

THE #1 PRESCRIBED HAE PREVENTIVE TREATMENT\*—APPROVED IN PATIENTS AS YOUNG AS 2 YEARS OF AGE. OVER 5 YEARS OF PATIENT EXPERIENCE AND 4000+ PATIENTS PRESCRIBED SINCE 2018.<sup>1†</sup>

Dennis

Real TAKHZYRO patient  
since 2018

# — THIS IS MY TAKHZYRO — EXPERIENCE

TAKHZYRO is clinically proven to help prevent HAE attacks, and patients experienced long-term freedom from attacks for an average of 14.8 months.<sup>1,2</sup>

- Evaluated in a 6.5-month study and a 2.5-year open-label extension (OLE) study
- Mean duration of the attack-free period in the OLE study was 14.8 (SD=12.4) months (N=209)

CLICK TO GET STARTED



\*Based on total patients on HAE preventive treatments according to US third-party industry healthcare data.

†The number of patients prescribed TAKHZYRO is based on third-party US specialty pharmacy data.

## INDICATION

TAKHZYRO is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients  $\geq 2$  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.

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).

TAKHZYRO<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg

### What is HAE?

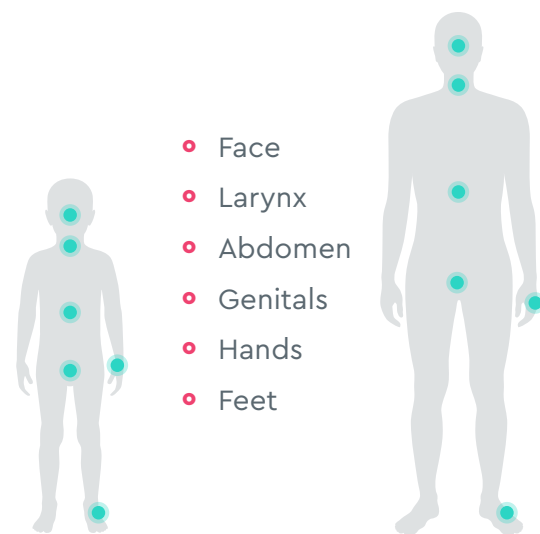
# AN UNPREDICTABLE AND POTENTIALLY LIFE-THREATENING GENETIC DISEASE

HAE is a rare genetic disease that causes recurrent, debilitating, and potentially life-threatening attacks of angioedema in the body. HAE affects about 1 in 50,000 people of all ages.<sup>3,4</sup>

An accurate and early diagnosis is an important first step in developing an effective management plan for your patients with HAE.

The frequency and severity of HAE attacks may vary for each individual over time regardless of age, meaning past attacks do not predict the severity of future attacks.<sup>5</sup>

**For both adult and pediatric patients, attacks can occur in the...<sup>6</sup>**



- Face
- Larynx
- Abdomen
- Genitals
- Hands
- Feet

**Attacks in the larynx can be life-threatening, and they are especially dangerous for children who lack the ability to self-administer treatment during an attack or who may be unable to describe their symptoms.<sup>6,7</sup>**

TAKHZYRO is not indicated for acute treatment.



**Long-term prevention should be individualized and considered in all patients with HAE.<sup>8</sup>**

### 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.

# CRAFT AN EFFECTIVE HAE MANAGEMENT PLAN

Your patients' needs and disease may change over time, and they may need a reminder that their management plan can change.<sup>3</sup>

- The 2020 US HAEA guidelines recommend:
  - Reviewing management plans for patients with HAE on a regular basis, including the need for preventive treatment<sup>3</sup>
  - TAKHZYRO as one of the first-line therapies for long-term prevention in adult and adolescent patients ≥12 years of age<sup>3</sup>
- The 2021 international WAO/EAACI guidelines state:
  - High HAE disease activity often comes with impact on daily life<sup>8</sup>
  - The daily lives of some patients with low attack rates are also impacted, thought to be linked to the unpredictability and continuous fear of HAE attacks, as well as other factors<sup>8</sup>

**Since most attacks are unpredictable and not prompted by triggers, guidelines suggest that physicians should not support excessive avoidance of suspected triggers, which can limit a patient's normal life.<sup>8</sup>**



**"HAE can be unpredictable and attacks could happen with no warning."**

— Andrew  
Real TAKHZYRO patient since 2018

**[Click here](#) to watch doctors and patients discuss the burden of HAE and trigger avoidance.**

EAACI=European Academy of Allergy and Clinical Immunology; HAEA=Hereditary Angioedema Association; WAO=World Allergy Organization.

