br>-0.14 (0.98)                                  | 70<br>30.54 (2.47)     | 70<br>-0.33 (0.91)                                  | N/A                                                                                     | N/A            |
|                                                                                      | End of Study      | 73<br>30.45 (2.75)     | 73<br>-0.12 (1.08)                                  | 72<br>30.47 (2.80)     | 72<br>-0.35 (1.15)                                  | 0.22 (0.19)                                                                             | 0.23           |

| Supplemental Table 10. Hematology Laboratory Summary and Change from Baseline |              |                      |                                           |                      |                                           |                                                                              |         |
|-------------------------------------------------------------------------------|--------------|----------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                               |              | Theranova 400        |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                     | Visit Week   | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Ery. Mean<br>Corpuscular HGB<br>Concentration<br>(g/L)                        | Baseline     | 86<br>314.09 (13.15) | N/A                                       | 86<br>313.15 (13.48) | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 76<br>307.26 (15.16) | 76<br>-6.72 (12.44)                       | 69<br>307.30 (14.06) | 69<br>-6.10 (11.42)                       | N/A                                                                          | N/A     |
|                                                                               | End of Study | 71<br>296.10 (15.20) | 71<br>-18.54 (16.05)                      | 65<br>296.62 (19.23) | 65<br>-15.12 (21.08)                      | -1.59 (2.85)                                                                 | 0.58    |
| Ery. Mean<br>Corpuscular<br>Volume (fL)                                       | Baseline     | 86<br>97.19 (8.70)   | N/A                                       | 86<br>98.65 (7.99)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 75<br>98.67 (8.78)   | 75<br>1.79 (3.92)                         | 67<br>99.79 (9.01)   | 67<br>1.12 (3.74)                         | N/A                                                                          | N/A     |
|                                                                               | End of Study | 60<br>101.75 (8.67)  | 60<br>4.88 (5.37)                         | 54<br>101.17 (9.19)  | 54<br>1.93 (4.78)                         | 2.55 (0.92)                                                                  | 0.0067  |
| Platelets (10 <sup>9</sup> /L)                                                | Baseline     | 86<br>223.48 (69.32) | N/A                                       | 86<br>214.09 (55.15) | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 75<br>231.40 (79.90) | 75<br>2.40 (48.04)                        | 70<br>221.79 (67.77) | 70<br>2.17 (44.05)                        | N/A                                                                          | N/A     |
|                                                                               | End of Study | 72<br>216.26 (69.36) | 72<br>-8.65 (41.71)                       | 73<br>224.27 (65.81) | 73<br>7.99 (49.22)                        | -14.93 (7.31)                                                                | 0.043   |
| Erythrocytes<br>(10 <sup>12</sup> /L)                                         | Baseline     | 86<br>3.74 (0.62)    | N/A                                       | 86<br>3.62 (0.39)    | N/A                                       | N/A                                                                          | N/A     |

| Supplemental Table 10. Hematology Laboratory Summary and Change from Baseline |              |                   |                                           |                   |                                           |                                                                              |         |
|-------------------------------------------------------------------------------|--------------|-------------------|-------------------------------------------|-------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                               |              | Theranova 400     |                                           | Elisio-17H        |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                     | Visit Week   | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                               | Week 12      | 76<br>3.86 (0.63) | 76<br>0.10 (0.39)                         | 70<br>3.67 (0.46) | 70<br>0.03 (0.37)                         | N/A                                                                          | N/A     |
|                                                                               | End of Study | 73<br>3.81 (0.67) | 73<br>0.10 (0.48)                         | 73<br>3.67 (0.49) | 73<br>0.04 (0.37)                         | 0.07 (0.070)                                                                 | 0.33    |
| Leukocytes<br>(10 <sup>9</sup> /L)                                            | Baseline     | 86<br>7.04 (2.24) | N/A                                       | 86<br>6.89 (1.90) | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 76<br>7.18 (2.41) | 76<br>0.08 (1.63)                         | 70<br>7.18 (2.91) | 70<br>0.08 (2.20)                         | N/A                                                                          | N/A     |
|                                                                               | End of Study | 73<br>6.84 (2.13) | 73<br>-0.22 (1.64)                        | 72<br>7.42 (2.70) | 72<br>0.49 (2.46)                         | -0.67 (0.33)                                                                 | 0.046   |
| Basophils (%)                                                                 | Baseline     | 86<br>0.48 (0.27) | N/A                                       | 86<br>0.46 (0.29) | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 77<br>0.51 (0.31) | 77<br>0.02 (0.33)                         | 71<br>0.45 (0.25) | 71<br>-0.03 (0.27)                        | N/A                                                                          | N/A     |
|                                                                               | End of Study | 76<br>0.54 (0.40) | 76<br>0.05 (0.37)                         | 75<br>0.45 (0.40) | 75<br>-0.02 (0.41)                        | 0.08 (0.060)                                                                 | 0.19    |
| Eosinophils (%)                                                               | Baseline     | 86<br>4.14 (3.92) | N/A                                       | 86<br>4.07 (2.80) | N/A                                       | N/A                                                                          | N/A     |

| Supplemental Table 10. Hematology Laboratory Summary and Change from Baseline |              |                    |                                           |                     |                                           |                                                                              |         |
|-------------------------------------------------------------------------------|--------------|--------------------|-------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                               |              | Theranova 400      |                                           | Elisio-17H          |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                     | Visit Week   | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                               | Week 12      | 77<br>4.14 (3.52)  | 77<br>-0.10 (1.84)                        | 71<br>4.07 (2.56)   | 71<br>-0.26 (1.72)                        | N/A                                                                          | N/A     |
|                                                                               | End of Study | 76<br>4.30 (3.19)  | 76<br>0.17 (3.26)                         | 75<br>3.88 (3.00)   | 75<br>-0.29 (2.40)                        | 0.44 (0.39)                                                                  | 0.26    |
|                                                                               |              |                    |                                           |                     |                                           |                                                                              |         |
| Lymphocytes (%)                                                               | Baseline     | 86<br>24.16 (7.26) | N/A                                       | 86<br>24.38 (7.003) | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 77<br>24.17 (8.12) | 77<br>0.05 (5.86)                         | 71<br>25.81 (8.83)  | 71<br>1.28 (6.98)                         | N/A                                                                          | N/A     |
|                                                                               | End of Study | 76<br>24.40 (7.37) | 76<br>0.14 (6.98)                         | 75<br>24.01 (8.17)  | 75<br>-0.69 (8.052)                       | 0.63 (1.10)                                                                  | 0.57    |
| Monocytes (%)                                                                 | Baseline     | 86<br>7.78 (2.58)  | N/A                                       | 86<br>7.94 (3.014)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                               | Week 12      | 77<br>7.35 (2.29)  | 77<br>-0.54 (2.25)                        | 71<br>7.44 (2.33)   | 71<br>-0.35 (2.37)                        | N/A                                                                          | N/A     |
|                                                                               | End of Study | 76<br>7.37 (2.80)  | 76<br>-0.49 (2.26)                        | 75<br>6.92 (2.97)   | 75<br>-1.07 (3.48)                        | 0.51 (0.41)                                                                  | 0.22    |
| Neutrophils (%)                                                               | Baseline     | 86<br>63.40 (8.53) | N/A                                       | 86<br>63.15 (8.61)  | N/A                                       | N/A                                                                          | N/A     |

