Abstract citation ID: bvac150.1674

Thyroid

PSAT265

Blood Glucose in Thyroid Eye Disease (TED) in Patients treated with Teprotumumab: Clinical Trials Data

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Background: Teprotumumab, an FDA-approved insulin-like growth factor-1 receptor inhibitor for TED, improves proptosis, diplopia, inflammation, and quality of life. In the pooled phase 2 and 3 trial analysis, 8/84 (10%) teprotumumab-treated patients reported hyperglycemia adverse events (AEs) versus 1/86 (1.2%) in placebo. Here, we discuss perturbations in serum glucose data reported in patients from two pivotal clinical trials with teprotumumab.

Methods: Glycemia data from two randomized, double-masked, placebo-controlled multicenter trials were analyzed throughout 8 teprotumumab vs. placebo infusions. Blood glucose was measured at Weeks 1, 4, 15, and 21 in phase 2 study patients. In phase 3, all patients with pre-existing diabetes had blood glucose measured at each study visit. Patients without pre-existing diabetes had fasting blood glucose measurements at Weeks 1 and 4. The remainder of blood glucoses in non-diabetics were non-fasting. HbA1c levels were measured at baseline, 12 and 24 weeks, in all patients.

Results: The mean patient age was 51.4 years, with 73% female. At baseline, diabetic patients were controlled with oral and/or insulin therapies at primary investigator discretion. Mean baseline non-fasting blood glucose in teprotumumab patients was 98.3 mg/dl versus 100.5 mg/dl in placebo. Mean non-fasting blood glucose increased from baseline in teprotumumab-treated patients by 6.9 mg/dl but decreased by 6.5 mg/dl in those receiving placebo at 24 weeks. Nine hyperglycemia AEs were reported in 8 teprotumumab-treated patients; 6 resolved during the treatment period, 2 resolved after the last dose, and 1 continued after study completion. Five of 8 patients who had hyperglycemia had pre-existing diabetes in this pooled analysis. All reported hyperglycemic AEs were Grade 1 (>160mg/dl) or 2 (161 mg/dl to 250 mg/dl). In the teprotumumab group follow-up, two patients had hyperglycemia-related AEs. One resolved without medication. Neither led to study drug discontinuation. HbA1c increased by 0.22% (mean, N=72) with teprotumumab compared to 0.04% (N=71) with placebo. There were no cases of diabetic ketoacidosis or hyperosmolar hyperglycemic state.

Conclusion: Approximately 10% of teprotumumab treated patients compared to 1% receiving placebo had hyperglycemic events. Most hyperglycemic cases were easily controlled with medication. In addition, no treatment discontinuation or complications were associated with these elevated blood glucose levels. This analysis demonstrates no evidence for severe diabetogenesis with teprotumumab treatment, although blood glucose monitoring is recommended for all patients.

Presentation: Saturday, June 11, 2022 1:00 p.m. - 3:00 p.m.