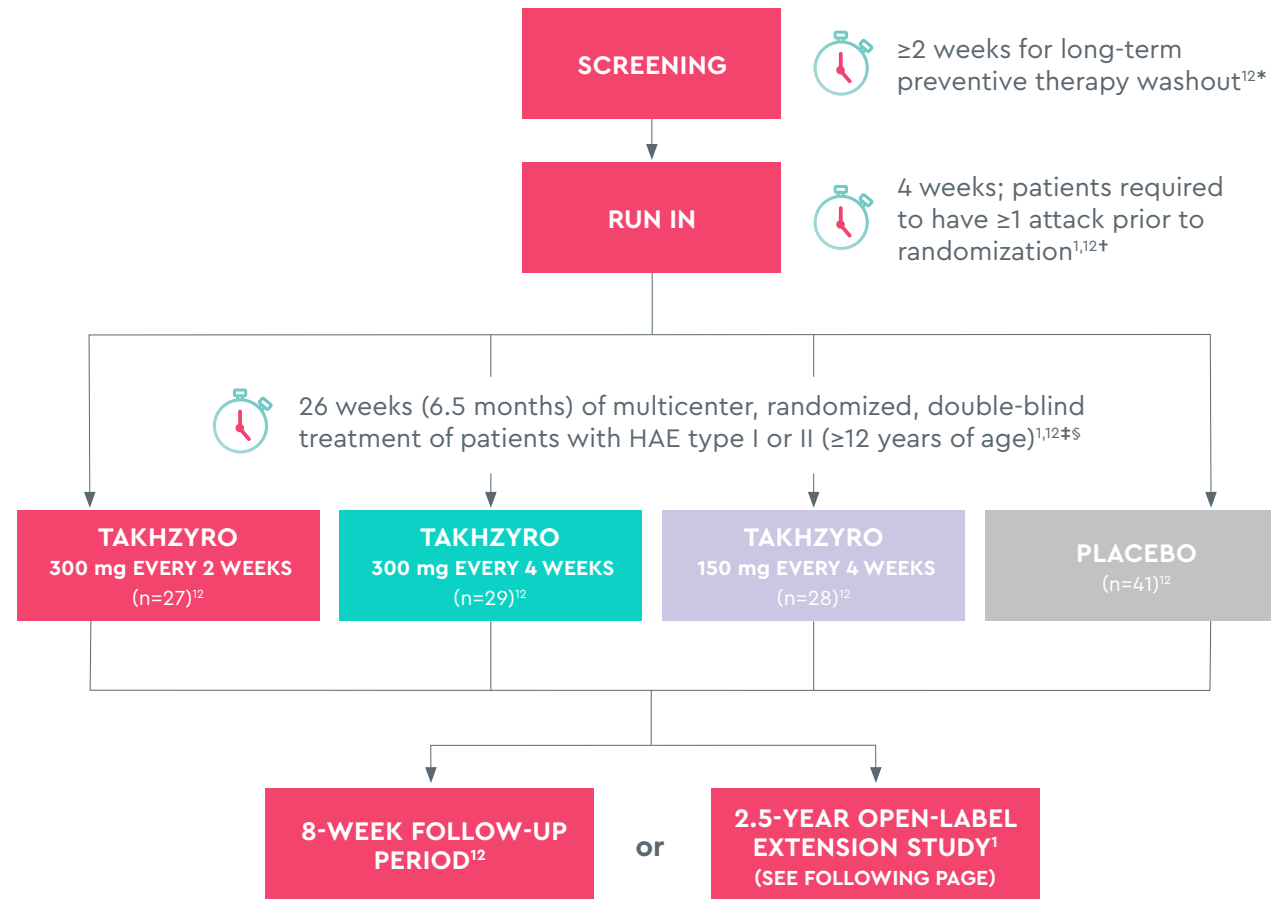
**Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).**



HELP study

WITH 125 PATIENTS, HELP IS THE LARGEST PIVOTAL STUDY IN HAE PREVENTION WITH THE LONGEST ACTIVE DURATION<sup>1,9-11</sup>

44% of patients at baseline in HELP had not previously received long-term preventive therapy<sup>12</sup>