| Supplemental Table 10. Hematology Laboratory Summary and Change from Baseline |              |                    |                                           |                     |                                           |                                                                              |         |
|-------------------------------------------------------------------------------|--------------|--------------------|-------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                               |              | Theranova 400      |                                           | Elisio-17H          |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                     | Visit Week   | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                               | Week 12      | 77<br>63.81 (9.87) | 77<br>0.58 (7.19)                         | 71<br>62.23 (10.54) | 71<br>-0.65 (8.30)                        | N/A                                                                          | N/A     |
|                                                                               | End of Study | 76<br>63.38 (8.95) | 76<br>0.16 (8.74)                         | 75<br>64.65 (8.86)  | 75<br>1.98 (9.49)                         | -1.53 (1.292)                                                                | 0.2386  |

| Supplemental Table 11. Small Uremic Solutes Summary and Change from Baseline |            |                    |                                           |                    |                                           |                                                                              |         |
|------------------------------------------------------------------------------|------------|--------------------|-------------------------------------------|--------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                              |            | Theranova 400      |                                           | Elisio-17H         |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                    | Visit Week | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Pre-Dialysis<br>Blood Urea<br>Nitrogen<br>(mmol/L)                           | Screening  | 83<br>19.37 (5.49) | N/A                                       | 84<br>20.49 (5.65) | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 4     | 80<br>18.86 (5.84) | 78<br>-0.60 (4.36)                        | 77<br>20.23 (6.38) | 77<br>-0.27 (5.69)                        | N/A                                                                          | N/A     |
|                                                                              | Week 8     | 78<br>19.06 (5.59) | 76<br>-0.24 (5.03)                        | 77<br>20.11 (6.67) | 76<br>-0.47 (5.75)                        | N/A                                                                          | N/A     |
|                                                                              | Week 12    | 77<br>18.37 (5.82) | 75<br>-1.35 (5.59)                        | 72<br>20.15 (6.21) | 71<br>-0.08 (5.06)                        | N/A                                                                          | N/A     |
|                                                                              | Week 16    | 72<br>19.56 (6.42) | 70<br>-0.27 (5.56)                        | 71<br>18.40 (6.36) | 70<br>-2.05 (4.97)                        | N/A                                                                          | N/A     |
|                                                                              | Week 20    | 66<br>18.71 (5.78) | 64<br>-1.58 (5.49)                        | 69<br>19.67 (6.67) | 68<br>-0.66 (5.33)                        | N/A                                                                          | N/A     |
|                                                                              | Week 24    | 64<br>18.42 (5.63) | 63<br>-1.82 (5.30)                        | 65<br>19.66 (6.20) | 64<br>-0.69 (4.78)                        | -1.14 (0.84)                                                                 | 0.18    |
| Post-Dialysis<br>Blood Urea<br>Nitrogen<br>(mmol/L)                          | Screening  | 83<br>5.39 (2.07)  | N/A                                       | 85<br>5.74 (1.85)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 4     | 79<br>4.87 (1.95)  | 79<br>-0.64 (1.93)                        | 77<br>5.29 (2.021) | 77<br>-0.72 (2.42)                        | N/A                                                                          | N/A     |
|                                                                              | Week 8     | 76<br>4.86 (1.99)  | 75<br>-0.78 (2.16)                        | 76<br>5.90 (4.46)  | 76<br>-0.12 (4.06)                        | N/A                                                                          | N/A     |

| Supplemental Table 11. Small Uremic Solutes Summary and Change from Baseline |            |                    |                                           |                     |                                           |                                                                              |         |
|------------------------------------------------------------------------------|------------|--------------------|-------------------------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                              |            | Theranova 400      |                                           | Elisio-17H          |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                    | Visit Week | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                              | Week 12    | 77<br>4.86 (2.05)  | 76<br>-0.82 (2.30)                        | 70<br>5.40 (2.30)   | 70<br>-0.52 (2.45)                        | N/A                                                                          | N/A     |
|                                                                              | Week 16    | 70<br>5.29 (2.27)  | 69<br>-0.57 (2.39)                        | 70<br>4.92 (2.16)   | 70<br>-1.12 (2.53)                        | N/A                                                                          | N/A     |
|                                                                              | Week 20    | 67<br>4.99 (1.92)  | 66<br>-0.93 (2.36)                        | 69<br>5.31 (2.21)   | 69<br>-0.71 (2.52)                        | N/A                                                                          | N/A     |
|                                                                              | Week 24    | 62<br>5.25 (2.73)  | 61<br>-0.53 (2.36)                        | 65<br>5.45 (2.16)   | 65<br>-0.57 (2.07)                        | -0.09 (0.36)                                                                 | 0.81    |
| Urea Reduction<br>Ratio                                                      | Screening  | 81<br>72.11 (6.19) | N/A                                       | 84<br>71.45 (7.36)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 4     | 78<br>74.23 (5.66) | 75<br>1.82 (5.66)                         | 76<br>73.30 (8.07)  | 75<br>2.09 (7.04)                         | N/A                                                                          | N/A     |
|                                                                              | Week 8     | 76<br>74.98 (5.42) | 72<br>3.10 (6.56)                         | 76<br>71.68 (10.24) | 74<br>0.35 (9.15)                         | N/A                                                                          | N/A     |
|                                                                              | Week 12    | 77<br>73.75 (6.43) | 73<br>1.77 (6.89)                         | 70<br>72.99 (6.72)  | 68<br>1.79 (7.83)                         | N/A                                                                          | N/A     |
|                                                                              | Week 16    | 70<br>73.28 (6.20) | 66<br>1.97 (6.38)                         | 70<br>73.30 (6.20)  | 68<br>2.11 (7.77)                         | N/A                                                                          | N/A     |
|                                                                              | Week 20    | 66<br>73.17 (7.55) | 62<br>1.80 (8.07)                         | 69<br>72.56 (8.01)  | 67<br>1.72 (8.34)                         | N/A                                                                          | N/A     |

| Supplemental Table 11. Small Uremic Solutes Summary and Change from Baseline |              |                       |                                           |                       |                                           |                                                                              |         |
|------------------------------------------------------------------------------|--------------|-----------------------|-------------------------------------------|-----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                              |              | Theranova 400         |                                           | Elisio-17H            |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                    | Visit Week   | n<br>Mean (SD)        | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)        | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                              | Week 24      | 62<br>71.74 (8.80)    | 60<br>0.33 (9.30)                         | 65<br>71.79 (8.88)    | 63<br>0.68 (8.96)                         | -0.06 (1.50)                                                                 | 0.97    |
| Creatinine<br>(μmol/L)                                                       | Baseline     | 86<br>837.24 (237.92) | N/A                                       | 86<br>802.01 (232.99) | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 12      | 77<br>821.62 (231.96) | 77<br>-29.86 (112.10)                     | 72<br>803.50 (227.60) | 72<br>0.36 (121.96)                       | N/A                                                                          | N/A     |
|                                                                              | End of Study | 75<br>833.08 (243.15) | 75<br>-17.45 (160.34)                     | 74<br>772.04 (242.83) | 74<br>-36.44 (153.17)                     | 27.34 (24.62)                                                                | 0.27    |

