REAL PATIENT JOURNEYS TO TAKHZYRO

Acute-only patient

INDICATION

TAKHZYRO is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥12 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.

Please see additional Important Safety Information throughout and full Prescribing Information.

TAKHZYRO®
(lanadelumab-flyo) injection

MEET JASON*

HAE history

- Type: **HAE type 1**
- Current age: **21 years old**
- Age at diagnosis: **12 years old**
- Primary attack location: **Abdominal**
- History of laryngeal attacks: **Yes, multiple**

Treatment history

- **Prophylaxis: None**
- **Acute treatment since age 14**

Jason's experience with HAE

- **Attack rate:** ~2 attacks/month
- **Common triggers:** Upper respiratory infections (ie, streptococcal pharyngitis)
- **Impact of attacks:** Abdominal attacks, with symptoms of sharp pains, vomiting, and diarrhea that would last several days, were disruptive to daily activities and led to absences from school
- **Administration preferences:** Expressed discomfort with IV administration
- **Request for re-evaluation:** Wanted to change his treatment approach from acute-only to prevention because he was beginning nursing school and concerned about the impact of his unpredictable attacks

"Considering preventive treatment for a patient is about more than attack frequency. For Jason, it was clear that he would be a good candidate for a preventive treatment that would offer him better control of his HAE."

Douglas Johnston, DO

Allergist/Clinical Immunologist
Charlotte, NC
15 years treating HAE, ~100 patients

IMPORTANT SAFETY INFORMATION (cont'd)

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

*Information based on a real patient. Patient's name has been changed.

STARTING TAKHZYRO WAS RIGHT FOR JASON

Dr. Johnston and Jason had a discussion about how this first-of-its-kind mAb preventive treatment could help Jason reimagine his life with HAE[1]

TAKHZYRO every 2 weeks was proven to significantly reduce mean monthly attacks vs placebo by 87% (0.26 vs 1.97), which included 83% fewer moderate or severe attacks (0.20 vs 1.22) and 87% fewer attacks requiring acute treatment (0.21 vs 1.64), in the largest prevention study in HAE with the longest active treatment duration[1-3†]

In an exploratory analysis, 44% of patients taking TAKHZYRO had zero attacks vs 2% taking placebo during the entire 26-week treatment period. In a post hoc analysis, 77% of patients taking TAKHZYRO had zero attacks vs 3% taking placebo during steady state[1,4‡]

One subcutaneous self-injection taken every 2 weeks in ≤1 minute for most patients,[1§] which addressed Jason's discomfort with IV administration

Available as a ready-to-use single-dose vial that does not require reconstitution[1]

mAb=monoclonal antibody.

Additional information about the clinical trial

†The clinical trial was a multicenter, double-blind, parallel-group, placebo-controlled, dose-ranging study, which assessed the safety and efficacy of TAKHZYRO in 125 patients with HAE type I or II (≥12 years of age). Patients were randomized to receive TAKHZYRO 150 mg every 4 weeks (n=28), TAKHZYRO 300 mg every 4 weeks (n=29), TAKHZYRO 300 mg every 2 weeks (n=27), or placebo (n=41) for 26 weeks (6.5 months, where 1 month was defined as 28 days). Patients with ≥1 investigator-confirmed HAE attack during the 4-week run-in period were eligible for study enrollment and randomization. The primary efficacy endpoint was the rate of investigator-confirmed attacks during the treatment period (time frame: from Day 0 to Day 182) (Adjusted $P<0.001$ vs placebo for all; adjusted P-values for multiple testing).[1,4]

‡Percentage of patients who had zero attacks over the entire 26-week study duration was a prespecified, exploratory endpoint; n=27 for TAKHZYRO, n=41 for placebo. Percentage of patients who had zero attacks during the steady-state period (Day 70 to Day 182) was a post hoc analysis; n=26 for TAKHZYRO, n=37 for placebo.[4]

§The recommended starting dose is 300 mg every 2 weeks. TAKHZYRO every 4 weeks is also effective and may be considered if the patient is well-controlled (eg, attack free) for more than 6 months. In clinical trials, the majority of patients self-administered TAKHZYRO within 10 to 60 seconds.[1]

"Ever since I started TAKHZYRO, I'm able to use my acute treatment less because I'm having fewer attacks overall. In fact, I've gone months without having any at all."

– Jason

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A FIRST-OF-ITS-KIND mAb PREVENTIVE TREATMENT FOR HAE[1]

Rediscover prevention

- Significant reduction in mean monthly attacks vs placebo[1]
- Secondary endpoints of moderate or severe attacks and attacks requiring acute treatment vs placebo were met[1]
- There were patients who had zero attacks according to an exploratory analysis[1]*

Rethink dosing and administration

- One subcutaneous self-injection every 2 weeks[1]†

Refine the approach

- The first and only mAb for HAE, TAKHZYRO inhibits plasma kallikrein activity[1]

Get your patients started today

Visit TAKHZYRO.com/hcp

IMPORTANT SAFETY INFORMATION (cont'd)

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

Use in Specific Populations: The safety and efficacy of TAKHZYRO in pediatric patients <12 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 1–800–828–2088, or FDA at 1–800–FDA–1088 or www.fda.gov/medwatch.

Please see full Prescribing Information.

See additional information about the clinical trial inside.

*Percentage of patients who had zero attacks over the entire 26-week study duration was a prespecified, exploratory endpoint.[1]
†The recommended starting dose is 300 mg every 2 weeks. TAKHZYRO every 4 weeks is also effective and may be considered if the patient is well-controlled (eg, attack free) for more than 6 months.[1]

References: 1. TAKHZYRO (lanadelumab-flyo) [prescribing information]. Lexington, MA: Shire LLC; 2018. **2.** HAEGARDA [prescribing information]. Kankakee, IL: CSL Behring LLC; 2017. **3.** CINRYZE (C1 esterase inhibitor [human]) [prescribing information]. Lexington, MA: Shire ViroPharma Incorporated; 2010. **4.** 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.

Takeda

S47896 06/19

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