**FIRST AND ONLY**
**FDA-APPROVED TREATMENT FOR THYROID EYE DISEASE**

# TEPEZZA™
teprotumumab-trbw

## IT'S TIME FOR A BREAKTHROUGH
## IT'S TIME FOR TEPEZZA

## TEPEZZA is proven to[1-4]:

- Decrease proptosis[1]
- Improve diplopia[1]
- Reduce orbital pain, redness, and swelling[2,3]
- Improve functional vision and patient appearance[2,3]

**...in patients with Thyroid Eye Disease (TED), without concomitant steroids (vs placebo at Week 24).[2-4]**

Both the safety and efficacy of TEPEZZA were evaluated in 2 randomized, double-masked, placebo-controlled clinical trials (Studies 1 and 2) consisting of 171 patients with TED (84 were randomized to TEPEZZA and 87 were randomized to placebo). The primary endpoint in Studies 1 and 2 was proptosis responder rate, defined as having a ≥2-mm reduction from baseline in proptosis in the study eye at Week 24 without deterioration (≥2-mm increase in proptosis) in the non-study eye.[1]

## SELECT IMPORTANT SAFETY INFORMATION

### Warnings and Precautions

**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.

**Please see additional Important Safety Information on following pages and Full Prescribing Information at TEPEZZAhcp.com.**

# TEPEZZA significantly decreased proptosis, one of the most disfiguring symptoms of TED[1,2,5,6]

**Proptosis responder rate* (primary endpoint; Study 2)[1,2,7]**

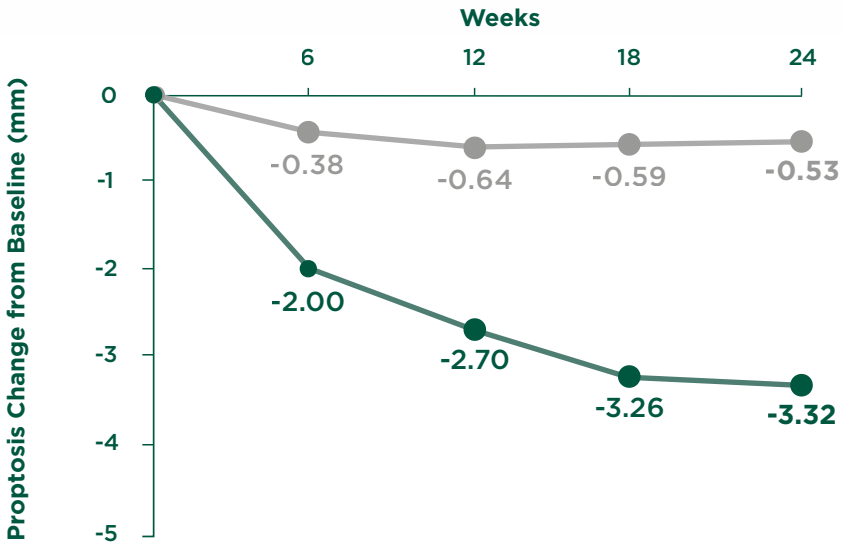

**Significantly greater proptosis response rate**

**TEPEZZA**
**83%**
vs placebo
**10%**
(Week 24)

- Similar results were seen in Study 1: TEPEZZA achieved a significantly greater proptosis response rate* vs placebo at Week 24 (71% vs 20%; *P*<0.001)[1,5]

*A proptosis responder was defined as having a ≥2-mm reduction in proptosis from baseline in the study eye at Week 24 without deterioration (≥2-mm increase in proptosis) in the non-study eye.[1]

**Average change from baseline in proptosis over 24 weeks (secondary endpoint; Study 2)[1]**




**Significantly decreased proptosis**

**TEPEZZA**
**-3.3 mm**
vs placebo
**-0.5 mm**
(Week 24)

- Mean change in proptosis across visits from baseline through Week 24 was -2.8 mm vs -0.5 mm with placebo in Study 2 (*P*<0.001)[1,2]