| Supplemental Table 12. Vitamin A and Lipids Summary and Change from Baseline |              |                   |                                           |                   |                                           |                                                                              |         |
|------------------------------------------------------------------------------|--------------|-------------------|-------------------------------------------|-------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                              |              | Theranova 400     |                                           | Elisio-17H        |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                    | Visit Week   | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Vitamin A<br>(µmol/L)                                                        | Baseline     | 81<br>2.70 (1.19) | N/A                                       | 82<br>2.67 (1.17) | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 4       | 79<br>2.45 (1.19) | 75<br>-0.29 (0.98)                        | 76<br>2.62 (1.18) | 74<br>-0.04 (0.94)                        | N/A                                                                          | N/A     |
|                                                                              | Week 24      | 62<br>2.51 (1.04) | 59<br>-0.33 (0.83)                        | 63<br>2.64 (1.14) | 61<br>-0.15 (1.10)                        | -0.16 (0.15)                                                                 | 0.30    |
|                                                                              | End of Study | 61<br>2.43 (1.03) | 58<br>-0.35 (0.83)                        | 59<br>2.69 (1.17) | 58<br>-0.01 (0.90)                        | N/A                                                                          | N/A     |
| Cholesterol<br>(mmol/L)                                                      | Baseline     | 86<br>4.04 (1.05) | N/A                                       | 86<br>4.04 (0.95) | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 12      | 77<br>4.01 (0.96) | 77<br>-0.07 (0.64)                        | 72<br>3.83 (0.98) | 72<br>-0.17 (0.48)                        | N/A                                                                          | N/A     |
|                                                                              | End of Study | 75<br>3.88 (1.03) | 75<br>-0.19 (0.77)                        | 74<br>3.89 (1.10) | 74<br>-0.24 (0.71)                        | 0.04 (0.12)                                                                  | 0.72    |
| HDL Cholesterol<br>(mmol/L)                                                  | Baseline     | 86<br>1.28 (0.39) | N/A                                       | 86<br>1.25 (0.39) | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 12      | 77<br>1.32 (0.45) | 77<br>0.05 (0.26)                         | 72<br>1.20 (0.37) | 72<br>-0.02 (0.17)                        | N/A                                                                          | N/A     |

| Supplemental Table 12. Vitamin A and Lipids Summary and Change from Baseline |              |                   |                                           |                    |                                           |                                                                              |         |
|------------------------------------------------------------------------------|--------------|-------------------|-------------------------------------------|--------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                              |              | Theranova 400     |                                           | Elisio-17H         |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                                    | Visit Week   | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                              | End of Study | 75<br>1.32 (0.39) | 75<br>0.04 (0.27)                         | 74<br>1.24 (0.47)  | 74<br>-0.03 (0.28)                        | 0.07 (0.04)                                                                  | 0.097   |
| LDL Cholesterol<br>(mmol/L)                                                  | Baseline     | 86<br>2.25 (0.89) | N/A                                       | 86<br>2.28 (0.98)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 12      | 77<br>2.27 (0.89) | 77<br>-0.03 (0.59)                        | 72<br>2.09 (0.91)  | 72<br>-0.16 (0.65)                        | N/A                                                                          | N/A     |
|                                                                              | End of Study | 75<br>2.21 (0.92) | 75<br>-0.07 (0.66)                        | 74<br>2.18 (1.039) | 74<br>-0.18 (0.81)                        | 0.09 (0.11)                                                                  | 0.45    |
| Triglycerides<br>(mmol/L)                                                    | Baseline     | 86<br>1.57 (0.84) | N/A                                       | 86<br>1.76 (1.01)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                              | Week 12      | 77<br>1.43 (0.67) | 77<br>-0.16 (0.56)                        | 72<br>1.70 (0.96)  | 72<br>-0.10 (0.60)                        | N/A                                                                          | N/A     |
|                                                                              | End of Study | 75<br>1.44 (0.71) | 75<br>-0.15 (0.66)                        | 74<br>1.75 (1.10)  | 74<br>-0.02 (0.67)                        | -0.18 (0.10)                                                                 | 0.073   |

| Supplemental Table 13. Liver Function Summary and Change from Screening |              |                      |                                           |                      |                                           |                                                                              |         |
|-------------------------------------------------------------------------|--------------|----------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                         |              | Theranova 400        |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                               | Visit Week   | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Alkaline Phosphatase<br>(U/L)                                           | Screening    | 83<br>109.18 (55.64) | N/A                                       | 84<br>103.74 (39.50) | N/A                                       | N/A                                                                          | N/A     |
|                                                                         | Week 12      | 77<br>108.49 (46.39) | 75<br>3.27 (26.50)                        | 72<br>110.18 (45.39) | 71<br>1.38 (28.64)                        | N/A                                                                          | N/A     |
|                                                                         | End of Study | 75<br>104.85 (45.26) | 74<br>-1.97 (37.78)                       | 74<br>107.68 (44.74) | 73<br>2.19 (32.73)                        | -3.42 (5.47)                                                                 | 0.53    |
| Alanine<br>Aminotransferase<br>(U/L)                                    | Screening    | 82<br>15.11 (9.59)   | N/A                                       | 82<br>14.27 (7.34)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                         | Week 12      | 73<br>14.29 (13.99)  | 70<br>-1.39 (14.73)                       | 68<br>13.41 (5.46)   | 67<br>-1.25 (6.37)                        | N/A                                                                          | N/A     |
|                                                                         | End of Study | 72<br>13.40 (6.19)   | 70<br>-2.17 (8.17)                        | 72<br>13.75 (8.54)   | 70<br>-0.51 (8.018)                       | -1.11 (1.076)                                                                | 0.30    |
| Aspartate<br>Aminotransferase<br>(U/L)                                  | Screening    | 82<br>15.95 (7.57)   | N/A                                       | 82<br>14.90 (5.25)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                         | Week 12      | 75<br>15.95 (18.46)  | 72<br>0.68 (18.68)                        | 69<br>15.03 (4.96)   | 67<br>-0.19 (4.95)                        | N/A                                                                          | N/A     |
|                                                                         | End of Study | 71<br>14.99 (6.65)   | 69<br>-0.75 (6.82)                        | 70<br>15.30 (6.63)   | 69<br>-0.01 (5.87)                        | -0.58 (0.98)                                                                 | 0.55    |
| Direct Bilirubin<br>(µmol/L)                                            | Screening    | 11<br>4.75 (2.29)    | N/A                                       | 15<br>3.82 (1.004)   | N/A                                       | N/A                                                                          | N/A     |

| Supplemental Table 13. Liver Function Summary and Change from Screening |              |                      |                                           |                      |                                           |                                                                              |         |
|-------------------------------------------------------------------------|--------------|----------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                         |              | Theranova 400        |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                               | Visit Week   | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                         | Week 12      | 9<br>3.79 (0.47)     | 5<br>-0.10 (0.72)                         | 11<br>3.95 (0.62)    | 7<br>-0.10 (1.11)                         | N/A                                                                          | N/A     |
|                                                                         | End of Study | 4<br>5.28 (2.34)     | 3<br>1.53 (2.60)                          | 13<br>4.11 (1.41)    | 7<br>0.23 (1.11)                          | 1.34 (1.18)                                                                  | 0.30    |
| Bilirubin (μmol/L)                                                      | Screening    | 83<br>7.53 (2.99)    | N/A                                       | 84<br>7.91 (2.68)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                         | Week 12      | 77<br>7.02 (2.45)    | 75<br>-0.28 (2.28)                        | 72<br>7.54 (2.65)    | 71<br>-0.53 (2.11)                        | N/A                                                                          | N/A     |
|                                                                         | End of Study | 73<br>6.42 (2.87)    | 72<br>-1.06 (2.96)                        | 74<br>7.39 (2.65)    | 73<br>-0.66 (2.040)                       | -0.63 (0.38)                                                                 | 0.10    |
| Gamma Glutamyl<br>Transferase (U/L)                                     | Screening    | 83<br>31.18 (30.81)  | N/A                                       | 84<br>33.89 (39.10)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                         | Week 12      | 77<br>32.09 (32.013) | 75<br>1.37 (21.13)                        | 72<br>32.64 (33.081) | 71<br>-1.63 (14.56)                       | N/A                                                                          | N/A     |
|                                                                         | End of Study | 75<br>30.19 (29.76)  | 74<br>-0.66 (22.59)                       | 74<br>32.42 (32.90)  | 73<br>-1.68 (21.72)                       | 0.02 (3.18)                                                                  | 0.10    |

