



T-2

Analyses of Patient Diaries in the NETTER-1 Study of ¹⁷⁷Lu-DOTATATE vs. High Dose OCTREOTIDE in Progressive Midgut Neuroendocrine Tumors

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BACKGROUND: The primary statistical analysis for the NETTER-1 trial showed a clinically and statistically significant PFS benefit with ¹⁷⁷Lu-DOTATATE vs. high-dose octreotide. ¹⁷⁷Lu-DOTATATE treatment was also correlated with a significant delay in time to deterioration in HRQoL. In addition to HRQoL questionnaires, patients were asked to record presence or absence of a range of symptoms in a daily diary.

METHODS: A Mixed Model Repeated Measures (MMRM) was used to analyze the change, compared to baseline, of the occurrence of Abdominal Pain, Diarrhea and Flushing of the Skin as these symptoms were regarded as the most relevant to judge the overall status of the disease. For each visit (week=0, 4, 8, etc.) the number of days with symptoms during the previous period was calculated. At baseline the number of days with symptoms was counted over the previous 6 weeks whereas the time frame between visits lasted 4 weeks.

RESULTS: The estimated number of days with symptoms declined significantly more in the LUTATHERA arm compared to the Octreotide arm. The difference in change and the confidence intervals for the symptoms abdominal pain, diarrhea and flushing of skin are, respectively: -3.11 [-4.88; -1.34], -3.11 [-5.04; -1.18] and -1.98 [-3.88; -0.08].

CONCLUSION: Analysis of symptom diaries confirms that ^{177}Lu -DOTATATE can palliate clinically relevant symptoms when compared to high-dose octreotide.