\*Long-term preventive therapy washout was only for patients ≥18 years of age.<sup>13</sup>  
 †Run-in period could be shortened if the patient experienced ≥3 HAE attacks before completion of the 4 weeks, and the period could be extended to 8 weeks if the patient did not experience any attacks during the 4 weeks. During the 8 weeks, the patient needed to have ≥2 attacks to proceed to enrollment and randomization.<sup>12</sup>  
 ‡Treatments were administered as 2 separate 1-mL injections in the upper arm every 2 weeks to maintain the blind.<sup>12</sup>  
 §One month was defined as 28 days in the trial.<sup>12</sup>

IMPORTANT SAFETY INFORMATION (cont'd)

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

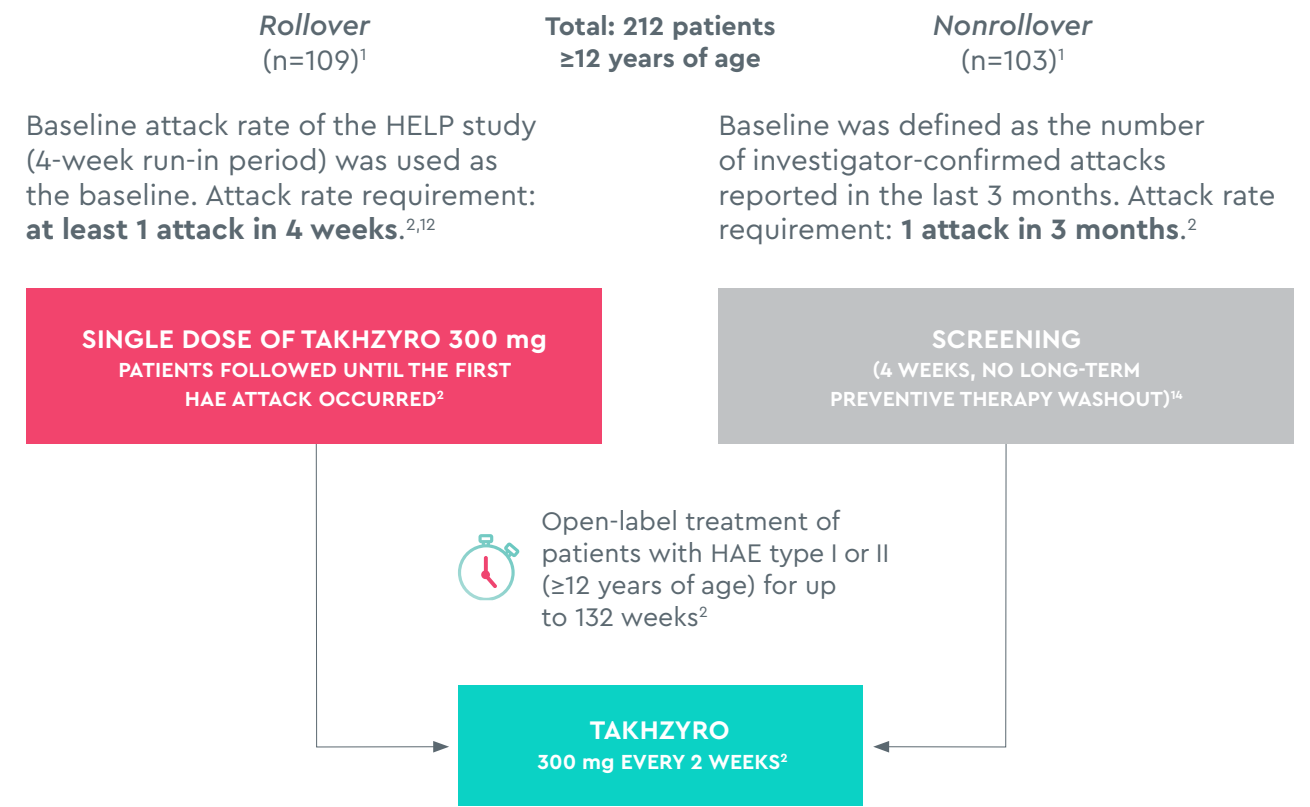
No data are available on TAKHZYRO in pregnant women. No data are available on the presence of lanadelumab in human milk or its effects on breastfed infants or milk production.

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](http://www.fda.gov/medwatch).

