



Integrated Clinical Trial Analysis Reinforces TEPEZZA Efficacy in Reducing Proptosis and Diplopia

Integrated efficacy data from the [Phase 2](#) and [Phase 3](#) clinical trials of TEPEZZA® (teprotumumab-trbw) for the treatment of Thyroid Eye Disease (TED) demonstrate reductions in inflammation, proptosis (eye bulging) and diplopia (double vision), as well as improvements in quality of life (QOL). TEPEZZA is the first and only medicine approved by the U.S. Food and Drug Administration (FDA) for the treatment of TED, which is a serious, progressive and vision-threatening rare autoimmune disease.

This analysis assessed 171 patients with recent onset of TED (less than nine months) randomized to TEPEZZA (n=84) or placebo (n=87) every three weeks for a total of eight infusions. Key study findings include the following:

- **Proptosis:** At Week 24, more TEPEZZA patients than placebo patients had a proptosis response (at least a 2 mm proptosis reduction in the study eye without deterioration in the fellow eye) (77.4 percent vs. 14.9 percent; $p < 0.001$) and mean reduction was greater in TEPEZZA patients than placebo patients (3.14 mm vs. 0.37 mm; $p < 0.001$). Both the number of proptosis responders and the mean reduction in proptosis were greater with TEPEZZA than placebo at all study visits ($p < 0.001$). Median time to first proptosis response was 6.4 weeks in the TEPEZZA group.
- **Diplopia:** At Week 24, among patients who had diplopia at baseline, more TEPEZZA patients than placebo patients had a diplopia improvement of 1 or more grades (69.7 percent vs. 30.5 percent; $p < 0.001$) and complete resolution of diplopia was seen in 53.0 percent of TEPEZZA patients vs. 25.4 percent of placebo patients ($p < 0.001$). Median time to first diplopia improvement was 11.9 weeks for TEPEZZA patients and 25.1 weeks in placebo patients. At each study visit, more TEPEZZA patients experienced improvements in diplopia than placebo patients ($p < 0.001$).
- **QOL:** At Week 24, overall TED QOL, as measured by the GO-QOL questionnaire, improved by 19.01 points from baseline in TEPEZZA patients vs. 6.30 points in placebo patients; subscales of GO-QOL-visual function improved 19.68 in TEPEZZA patients versus 6.95 in placebo patients; and GO-QOL-appearance improved 17.73 in TEPEZZA patients versus 5.64 in placebo patients (all $p < 0.001$).
- **Safety:** The majority of patients in both the placebo and TEPEZZA groups experienced at least one adverse event, but most were mild or moderate in intensity and few led to study discontinuation.

About TEPEZZA

INDICATION

TEPEZZA is indicated for the treatment of Thyroid Eye Disease.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions



Infusion Reactions: TEPEZZA may cause infusion reactions. Infusion reactions have been reported in approximately 4% of patients treated with TEPEZZA. Reported infusion reactions have usually been mild or moderate in severity. Signs and symptoms may include transient increases in blood pressure, feeling hot, tachycardia, dyspnea, headache and muscular pain. Infusion reactions may occur during an infusion or within 1.5 hours after an infusion. In patients who experience an infusion reaction, consideration should be given to premedicating with an antihistamine, antipyretic, or corticosteroid and/or administering all subsequent infusions at a slower infusion rate.

Preexisting Inflammatory Bowel Disease: TEPEZZA may cause an exacerbation of preexisting inflammatory bowel disease (IBD). Monitor patients with IBD for flare of disease. If IBD exacerbation is suspected, consider discontinuation of TEPEZZA.

Hyperglycemia: Increased blood glucose or hyperglycemia may occur in patients treated with TEPEZZA. In clinical trials, 10% of patients (two-thirds of whom had preexisting diabetes or impaired glucose tolerance) experienced hyperglycemia. Hyperglycemic events should be managed with medications for glycemic control, if necessary. Monitor patients for elevated blood glucose and symptoms of hyperglycemia while on treatment with TEPEZZA. Patients with preexisting diabetes should be under appropriate glycemic control before receiving TEPEZZA.

Adverse Reactions

The most common adverse reactions (incidence $\geq 5\%$ and greater than placebo) are muscle spasm, nausea, alopecia, diarrhea, fatigue, hyperglycemia, hearing impairment, dysgeusia, headache and dry skin.

For additional information on TEPEZZA, please see [Full Prescribing Information](#) at TEPEZZAhcp.com.