| Supplemental Table 14. Proteins Summary and Change from Baseline |              |                    |                                           |                    |                                           |                                                                              |         |
|------------------------------------------------------------------|--------------|--------------------|-------------------------------------------|--------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                  |              | Theranova 400      |                                           | Elisio-17H         |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                        | Visit Week   | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Protein (g/L)                                                    | Screening    | 83<br>70.23 (5.45) | N/A                                       | 84<br>70.18 (5.80) | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 12      | 77<br>69.21 (4.70) | 75<br>-0.89 (4.10)                        | 72<br>70.15 (6.14) | 71<br>-0.06 (4.32)                        | N/A                                                                          | N/A     |
|                                                                  | End of Study | 75<br>68.57 (4.56) | 74<br>-1.55 (4.58)                        | 74<br>69.58 (6.95) | 73<br>-0.95 (4.22)                        | -0.71 (0.69)                                                                 | 0.31    |
| Globulin (g/L)                                                   | Screening    | 83<br>30.47 (5.49) | N/A                                       | 84<br>30.35 (5.52) | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 12      | 77<br>30.00 (4.79) | 75<br>-0.41 (3.18)                        | 72<br>30.40 (5.00) | 71<br>0.11 (3.42)                         | N/A                                                                          | N/A     |
|                                                                  | End of Study | 75<br>28.29 (4.85) | 74<br>-2.07 (3.64)                        | 74<br>29.39 (5.64) | 73<br>-1.27 (3.22)                        | -0.85 (0.53)                                                                 | 0.11    |
| High-sensitivity<br>C-reactive Protein<br>(mg/L)                 | Baseline     | 75<br>5.71 (5.064) | N/A                                       | 77<br>7.34 (5.59)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4       | 70<br>5.07 (5.075) | 64<br>-0.20 (3.77)                        | 67<br>6.97 (5.61)  | 59<br>-0.44 (4.22)                        | N/A                                                                          | N/A     |
|                                                                  | Week 8       | 65<br>6.16 (5.62)  | 61<br>0.36 (3.92)                         | 68<br>7.13 (6.00)  | 61<br>-0.41 (5.34)                        | N/A                                                                          | N/A     |
|                                                                  | Week 12      | 68<br>5.65 (5.30)  | 64<br>-0.01 (4.42)                        | 61<br>7.10 (5.63)  | 56<br>-0.06 (4.42)                        | N/A                                                                          | N/A     |

| Supplemental Table 14. Proteins Summary and Change from Baseline |            |                   |                                           |                   |                                           |                                                                              |         |
|------------------------------------------------------------------|------------|-------------------|-------------------------------------------|-------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                  |            | Theranova 400     |                                           | Elisio-17H        |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                        | Visit Week | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                  | Week 16    | 62<br>4.91 (4.36) | 56<br>-0.56 (4.40)                        | 60<br>7.31 (5.61) | 55<br>-0.46 (4.56)                        | N/A                                                                          | N/A     |
|                                                                  | Week 20    | 59<br>5.50 (4.83) | 52<br>-0.43 (4.052)                       | 59<br>5.94 (5.14) | 54<br>-0.88 (4.61)                        | N/A                                                                          | N/A     |
|                                                                  | Week 24    | 53<br>4.42 (4.12) | 47<br>-0.96 (4.17)                        | 53<br>6.63 (5.58) | 49<br>-0.40 (4.60)                        | -1.44 (0.80)                                                                 | 0.08    |
| Albumin (g/dL)                                                   | Baseline   | 86<br>4.04 (0.31) | N/A                                       | 86<br>4.00 (0.28) | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4     | 80<br>3.97 (0.31) | 80<br>-0.08 (0.24)                        | 77<br>4.01 (0.28) | 77<br>0.00 (0.20)                         | N/A                                                                          | N/A     |
|                                                                  | Week 8     | 78<br>3.93 (0.28) | 78<br>-0.11 (0.25)                        | 77<br>4.01 (0.26) | 77<br>0.00 (0.22)                         | N/A                                                                          | N/A     |
|                                                                  | Week 12    | 77<br>3.92 (0.34) | 77<br>-0.12 (0.29)                        | 72<br>3.97 (0.33) | 72<br>-0.04 (0.23)                        | N/A                                                                          | N/A     |
|                                                                  | Week 16    | 72<br>3.93 (0.37) | 72<br>-0.13 (0.34)                        | 71<br>3.99 (0.38) | 71<br>-0.03 (0.32)                        | N/A                                                                          | N/A     |
|                                                                  | Week 20    | 66<br>3.95 (0.34) | 66<br>-0.08 (0.28)                        | 69<br>4.04 (0.31) | 69<br>0.02 (0.26)                         | N/A                                                                          | N/A     |
|                                                                  | Week 24    | 64<br>4.04 (0.28) | 64<br>0.01 (0.25)                         | 65<br>4.06 (0.35) | 65<br>0.04 (0.26)                         | -0.03 (0.042)                                                                | 0.45    |

| Supplemental Table 14. Proteins Summary and Change from Baseline |                            |                      |                                           |                      |                                           |                                                                              |         |
|------------------------------------------------------------------|----------------------------|----------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                  |                            | Theranova 400        |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                        | Visit Week                 | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                  | End of Study               | 75<br>4.03 (0.35)    | 75<br>-0.02 (0.30)                        | 74<br>4.02 (0.43)    | 74<br>0.01 (0.32)                         | N/A                                                                          | N/A     |
| Tumor Necrosis<br>Factor (pg/mL)                                 | Baseline                   | 86<br>7.86 (2.88)    | N/A                                       | 85<br>7.12 (1.96)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4                     | 80<br>7.84 (2.77)    | 80<br>-0.09 (1.62)                        | 78<br>7.41 (1.99)    | 78<br>0.30 (1.56)                         | N/A                                                                          | N/A     |
|                                                                  | Week 4(Post-<br>Dialysis)  | 81<br>4.17 (2.30)    | N/A                                       | 78<br>4.60 (1.41)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 24                    | 64<br>7.33 (1.99)    | 64<br>-0.47 (2.00)                        | 65<br>7.15 (2.035)   | 65<br>0.08 (1.65)                         | -0.26 (0.29)                                                                 | 0.38    |
|                                                                  | Week 24(Post-<br>Dialysis) | 63<br>4.02 (1.08)    | N/A                                       | 65<br>4.65 (1.45)    | N/A                                       | N/A                                                                          | N/A     |
| λ Light Chain,<br>Free (mg/L)                                    | Baseline                   | 86<br>139.62 (56.07) | N/A                                       | 86<br>138.12 (65.43) | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4                     | 80<br>126.41 (49.09) | 80<br>-13.46 (20.51)                      | 77<br>142.31 (63.53) | 77<br>2.08 (22.11)                        | N/A                                                                          | N/A     |
|                                                                  | Week 4(Post-<br>Dialysis)  | 81<br>85.61 (40.80)  | N/A                                       | 76<br>128.25 (69.73) | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 24                    | 64<br>124.48 (42.99) | 64<br>-19.40 (31.64)                      | 65<br>136.56 (63.52) | 65<br>1.75 (29.95)                        | -19.56 (5.17)                                                                | <0.001  |