## SELECT IMPORTANT SAFETY INFORMATION

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

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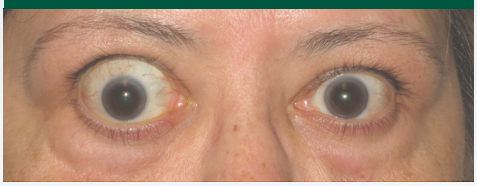
# TEPEZZA showed significantly higher response rate for proptosis reduction and improved inflammatory signs of TED (pain, redness, and swelling)[1-3]

## See the TEPEZZA transformation[7]

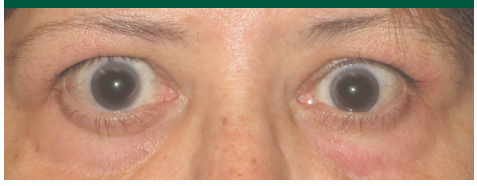
**BASELINE**
**Proptosis: 25 mm**
**Diplopia: 3**



**Inflammatory signs and symptoms:**

- Spontaneous orbital pain
- Gaze-evoked orbital pain
- Eyelid swelling
- Eyelid erythema
- Conjunctival redness

**POST-TREATMENT (WEEK 24)**
**Proptosis: 21 mm**
**Diplopia: 0**



**Inflammatory signs and symptoms:**

No inflammatory signs or symptoms

Patient treated with TEPEZZA in a clinical trial. Results shown are with no surgical intervention. Individual results may vary.

## More overall responders[8†]

**TEPEZZA**
**78%**
vs placebo
**7%**
(Study 2; Week 24)

Similar results were seen in Study 1: more patients were overall responders† with TEPEZZA vs placebo at Week 24 (69% vs 20%).[3]

†An overall responder was defined as having a ≥2-mm reduction in proptosis in the study eye from baseline and a ≥2-point reduction in CAS (a 7-point scale where a lower score indicates fewer symptoms) without deterioration (≥2-mm increase in proptosis or ≥2-point increase in CAS) in the non-study eye.[3]

## Durable proptosis response was demonstrated 51 weeks after the last infusion of TEPEZZA in Study 1[1]

- 53% of patients (16 of 30) who were proptosis responders at Week 24 maintained a ≥2-mm reduction from baseline at Week 72 (~1 year off treatment)[1]

## SELECT IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

**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.

**Please see additional Important Safety Information on following pages and Full Prescribing Information at TEPEZZAhcp.com.**

# TEPEZZA resolved diplopia, a debilitating symptom of TED, in significantly more patients[1,9]

**Diplopia responders**
**(Grade 0/no diplopia)[1‡]**

**TEPEZZA**
**53%**
vs placebo
**25%**
(Studies 1 and 2 combined)

*P*<0.01 at Week 24
**TEPEZZA (n=66)**
Placebo (n=59)

‡Diplopia was evaluated in a subgroup of patients who had diplopia at baseline in Studies 1 and 2 (n=125). Diplopia was evaluated on a 4-point scale where scores ranged from 0 for no diplopia to 3 for constant diplopia. A diplopia responder was defined as a patient with baseline diplopia >0 and a score of 0 at Week 24.[1]

## Durable diplopia response was demonstrated 51 weeks after the last infusion of TEPEZZA in Study 1[1]

- 67% of patients (12 of 18) who were diplopia responders (Grade 0) at Week 24 maintained a response at Week 72[1]

## SELECT IMPORTANT SAFETY INFORMATION

### Warnings and Precautions (continued)

**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.

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# TEPEZZA was generally well tolerated—most adverse events were mild or moderate, were manageable, and resolved during or after treatment[1]

| Adverse reactions occurring in ≥5% of patients treated with TEPEZZA and with greater incidence than placebo[1] | | |
|---|---|---|
| ADVERSE REACTIONS | TEPEZZA N=84 n (%) | Placebo N=86 n (%) |
| Muscle spasms | 21 (25%) | 6 (7%) |
| Nausea | 14 (17%) | 8 (9%) |
| Alopecia | 11 (13%) | 7 (8%) |
| Diarrhea | 10 (12%) | 7 (8%) |
| Fatigue[a] | 10 (12%) | 6 (7%) |
| Hyperglycemia[b] | 8 (10%) | 1 (1%) |
| Hearing impairment[c] | 8 (10%) | 0 |
| Dysgeusia | 7 (8%) | 0 |
| Headache | 7 (8%) | 6 (7%) |
| Dry skin | 7 (8%) | 0 |

[a]Fatigue includes asthenia.
[b]Hyperglycemia includes blood glucose increase.
[c]Hearing impairment includes deafness, eustachian tube dysfunction, hyperacusis, hypoacusis, and autophony.

