

group, the least square mean change from baseline in overall GO-QOL score improved by 23.4 ± 6.4 , which was a large clinical change. In contrast, the placebo group improved by 6.9 ± 7.4 . **Conclusions:** After 24 weeks, responses to teprotumumab were greater versus placebo in patients with low baseline FT4 in two clinical trials. Responses in these mildly hypothyroid patients in this study were consistent with those in the overall pooled population as follows: Proptosis response: 78% and 77%, respectively; mean proptosis reduction: 2.9 mm and 3.14 mm; diplopia response 86% and 70%; CAS response 67% and 62%, respectively. Thus, pretreatment hypothyroid status does not affect clinical responses to teprotumumab in TED. **References** Bartalena L. *Best Pract Res Clin Endocrinol Metab* 2012; 26: 371-379. Patel P, et al. *Ophthalmic Plast Reconstr Surg* 2015; 31(6): 445-448. Kahaly et al. *Lancet Diabetes and Endocrinol* 2021; 9(6): 360-372

Presentation: Saturday, June 11, 2022 1:00 p.m. - 3:00 p.m., Monday, June 13, 2022 12:26 p.m. - 12:41 p.m.

Abstract citation ID: bvac150.1780

Thyroid

RF35 | PSAT263

Efficacy of Teprotumumab for Thyroid Eye Disease in Hypothyroid Patients

Terry J Smith, MD, Chitra Choudhary, MD,

Rajib J Bhattacharya, MD, and Robert Holt, PharmD, MBA

Background: Thyroid eye disease (TED) is an autoimmune inflammatory process that can lead to eye-bulging (proptosis) and double-vision (diplopia). Teprotumumab, an insulin-like growth factor-I receptor inhibitory antibody, has demonstrated improvements in proptosis and diplopia. Thyroid dysregulation has been linked to increased TED severity¹ and may trigger TED flares,² thus, treatment efficacy of hypo- or hyperthyroid patients with teprotumumab is of interest. This post-hoc analysis of pooled phase 2 and 3 trial data³ examined teprotumumab efficacy in patients with low baseline FT4 levels.

Methods: Patients from Phase 2 and 3 teprotumumab trials with low baseline FT4 (≤ 11.5 pmol/L) were included. Patients received teprotumumab or placebo for 24 weeks (8 infusions). Proportions of proptosis (≥ 2 mm reduction), clinical activity score (CAS, 7-point scale, CAS 0 or 1), and diplopia (≥ 1 Gorman diplopia scale grade improvement) responders were determined at Week 24. Additionally, the Graves' ophthalmopathy- quality of life (GO-QOL) questionnaire measured quality of life.

Results: Nine teprotumumab-treated patients (6 female [67%], 54.6 ± 10.7 years old) and 8 (6 female [75%], 50.0 ± 14.9 years old) patients made up the teprotumumab and placebo groups, respectively. Mean baseline proptosis in the study eye was 25.1 ± 3.9 mm in teprotumumab patients and 21.9 ± 3.8 mm in placebo patients. At Week 24, 78% (7/9) teprotumumab-treated vs. 38% (3/8) placebo-treated patients were proptosis responders. Further, mean proptosis reduction was 2.9 ± 0.6 mm with teprotumumab vs. 1.2 ± 0.7 mm with placebo. 67% (6/9) vs. 13% (1/8) of teprotumumab vs. placebo patients were CAS responders at Week 24. Of those with baseline diplopia, 86% (6/7) vs. 40% (2/5) were diplopia responders, respectively. In the teprotumumab