| Supplemental Table 14. Proteins Summary and Change from Baseline |                        |                     |                                           |                      |                                           |                                                                              |         |
|------------------------------------------------------------------|------------------------|---------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                  |                        | Theranova 400       |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                        | Visit Week             | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                  | Week 24(Post-Dialysis) | 63<br>94.08 (36.61) | N/A                                       | 65<br>125.11 (61.26) | N/A                                       | N/A                                                                          | N/A     |
| Interleukin 6<br>(pg/mL)                                         | Baseline               | 85<br>3.60 (3.72)   | N/A                                       | 84<br>3.14 (3.27)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4                 | 80<br>3.59 (5.48)   | 79<br>0.18 (4.82)                         | 78<br>3.24 (3.20)    | 77<br>0.02 (1.93)                         | N/A                                                                          | N/A     |
|                                                                  | Week 4(Post-Dialysis)  | 81<br>3.23 (4.40)   | N/A                                       | 78<br>3.51 (3.39)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 24                | 64<br>3.53 (5.28)   | 64<br>0.20 (5.45)                         | 65<br>4.82 (7.19)    | 65<br>1.64 (6.47)                         | -1.39 (1.04)                                                                 | 0.18    |
|                                                                  | Week 24(Post-Dialysis) | 63<br>3.06 (3.64)   | N/A                                       | 65<br>4.73 (5.42)    | N/A                                       | N/A                                                                          | N/A     |
| Complement<br>Factor D<br>(mcg/mL)                               | Baseline               | 85<br>28.66 (7.04)  | N/A                                       | 85<br>27.91 (8.32)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4                 | 83<br>26.74 (6.56)  | 82<br>-1.82 (5.60)                        | 78<br>27.77 (8.05)   | 78<br>-0.03 (6.19)                        | N/A                                                                          | N/A     |
|                                                                  | Week 4(Post-Dialysis)  | 83<br>16.45 (5.80)  | N/A                                       | 76<br>23.73 (7.13)   | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 24                | 63<br>28.87 (5.61)  | 62<br>0.13 (4.74)                         | 65<br>29.03 (6.86)   | 65<br>1.89 (4.84)                         | -1.24 (0.74)                                                                 | 0.096   |

| Supplemental Table 14. Proteins Summary and Change from Baseline |                        |                       |                                           |                       |                                           |                                                                              |         |
|------------------------------------------------------------------|------------------------|-----------------------|-------------------------------------------|-----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                  |                        | Theranova 400         |                                           | Elisio-17H            |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                        | Visit Week             | n<br>Mean (SD)        | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)        | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                  | Week 24(Post-Dialysis) | 63<br>17.74 (4.49)    | N/A                                       | 65<br>24.75 (6.37)    | N/A                                       | N/A                                                                          | N/A     |
| κ Light Chain,<br>Free (mg/L)                                    | Baseline               | 86<br>256.71 (148.22) | N/A                                       | 86<br>250.08 (134.72) | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4                 | 80<br>208.11 (96.56)  | 80<br>-49.08 (73.82)                      | 77<br>237.26 (117.35) | 77<br>-11.92 (67.00)                      | N/A                                                                          | N/A     |
|                                                                  | Week 4(Post-Dialysis)  | 81<br>70.37 (42.85)   | N/A                                       | 76<br>113.09 (51.72)  | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 24                | 64<br>176.72 (75.38)  | 64<br>-84.81 (97.36)                      | 65<br>202.09 (106.95) | 65<br>-43.01 (75.68)                      | -34.02 (10.23)                                                               | 0.0012  |
|                                                                  | Week 24(Post-Dialysis) | 63<br>70.41 (33.46)   | N/A                                       | 65<br>110.04 (54.94)  | N/A                                       | N/A                                                                          | N/A     |
| β2-Microglobulin<br>(mg/L)                                       | Baseline               | 86<br>32.45 (8.73)    | N/A                                       | 84<br>30.68 (9.15)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 4                 | 80<br>30.10 (8.51)    | 80<br>-2.39 (5.75)                        | 77<br>30.61 (7.59)    | 76<br>0.03 (7.18)                         | N/A                                                                          | N/A     |
|                                                                  | Week 4(Post-Dialysis)  | 79<br>8.20 (4.00)     | N/A                                       | 77<br>11.89 (4.13)    | N/A                                       | N/A                                                                          | N/A     |
|                                                                  | Week 24                | 64<br>29.80 (7.12)    | 64<br>-3.95 (5.61)                        | 65<br>28.68 (6.76)    | 64<br>-1.16 (6.13)                        | -1.17 (0.86)                                                                 | 0.18    |

| Supplemental Table 14. Proteins Summary and Change from Baseline |                        |                   |                                           |                    |                                           |                                                                              |         |
|------------------------------------------------------------------|------------------------|-------------------|-------------------------------------------|--------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
|                                                                  |                        | Theranova 400     |                                           | Elisio-17H         |                                           | Theranova 400 - Elisio-17H<br>ANCOVA Model Results                           |         |
| Parameter                                                        | Visit Week             | n<br>Mean (SD)    | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)     | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
|                                                                  | Week 24(Post-Dialysis) | 63<br>8.85 (4.18) | N/A                                       | 65<br>11.16 (4.21) | N/A                                       | N/A                                                                          | N/A     |

**Supplemental Table 15. Sensitivity Analysis – Reduction Ratio of  $\lambda$  FLC at 24 Weeks  
Last Observation Carried Forward**

|                                      | Theranova 400                        | Elisio-17H                           | Theranova 400 - Elisio-17H                         |                                                   |
|--------------------------------------|--------------------------------------|--------------------------------------|----------------------------------------------------|---------------------------------------------------|
| Parameter                            | n<br>Mean (SD)<br>Median<br>Min, Max | n<br>Mean (SD)<br>Median<br>Min, Max | Mean Estimated<br>Treatment Difference<br>(ANCOVA) | Two-Sided 95%<br>Confidence Interval <sup>1</sup> |
| Reduction Ratio of $\lambda$ FLC (%) | 82                                   | 79                                   |                                                    |                                                   |
|                                      | 34.2 (14.37)                         | 17.7 (12.37)                         | 16.749                                             | (12.685, 20.813)                                  |
|                                      | 35.9                                 | 16.3                                 |                                                    |                                                   |
|                                      | -46.17, 56.98                        | -10.69, 74.2                         |                                                    |                                                   |

1. If the lower bound of the two-sided 95% confidence interval around the mean estimated treatment difference between Theranova 400 and Elisio-17H is  $> 0$  then superiority can be claimed.