## There was a low rate of discontinuation

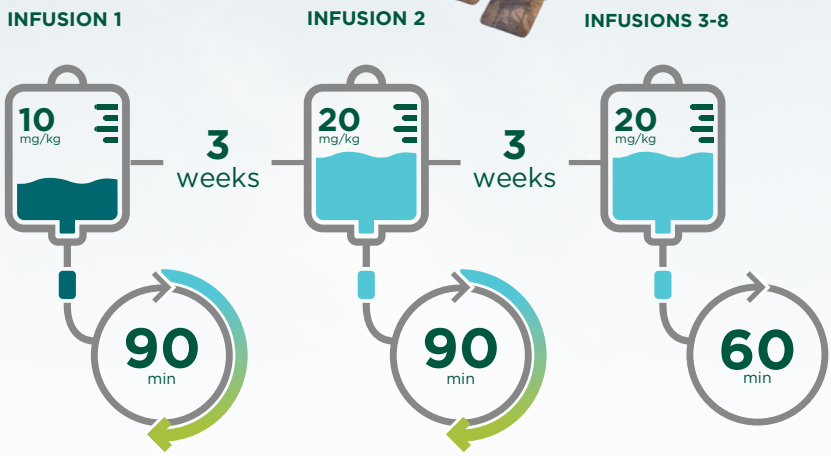
**89%** of patients completed treatment with TEPEZZA vs 93% with placebo[1]

**Please see Important Safety Information on following pages and Full Prescribing Information at TEPEZZAhcp.com.**

# TEPEZZA is given once every 3 weeks for a total of 8 infusions[1]

## Dosing and administration

- TEPEZZA is dosed according to the patient's actual weight[1]
- Administer the diluted solution as an IV solution over 90 minutes for the first 2 infusions[1]
- If well tolerated, the minimum time for subsequent infusions can be reduced to 60 minutes[1]
  - –If not well tolerated, the minimum time for subsequent infusions should remain at 90 minutes[1]




## Other considerations

- Educate and counsel females of reproductive potential about the need to use effective contraception prior to initiation, during treatment with TEPEZZA, and for 6 months after the last dose[1]
- Patients' glucose levels should be monitored for hyperglycemic reactions[1]
- Patients with preexisting diabetes or impaired glucose tolerance should be under appropriate glycemic control before receiving TEPEZZA[1]

**Learn more at TEPEZZAhcp.com**

## SELECT IMPORTANT SAFETY INFORMATION

### Adverse Reactions

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

**Please see additional Important Safety Information on previous pages and Full Prescribing Information at TEPEZZAhcp.com.**

**References: 1.** TEPEZZA (teprotumumab-trbw) [prescribing information] Horizon. **2.** Douglas RS, Kahaly GJ, Patel A, et al. Teprotumumab for the treatment of active thyroid eye disease. *N Engl J Med.* 2020;382(4):341-352. **3.** Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for thyroid-associated ophthalmopathy. *N Engl J Med.* 2017;376(18):1748-1761. **4.** Smith TJ, Kahaly GJ, Ezra DG, et al. Teprotumumab for thyroid-associated ophthalmopathy. *N Engl J Med.* 2017;376(18)(suppl):1748-1761. https://www.nejm.org/doi/suppl/10.1056/NEJMoa1614949/suppl_file/nejmoa1614949_appendix.pdf. **5.** Data on File. Horizon, December 2019. **6.** Bruscolini A, Sacchetti M, La Cava M, et al. Quality of life and neuropsychiatric disorders in patients with Graves' orbitopathy: current concepts. *Autoimmun Rev.* 2018;17(7):639-643. **7.** Data on File. Horizon, January 2020. **8.** Data on File. Horizon, April 2019. **9.** Ponto KA, Merkesdal S, Hommel G, Pitz S, Pfeiffer N, Kahaly GJ. Public health relevance of Graves' orbitopathy. *J Clin Endocrinol Metab.* 2013;98(1):145-152.



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