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93 - DIPLOPIA IMPROVEMENT WITH TEPROTUMUMAB IN PATIENTS WITH HIGH INFLAMMATION/RECENT ONSET AND LOW INFLAMMATION/LONGER DURATION THYROID EYE DISEASE (TED)

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Resumen

Introduction: We assessed teprotumumab diplopia responses vs. placebo regardless of baseline diplopia.

Methods: Data included: phase 2/3 (high inflammation TED, CAS#14/onset #2 9 months) and phase4 (long duration (2-10 yr)/low inflammation (CAS #2 1) trial subjects, who received teprotumumab/placebo. Baseline change as ordinal response in Gorman diplopia categories with/without baseline diplopia to Week 24 noted as improvement, significant improvement, no change, worsening or significant worsening. Proportional Odds Model and Cochran-Mantel-Haenszel tests compared teprotumumab and placebo with any improvement/worsening in the trials.

Results: Acute/high inflammation TED patients (N = 79) were five times more likely to have diplopia improvements vs. placebo patients (N = 80, Week 24): Odds Ratio (OR) 5.17, 95%CI (2.73, 9.78), p < 0.0001. Significant improvement was observed in 25 (31.6%) vs. 6 (7.5%), improvement in 21 (26.6%) vs. 12 (15%), no change in 29 (36.7%) vs. 44 (55%), worsening in 3 (3.8%) vs. 12 (15%) and significant worsening in 1 (1.3%) vs. 6 (7.5%) patients. Long duration/low inflammation TED diplopia baseline change at Week24 favored teprotumumab (N = 39) over placebo (N = 20) but was not significant (OR 2.26, 95%CI (0.42, 12.22), p = 0.344). For all teprotumumab (N = 118) vs. placebo (N = 100) patients, significant improvement occurred in 27 (22.9%) vs. 7 (7%), improvement in 25 (21.2%) vs. 13 (13%), no change in 62 (52.5%) vs. 61 (61%), worsening in 3 (2.5%) vs. 13 (13%) and significant worsening in 1 (0.8%) vs. 6 (6%) patients. Diplopia responder rate was significantly higher in teprotumumab vs. placebo (difference 28.2%, CI (16.6%, 39.7%), p < 0.001).

Conclusions: Combined diplopia teprotumumab/placebo trial data suggests significantly less diplopia worsening and more improvement vs. placebo. Significant improvements were observed in the high inflammation patients with teprotumumab vs. placebo; improvements in the low inflammation patients were not significant, possibly due to low numbers.

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