| <b>Supplemental Table 16. Change from Baseline of Pre-Dialysis Levels of Middle Molecules After 4 and 24 Weeks</b> |                 |                     |                      |                                        |                |                      |                      |                                        |                  |
|--------------------------------------------------------------------------------------------------------------------|-----------------|---------------------|----------------------|----------------------------------------|----------------|----------------------|----------------------|----------------------------------------|------------------|
| <b>Parameter</b>                                                                                                   | <b>Dialyzer</b> | <b>Week 4<br/>n</b> | <b>Mean<br/>(SD)</b> | <b>95%<br/>Confidence<br/>Interval</b> | <b>p-value</b> | <b>Week 24<br/>n</b> | <b>Mean<br/>(SD)</b> | <b>95%<br/>Confidence<br/>Interval</b> | <b>p-value</b>   |
| Change in pre-dialysis $\lambda$ FLC from baseline (mg/L)                                                          | Theranova       | 80                  | -13.5<br>(20.5)      | (-18.0, -8.9)                          | -              | 64                   | -19.40<br>(31.64)    | (-27.304, -11.499)                     | <b>&lt;0.001</b> |
|                                                                                                                    | Control         | 77                  | 2.08<br>(22.11)      | (-2.944, 7.094)                        |                | 65                   | 1.75 (29.95)         | (-5.666, 9.174)                        |                  |
| Change in pre-dialysis CFD from baseline ( $\mu$ g/dL)                                                             | Theranova       | 82                  | -1.82<br>(5.60)      | (-3.05, -0.59)                         | -              | 62                   | 0.13 (4.74)          | (-1.078, 1.331)                        | <b>0.10</b>      |
|                                                                                                                    | Control         | 78                  | -0.03<br>(6.19)      | (-1.428, 1.363)                        |                | 65                   | 1.89 (4.84)          | (0.696, 3.094)                         |                  |
| Change in pre-dialysis $\kappa$ FLC from baseline (mg/L)                                                           | Theranova       | 80                  | -49.08<br>(73.82)    | (-65.505, -32.650)                     | -              | 64                   | -84.81<br>(97.36)    | (-109.129, -60.490)                    | <b>0.001</b>     |
|                                                                                                                    | Control         | 77                  | -11.92<br>(67.00)    | (-27.130, 3.286)                       |                | 65                   | -43.01<br>(75.68)    | (-61.763, -24.259)                     |                  |
| Change in pre-dialysis IL-6 from baseline (pg/mL)                                                                  | Theranova       | 79                  | 0.18 (4.82)          | (-0.900, 1.260)                        | -              | 64                   | 0.20 (5.45)          | (-1.165, 1.557)                        | <b>0.18</b>      |
|                                                                                                                    | Control         | 77                  | 0.02 (1.93)          | (-0.422, 0.454)                        |                | 65                   | 1.64 (6.47)          | (0.037, 3.245)                         |                  |
| Change in pre-dialysis TNF $\alpha$ from baseline (pg/mL)                                                          | Theranova       | 80                  | -0.09<br>(1.62)      | (-0.449, 0.271)                        | -              | 64                   | -0.47 (2)            | (-0.974, 0.025)                        | <b>0.38</b>      |
|                                                                                                                    | Control         | 78                  | 0.30 (1.56)          | (-0.056, 0.650)                        |                | 65                   | 0.08 (1.65)          | (-0.325, 0.490)                        |                  |
| Change in pre-dialysis $\beta$ 2-microglobulin from baseline (mg/L)                                                | Theranova       | 80                  | -2.39<br>(5.75)      | (-3.675, -1.115)                       | -              | 64                   | -3.95 (5.61)         | (-5.356, -2.551)                       | <b>0.18</b>      |
|                                                                                                                    | Control         | 76                  | 0.03 (7.18)          | (-1.609, 1.672)                        | -              | 64                   | -1.16 (6.13)         | (-2.690, 0.371)                        |                  |

| Supplemental Table 17. Monthly single-pool Kt/V <sub>urea</sub> |            |                   |                   |                                                   |         |
|-----------------------------------------------------------------|------------|-------------------|-------------------|---------------------------------------------------|---------|
|                                                                 |            | Theranova 400     | Elisio-17H        | Theranova 400 - Elisio-17H<br>MMRM Model Results  |         |
| Parameter                                                       | Visit Week | n<br>Mean (SD)    | n<br>Mean (SD)    | Estimated Treatment<br>Difference<br>in Mean (SE) | p-Value |
| single-pool<br>Kt/V <sub>urea</sub>                             | Week 4     | 78<br>1.58 (0.27) | 76<br>1.58 (0.43) | 0.00 (0.057)                                      | 0.95    |
|                                                                 | Week 8     | 76<br>1.62 (0.29) | 76<br>1.51 (0.32) | 0.12 (0.049)                                      | 0.019   |
|                                                                 | Week 12    | 77<br>1.58 (0.29) | 70<br>1.55 (0.33) | 0.03 (0.051)                                      | 0.62    |
|                                                                 | Week 16    | 69<br>1.56 (0.27) | 70<br>1.59 (0.48) | -0.03 (0.066)                                     | 0.61    |
|                                                                 | Week 20    | 66<br>1.57 (0.30) | 69<br>1.55 (0.37) | 0.03 (0.058)                                      | 0.65    |
|                                                                 | Week 24    | 62<br>1.51 (0.31) | 65<br>1.54 (0.47) | -0.03 (0.071)                                     | 0.68    |

**Supplemental Table 18 Patients' self-rated health on a vertical visual analogue scale**

|                                           |            | Theranova 400        |                         | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>MMRM Model Results                             |         |
|-------------------------------------------|------------|----------------------|-------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
| Individual Scale                          | Study Week | n<br>Mean (SD)       | Change from<br>Baseline | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Symptom/Problem<br>List <sup>1</sup>      | Baseline   | 77<br>71.32 (7.039)  | N/A                     | 75<br>69.64 (8.271)  | N/A                                       | N/A                                                                          | N/A     |
|                                           | Week 12    | 74<br>70.30 (7.324)  | 67<br>-1.06 (7.730)     | 68<br>70.50 (6.778)  | 61<br>-0.00 (7.227)                       | -0.54 (1.119)                                                                | 0.6290  |
|                                           | Week 24    | 53<br>70.32 (7.995)  | 49<br>-0.77 (8.448)     | 55<br>69.66 (6.010)  | 52<br>-1.44 (7.657)                       | 0.79 (1.255)                                                                 | 0.5310  |
| Effects of Kidney<br>Disease <sup>2</sup> | Baseline   | 77<br>73.96 (12.203) | N/A                     | 75<br>75.71 (11.989) | N/A                                       | N/A                                                                          | N/A     |
|                                           | Week 12    | 74<br>74.71 (12.735) | 67<br>0.49 (10.280)     | 68<br>75.55 (11.052) | 61<br>0.72 (11.445)                       | -1.08 (1.693)                                                                | 0.5244  |
|                                           | Week 24    | 53<br>76.59 (11.702) | 49<br>2.59 (10.551)     | 55<br>77.73 (10.208) | 52<br>2.04 (9.134)                        | 0.25 (1.687)                                                                 | 0.8835  |
| Burden of Kidney<br>Disease <sup>3</sup>  | Baseline   | 77<br>38.39 (12.773) | N/A                     | 75<br>37.33 (12.791) | N/A                                       | N/A                                                                          | N/A     |
|                                           | Week 12    | 74<br>37.16 (11.280) | 67<br>-1.03 (12.809)    | 68<br>36.58 (11.940) | 61<br>-0.41 (12.954)                      | 0.44 (1.879)                                                                 | 0.8137  |
|                                           | Week 24    | 53<br>34.32 (12.417) | 49<br>-3.19 (14.994)    | 55<br>37.05 (11.590) | 52<br>1.44 (15.686)                       | -3.46 (2.312)                                                                | 0.1369  |
|                                           | Baseline   | 77<br>42.56 (4.869)  | N/A                     | 75<br>43.63 (4.917)  | N/A                                       | N/A                                                                          | N/A     |