HELP open-label extension (OLE) study

ABOUT 97% OF PATIENTS IN THE HELP STUDY ENROLLED IN THE 2.5-YEAR EXTENSION STUDY<sup>2</sup>

41% of patients at baseline in HELP OLE had not previously received long-term preventive therapy<sup>2</sup>



- Patients were given TAKHZYRO 300 mg every 2 weeks for a mean duration of **29.6 (SD=8.2) months<sup>2</sup>**
- 81.6% of patients completed the study or enrolled in commercial product<sup>2</sup>

The long-term safety of TAKHZYRO was the primary endpoint in this study.<sup>2</sup>

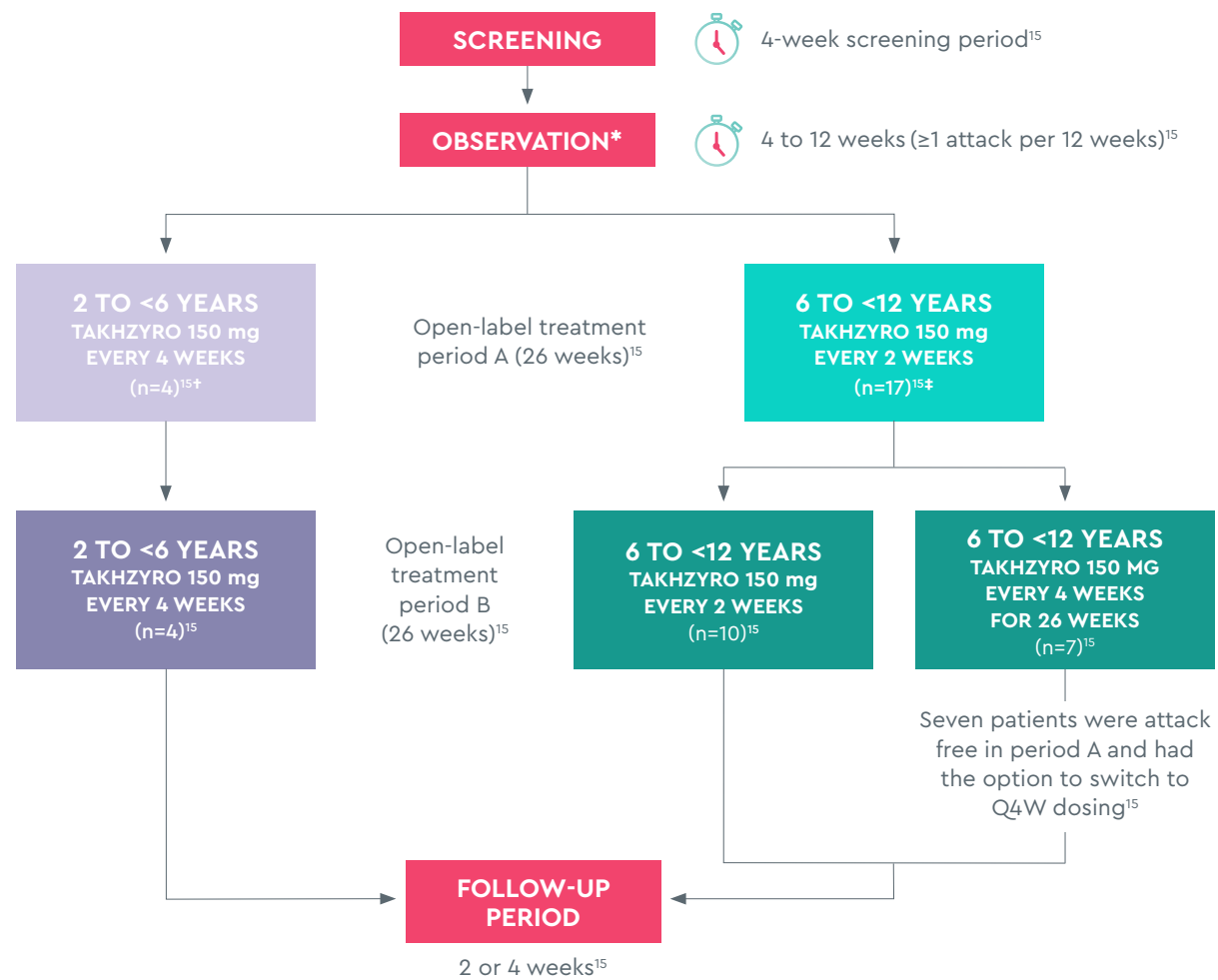
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TAKHZYRO<sup>®</sup>  
 (lanadelumab-flyo) injection 300mg-150mg

