

Table 8: Summary of GH Level (µg/L) at baseline, end of treatment and change from baseline on the original scale (ITT Analysis Set)

| | OCR 100 µg N=41 | | ITF2984 500 µg N=43 | | ITF2984 1000 µg N=47 | | ITF2984 2000 µg N=42 | |
|------------------|--------------------|----------------------|------------------------|----------------------|-------------------------|----------------------|-------------------------|----------------------|
| | Observed value | Change from Baseline | Observed value | Change from Baseline | Observed value | Change from Baseline | Observed value | Change from Baseline |
| Period 1 | | | | | | | | |
| Baseline | | | | | | | | |
| n | 11 | | 12 | | 11 | | 12 | |
| Mean | 13.68 | | 7.99 | | 10.17 | | 6.28 | |
| SD | 10.551 | | 8.263 | | 7.142 | | 4.591 | |
| End of treatment | | | | | | | | |
| n | 11 | 11 | 12 | 12 | 9 | 9 | 12 | 12 |
| Mean | 11.45 | -2.23 | 7.03 | -0.96 | 9.19 | -2.00 | 3.44 | -2.84 |
| SD | 15.125 | 9.096 | 6.352 | 2.417 | 10.495 | 6.071 | 3.110 | 4.223 |
| Period 2 | | | | | | | | |
| Baseline | | | | | | | | |
| n | 12 | | 9 | | 12 | | 11 | |
| Mean | 7.32 | | 9.99 | | 4.73 | | 18.51 | |
| SD | 7.174 | | 7.094 | | 3.324 | | 20.771 | |
| End of treatment | | | | | | | | |
| n | 12 | 12 | 8 | 8 | 12 | 12 | 11 | 11 |
| Mean | 4.90 | -2.42 | 10.29 | -0.13 | 4.29 | -0.44 | 5.47 | -13.04 |
| SD | 3.157 | 7.056 | 9.139 | 2.590 | 3.640 | 1.151 | 5.658 | 18.977 |
| Period 3 | | | | | | | | |
| Baseline | | | | | | | | |
| n | 11 | | 11 | | 12 | | 8 | |
| Mean | 5.17 | | 13.29 | | 7.63 | | 13.34 | |
| SD | 5.562 | | 15.244 | | 8.366 | | 10.042 | |
| End of treatment | | | | | | | | |
| n | 11 | 11 | 11 | 11 | 11 | 11 | 8 | 8 |
| Mean | 6.14 | 0.96 | 11.05 | -2.25 | 5.80 | -1.95 | 7.35 | -5.99 |
| SD | 3.842 | 3.375 | 10.675 | 7.290 | 3.650 | 6.617 | 8.873 | 8.316 |

Table 8: Summary of GH Level (µg/L) at baseline, end of treatment and change from baseline on the original scale (ITT Analysis Set)

| | OCR 100 µg N=41 | | ITF2984 500 µg N=43 | | ITF2984 1000 µg N=47 | | ITF2984 2000 µg N=42 | |
|------------------|--------------------|-------------------------|------------------------|-------------------------|-------------------------|-------------------------|-------------------------|-------------------------|
| | Observed value | Change from Baseline | Observed value | Change from Baseline | Observed value | Change from Baseline | Observed value | Change from Baseline |
| Period 4 | | | | | | | | |
| Baseline | | | | | | | | |
| n | 7 | | 11 | | 11 | | 11 | |
| Mean | 11.47 | | 5.37 | | 15.85 | | 4.64 | |
| SD | 10.240 | | 5.738 | | 18.326 | | 1.872 | |
| End of treatment | | | | | | | | |
| n | 7 | 7 | 11 | 11 | 11 | 11 | 11 | 11 |
| Mean | 10.10 | -1.37 | 4.91 | -0.46 | 6.38 | -9.47 | 3.85 | -0.79 |
| SD | 12.389 | 12.357 | 3.514 | 2.501 | 5.166 | 15.874 | 2.966 | 2.204 |
| Overall | | | | | | | | |
| Baseline | | | | | | | | |
| n | 41 | | 43 | | 46 | | 42 | |
| Mean | 9.16 | | 9.10 | | 9.45 | | 10.40 | |
| SD | 8.797 | | 9.970 | | 11.079 | | 12.734 | |
| End of treatment | | | | | | | | |
| n | 41 | 41 | 42 | 42 | 43 | 43 | 42 | 42 |
| Mean | 7.88 | -1.28 | 8.15 | -1.01 | 6.24 | -3.47 | 4.82 | -5.57 |
| SD | 9.722 | 7.884 | 7.888 | 4.224 | 6.081 | 9.535 | 5.307 | 11.354 |

Baseline is defined as Day 0 of each period; At each time point, only subjects with a value at both Baseline and that time point were included in the change from Baseline column.

N = the number of subjects in the analysis set receiving the specified treatment; n = the number of subjects with a measurement in this time period; OCR = octreotide; SD = standard deviation

Data Source: Section 14, [Table 14.2.1.1](#)