**Supplemental Table 18 Patients' self-rated health on a vertical visual analogue scale**

|                                                    |            | Theranova 400       |                         | Elisio-17H          |                                           | Theranova 400 - Elisio-17H<br>MMRM Model Results                             |         |
|----------------------------------------------------|------------|---------------------|-------------------------|---------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
| Individual Scale                                   | Study Week | n<br>Mean (SD)      | Change from<br>Baseline | n<br>Mean (SD)      | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| SF-12 Physical<br>Health<br>Composite <sup>4</sup> |            |                     |                         |                     |                                           |                                                                              |         |
|                                                    | Week 12    | 74<br>43.22 (5.267) | 67<br>0.53 (5.469)      | 68<br>43.69 (4.973) | 61<br>-0.46 (5.845)                       | -0.05 (0.848)                                                                | 0.9500  |
|                                                    | Week 24    | 53<br>42.68 (5.141) | 49<br>0.42 (5.426)      | 55<br>44.25 (4.843) | 52<br>-0.31 (5.720)                       | -0.76 (0.934)                                                                | 0.4171  |
| SF-12 Mental<br>Health<br>Composite <sup>4</sup>   | Baseline   | 77<br>45.00 (5.275) | N/A                     | 75<br>45.17 (5.707) | N/A                                       | N/A                                                                          | N/A     |
|                                                    | Week 12    | 74<br>44.93 (6.388) | 67<br>0.41 (5.603)      | 68<br>45.98 (6.357) | 61<br>1.09 (6.871)                        | -0.47 (0.994)                                                                | 0.6389  |
|                                                    | Week 24    | 53<br>44.66 (7.357) | 49<br>-0.35 (6.849)     | 55<br>44.16 (5.838) | 52<br>-0.28 (6.757)                       | 0.14 (1.238)                                                                 | 0.9091  |

KDQOL = Kidney Disease and Quality of Life

1. Average of the scaled scores of questions 17 – 28b
2. Average of the scaled scores of questions 29 - 36
3. Average of the scaled scores of questions 13 – 16
4. Composite of the scaled scores of questions 1 – 12

**Supplemental Table 19. Exploratory Analysis - Patient-Reported Outcome Measures EQ-5D-5L Your Health Today and Index Value**

|                          |            | Theranova 400        |                                           | Elisio-17H           |                                           | Theranova 400 - Elisio-17H<br>MMRM Model Results                             |         |
|--------------------------|------------|----------------------|-------------------------------------------|----------------------|-------------------------------------------|------------------------------------------------------------------------------|---------|
| Dimension                | Study Week | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | n<br>Mean (SD)       | Change from<br>Baseline<br>n<br>Mean (SD) | Estimated<br>Treatment<br>Difference<br>in Change from<br>Baseline Mean (SE) | p-Value |
| Your Health Today        | Baseline   | 77<br>73.13 (17.223) | N/A                                       | 74<br>73.80 (19.762) | N/A                                       | N/A                                                                          | N/A     |
|                          | Week 12    | 73<br>71.40 (17.899) | 67<br>-0.96 (15.901)                      | 63<br>75.86 (18.104) | 58<br>1.69 (19.284)                       | -3.90 (2.669)                                                                | 0.1465  |
|                          | Week 24    | 52<br>73.58 (16.109) | 49<br>-0.29 (17.098)                      | 55<br>72.07 (20.769) | 51<br>-2.67 (23.303)                      | 1.28 (3.458)                                                                 | 0.7123  |
| Index Value <sup>1</sup> | Baseline   | 77<br>0.79 (0.165)   | N/A                                       | 74<br>0.81 (0.179)   | N/A                                       | N/A                                                                          | N/A     |
|                          | Week 12    | 73<br>0.79 (0.158)   | 67<br>-0.01 (0.123)                       | 63<br>0.80 (0.176)   | 58<br>-0.00 (0.174)                       | -0.01 (0.024)                                                                | 0.5719  |
|                          | Week 24    | 52<br>0.80 (0.173)   | 49<br>0.01 (0.185)                        | 55<br>0.84 (0.163)   | 51<br>0.03 (0.180)                        | -0.03 (0.030)                                                                | 0.3243  |

1. Index value calculated via the Index Value Calculator Tool van Hout B, Janssen MF, et al. Interim scoring for the EQ-5D-5L: Mapping the EQ-5D-5L to EQ-5D-3L value sets. Value in Health 2012 Jul-Aug;15:708-15.

**Supplemental Table 20. Exploratory Analysis - Patient-Reported Outcome Measures EQ-5D-5L Dimensions**

| <b>Dimension</b> | <b>Visit</b> | <b>Response</b>                                     | <b>Theranova 400<br/>n (%)</b> | <b>Elisio-17H<br/>n (%)</b> |
|------------------|--------------|-----------------------------------------------------|--------------------------------|-----------------------------|
| Mobility         | Baseline     | I am unable to walk                                 | 3 (3.5)                        | 1 (1.2)                     |
|                  |              | I have moderate problems walking                    | 14 (16.3)                      | 8 (9.3)                     |
|                  |              | I have no problems walking                          | 38 (44.2)                      | 33 (38.4)                   |
|                  |              | I have severe problems walking                      | 1 (1.2)                        | 6 (7.0)                     |
|                  |              | I have slight problems walking                      | 21 (24.4)                      | 26 (30.2)                   |
|                  | Week 12      | I am unable to walk                                 | 1 (1.2)                        | 1 (1.2)                     |
|                  |              | I have moderate problems walking                    | 10 (11.6)                      | 16 (18.6)                   |
|                  |              | I have no problems walking                          | 37 (43.0)                      | 26 (30.2)                   |
|                  |              | I have severe problems walking                      | 4 (4.7)                        | 3 (3.5)                     |
|                  |              | I have slight problems walking                      | 21 (24.4)                      | 17 (19.8)                   |
|                  | Week 24      | I am unable to walk                                 | 1 (1.2)                        | 1 (1.2)                     |
|                  |              | I have moderate problems walking                    | 7 (8.1)                        | 3 (3.5)                     |
|                  |              | I have no problems walking                          | 25 (29.1)                      | 27 (31.4)                   |
|                  |              | I have severe problems walking                      | 3 (3.5)                        | 4 (4.7)                     |
|                  |              | I have slight problems walking                      | 16 (18.6)                      | 20 (23.3)                   |
| Self-Care        | Baseline     | I have no problems washing or dressing myself       | 60 (69.8)                      | 64 (74.4)                   |
|                  |              | I have slight problems washing or dressing myself   | 13 (15.1)                      | 6 (7.0)                     |
|                  |              | I have moderate problems washing or dressing myself | 4 (4.7)                        | 1 (1.2)                     |
|                  |              | I have severe problems washing or dressing myself   | 0 (0.0)                        | 3 (3.5)                     |
|                  | Week 12      | I am unable to wash or dress myself                 | 1 (1.2)                        | 1 (1.2)                     |

