

Learn about a patient with a history of ~2 attacks per month and see data from the pivotal and open-label extension studies

#### INDICATION

TAKHZYRO is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥2 years of age.

#### **IMPORTANT SAFETY INFORMATION**

**Hypersensitivity reactions** have been observed. In case of a severe hypersensitivity reaction, discontinue TAKHZYRO administration and institute appropriate treatment.



# MEET ANDREW



# **HAE** history

- **Age:** 30s
- Age at diagnosis: 10
- Primary attack locations: Abdomen, face, extremities
- History of laryngeal attacks: No

## **Treatment history**

- Andrew treated his HAE attacks with pain medications and increased fluid intake during his teenage years
- Participated in 2 clinical trials while in high school to help both himself and the larger HAE community discover new treatments for the disease
- Found an acute treatment that lessened the severity of attacks when they occurred, but decided that he wanted a treatment option that could help prevent attacks

# **Experience with HAE**

- Attack rate: ~2 attacks/month
- Debilitating attacks: Andrew's first attacks occurred in his abdominal area, resulting in intense pain as the waves of swelling would come and go
- Impact of attacks: Andrew's attacks would leave him bedridden for days. He often worried about when the next attack would happen
- Family history: Andrew is the only member of both his immediate and extended family with HAE

Individuals featured are TAKHZYRO patients as of 2023 and are sharing their own experiences. Individual experiences may vary.

### **IMPORTANT SAFETY INFORMATION (cont'd)**

Adverse Reactions: The most commonly observed adverse reactions (≥10%) associated with TAKHZYRO were injection site reactions consisting mainly of pain, erythema, and bruising at the injection site; upper respiratory infection; headache; rash; dizziness; diarrhea; and myalgia. Less common adverse reactions observed included elevated levels of transaminases; one patient discontinued the trial for elevated transaminases.

Please see additional <u>Important Safety Information</u> throughout and full <u>Prescribing Information</u>.

# ANDREW NEEDED EFFECTIVE PREVENTION IN THE LONG TERM



# Clinically proven to reduce attacks

#### **HELP study**

- In the HELP pivotal study, 125 patients (≥12 years of age) were randomized to receive TAKHZYRO 300 mg every 2 weeks or placebo for 6.5 months<sup>1,2</sup>
- Safety results: Injection site reactions were the most common adverse reactions in the HELP study. Injection site reactions consisted mainly of pain, erythema, and bruising at the injection site<sup>1</sup>
- Primary endpoint: 87% mean attack reduction for patients taking TAKHZYRO (n=27) vs placebo (n=41; Adjusted P<0.001)<sup>1,2\*</sup>
- Secondary endpoints: Patients taking TAKHZYRO had 83% fewer moderate or severe attacks and 87% fewer attacks that needed acute treatment (n=27) vs placebo (n=41; Adjusted P<0.001)<sup>1,2\*</sup>

# HELP OLE study, in which long-term safety was the primary endpoint<sup>3</sup>

- In the HELP OLE study, 212 patients (rollover and nonrollover, ≥12 years of age) received TAKHZYRO 300 mg every 2 weeks, with a mean treatment duration of 29.6 (SD=8.2) months<sup>3</sup>
- Safety results: Injection site pain was the most common adverse reaction in the HELP OLE study. The overall safety results were consistent with the HELP study<sup>1,3</sup>
- Secondary endpoint: 87% mean attack reduction, consistent with the HELP study, for patients taking TAKHZYRO compared to baseline (N=209)<sup>3</sup>



# Zero attacks for extended periods of time

#### **HELP study**

- Exploratory endpoints:
- 44% of patients taking TAKHZYRO (n=27)
  had zero attacks vs 2% of patients taking
  placebo (n=41) during the entire 6.5-month
  study duration (prespecified)<sup>1,2</sup>
- 77% of patients taking TAKHZYRO (n=26) had zero attacks vs 3% of patients taking placebo (n=37) from Day 70 to Day 182 (post hoc analysis)<sup>2</sup>

All data presented are for TAKHZYRO 300 mg every 2 weeks.

The recommended starting dosage in adult and pediatric patients 12 years of age and older is 300 mg every 2 weeks. TAKHZYRO 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (eg, attack free) for more than 6 months.<sup>1</sup>

<sup>†</sup>The percentage of days with zero attacks was calculated by counting the number of days in the treatment period without an HAE attack and dividing by the number of days the patient spent in the treatment period.<sup>4</sup> OLE=open-label extension.

#### **HELP OLE study**

- Prespecified exploratory endpoints:
- Patients had zero attacks for 98% of days, on average, during the treatment period (N=209)<sup>3+</sup>
- 82% of patients had zero attacks for at least a 6-month period (N=209; average time on study was 29.6 [SD=8.2] months)<sup>3</sup>
- 14.8 months was the mean duration of the attack-free period (415 days, SD=12.4 months; N=209)<sup>3</sup>



<sup>\*</sup>Adjusted P-values for multiple testing.1

Since starting TAKHZYRO...the frequency of my attacks has lessened, and I even had a 6-month period on the therapy without a single swell."

#### Andrew

Real TAKHZYRO patient since 2018

Learn more about TAKHZYRO at TAKHZYRO.com/hcp/efficacy.

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**Use in Specific Populations:** The safety and efficacy of TAKHZYRO in pediatric patients <2 years of age have not been established.

No data are available on TAKHZYRO in pregnant women. No data are available on the presence of lanadelumab in human milk or its effects on breastfed infants or milk production.

To report SUSPECTED ADVERSE REACTIONS, contact Dyax Corp., a Takeda company, at 1-877-TAKEDA-7 (1-877-825-3327), or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional <u>Important Safety Information</u> throughout and full <u>Prescribing Information</u>.

References: 1. Takhzyro. Prescribing information. Dyax Corp; 2023. 2. Banerji A, Riedl MA, Bernstein JA, et al. Effect of lanadelumab compared with placebo on prevention of hereditary angioedema attacks: a randomized clinical trial. *JAMA*. 2018;320(20):2108-2121. doi:10.1001/jama.2018.16773 3. Banerji A, Bernstein JA, Johnston DT, et al; HELP OLE Investigators. Long-term prevention of hereditary angioedema attacks with lanadelumab: the HELP OLE study. *Allergy*. 2022;77(3):979-990. doi:10.1111/all.15011 4. Data on file, TAK743-098, Takeda Pharmaceuticals USA. Inc.