**Supplemental Table 20. Exploratory Analysis - Patient-Reported Outcome Measures EQ-5D-5L Dimensions**

| <b>Dimension</b> | <b>Visit</b> | <b>Response</b>                                     | <b>Theranova 400<br/>n (%)</b> | <b>Elisio-17H<br/>n (%)</b> |
|------------------|--------------|-----------------------------------------------------|--------------------------------|-----------------------------|
|                  |              | I have moderate problems washing or dressing myself | 6 (7.0)                        | 5 (5.8)                     |
|                  |              | I have no problems washing or dressing myself       | 55 (64.0)                      | 51 (59.3)                   |
|                  |              | I have severe problems washing or dressing myself   | 3 (3.5)                        | 0 (0.0)                     |
|                  |              | I have slight problems washing or dressing myself   | 8 (9.3)                        | 6 (7.0)                     |
|                  | Week 24      | I am unable to wash or dress myself                 | 0 (0.0)                        | 1 (1.2)                     |
|                  |              | I have moderate problems washing or dressing myself | 3 (3.5)                        | 1 (1.2)                     |
|                  |              | I have no problems washing or dressing myself       | 44 (51.2)                      | 46 (53.5)                   |
|                  |              | I have slight problems washing or dressing myself   | 5 (5.8)                        | 7 (8.1)                     |
| Usual Activities | Baseline     | I am unable to do my usual activities               | 1 (1.2)                        | 1 (1.2)                     |
|                  |              | I have moderate problems doing my usual activities  | 15 (17.4)                      | 13 (15.1)                   |
|                  |              | I have no problems doing my usual activities        | 33 (38.4)                      | 43 (50.0)                   |
|                  |              | I have severe problems doing my usual activities    | 2 (2.3)                        | 3 (3.5)                     |
|                  |              | I have slight problems doing my usual activities    | 26 (30.2)                      | 14 (16.3)                   |
|                  | Week 12      | I have no problems doing my usual activities        | 39 (45.3)                      | 35 (40.7)                   |
|                  |              | I am unable to do my usual activities               | 2 (2.3)                        | 1 (1.2)                     |
|                  |              | I have moderate problems doing my usual activities  | 10 (11.6)                      | 9 (10.5)                    |
|                  |              | I have severe problems doing my usual activities    | 2 (2.3)                        | 1 (1.2)                     |
|                  |              | I have slight problems doing my usual activities    | 20 (23.3)                      | 17 (19.8)                   |
|                  | Week 24      | I am unable to do my usual activities               | 1 (1.2)                        | 1 (1.2)                     |
|                  |              | I have moderate problems doing my usual activities  | 6 (7.0)                        | 7 (8.1)                     |

**Supplemental Table 20. Exploratory Analysis - Patient-Reported Outcome Measures EQ-5D-5L Dimensions**

| <b>Dimension</b>   | <b>Visit</b> | <b>Response</b>                                  | <b>Theranova 400<br/>n (%)</b> | <b>Elisio-17H<br/>n (%)</b> |
|--------------------|--------------|--------------------------------------------------|--------------------------------|-----------------------------|
|                    |              | I have no problems doing my usual activities     | 30 (34.9)                      | 37 (43.0)                   |
|                    |              | I have severe problems doing my usual activities | 1 (1.2)                        | 2 (2.3)                     |
|                    |              | I have slight problems doing my usual activities | 14 (16.3)                      | 8 (9.3)                     |
| Pain/Discomfort    | Baseline     | I have extreme pain or discomfort                | 1 (1.2)                        | 3 (3.5)                     |
|                    |              | I have moderate pain or discomfort               | 17 (19.8)                      | 11 (12.8)                   |
|                    |              | I have no pain or discomfort                     | 30 (34.9)                      | 37 (43.0)                   |
|                    |              | I have severe pain or discomfort                 | 3 (3.5)                        | 4 (4.7)                     |
|                    |              | I have slight pain or discomfort                 | 26 (30.2)                      | 19 (22.1)                   |
|                    | Week 12      | I have moderate pain or discomfort               | 13 (15.1)                      | 12 (14.0)                   |
|                    |              | I have no pain or discomfort                     | 27 (31.4)                      | 31 (36.0)                   |
|                    |              | I have slight pain or discomfort                 | 28 (32.6)                      | 16 (18.6)                   |
|                    |              | I have extreme pain or discomfort                | 0 (0.0)                        | 2 (2.3)                     |
|                    |              | I have severe pain or discomfort                 | 5 (5.8)                        | 2 (2.3)                     |
|                    | Week 24      | I have extreme pain or discomfort                | 2 (2.3)                        | 0 (0.0)                     |
|                    |              | I have moderate pain or discomfort               | 7 (8.1)                        | 5 (5.8)                     |
|                    |              | I have no pain or discomfort                     | 24 (27.9)                      | 35 (40.7)                   |
|                    |              | I have severe pain or discomfort                 | 3 (3.5)                        | 1 (1.2)                     |
|                    |              | I have slight pain or discomfort                 | 16 (18.6)                      | 14 (16.3)                   |
| Anxiety/Depression | Baseline     | I am extremely anxious or depressed              | 1 (1.2)                        | 1 (1.2)                     |
|                    |              | I am moderately anxious or depressed             | 13 (15.1)                      | 6 (7.0)                     |

**Supplemental Table 20. Exploratory Analysis - Patient-Reported Outcome Measures EQ-5D-5L Dimensions**

| <b>Dimension</b> | <b>Visit</b> | <b>Response</b>                      | <b>Theranova 400<br/>n (%)</b> | <b>Elisio-17H<br/>n (%)</b> |
|------------------|--------------|--------------------------------------|--------------------------------|-----------------------------|
|                  |              | I am not anxious or depressed        | 45 (52.3)                      | 48 (55.8)                   |
|                  |              | I am severely anxious or depressed   | 0 (0.0)                        | 2 (2.3)                     |
|                  |              | I am slightly anxious or depressed   | 18 (20.9)                      | 17 (19.8)                   |
|                  | Week 12      | I am extremely anxious or depressed  | 0 (0.0)                        | 2 (2.3)                     |
|                  |              | I am moderately anxious or depressed | 11 (12.8)                      | 8 (9.3)                     |
|                  |              | I am not anxious or depressed        | 39 (45.3)                      | 43 (50.0)                   |
|                  |              | I am severely anxious or depressed   | 2 (2.3)                        | 1 (1.2)                     |
|                  |              | I am slightly anxious or depressed   | 21 (24.4)                      | 9 (10.5)                    |
|                  | Week 24      | I am extremely anxious or depressed  | 1 (1.2)                        | 0 (0.0)                     |
|                  |              | I am moderately anxious or depressed | 3 (3.5)                        | 3 (3.5)                     |
|                  |              | I am not anxious or depressed        | 35 (40.7)                      | 37 (43.0)                   |
|                  |              | I am severely anxious or depressed   | 2 (2.3)                        | 3 (3.5)                     |
|                  |              | I am slightly anxious or depressed   | 11 (12.8)                      | 12 (14.0)                   |