SPRING study

# AN OPEN-LABEL, MULTICENTER STUDY IN PATIENTS WITH HAE AS YOUNG AS 2 YEARS OF AGE<sup>1</sup>

TAKHZYRO was studied in 21 pediatric patients 2 to <12 years of age with HAE type I or II<sup>1</sup>



The safety and pharmacokinetics of TAKHZYRO were the co-primary endpoints in the SPRING study.<sup>15</sup>

\*Eligible patients underwent a 4- to 12-week baseline observation period before initiating treatment with TAKHZYRO.<sup>15</sup>

†Patients aged 2 to <6 years received 150 mg every 4 weeks for the 52-week treatment period.<sup>15</sup>

‡Patients aged 6 to <12 years were to receive 150 mg every 2 weeks for 52 weeks and had an option to switch to every 4 weeks if they were attack free for 26 weeks.<sup>15</sup>

Q4W=every 4 weeks.



## 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](#).

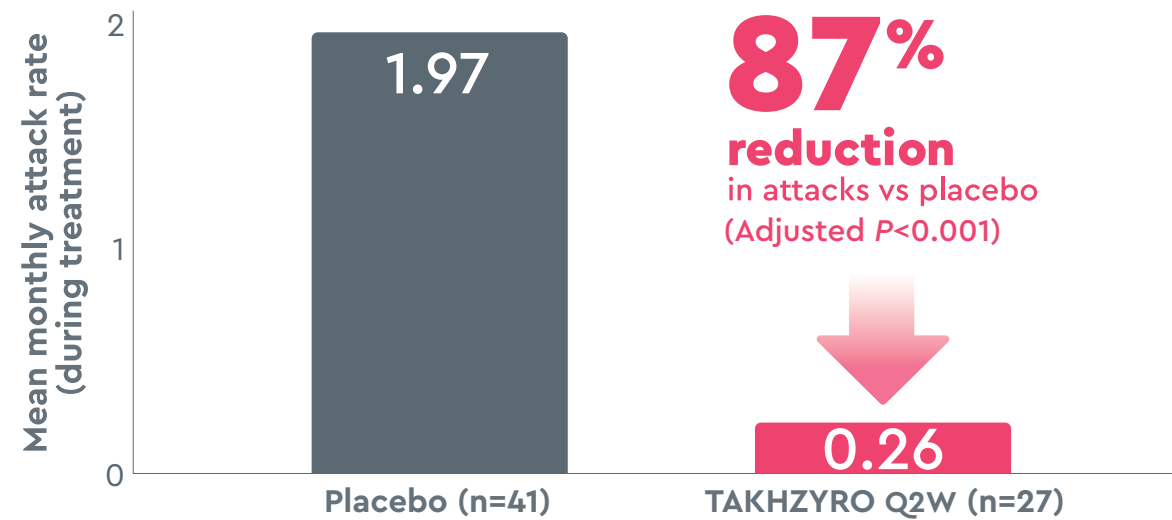
**TAKHZYRO**<sup>®</sup>  
(lanadelumab-flyo) injection 300 mg/150 mg

HELP primary endpoint

# REDISCOVER EFFECTIVE PREVENTION

Significant reduction in mean attack rate\* vs placebo at 6.5 months<sup>1,12</sup>

## TAKHZYRO vs placebo



- TAKHZYRO 300 mg every 4 weeks resulted in a 73% reduction in attacks vs placebo (Adjusted  $P < 0.001$ )<sup>†</sup>
  - Please see page 10 for additional subanalysis of the Q4W cohort

### Mean monthly attack rate during the run-in period<sup>12</sup>:

<b>3.52</b> for Q2W arm (n=27)	<b>3.71</b> for Q4W arm (n=29)	<b>4.02</b> for placebo arm (n=41)
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### Mean monthly attack rate during the treatment period<sup>1</sup>:

<b>0.26</b> for Q2W arm	<b>0.53</b> for Q4W arm	<b>1.97</b> for placebo arm
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All data presented are for TAKHZYRO 300 mg every 2 weeks unless otherwise indicated.

\*Mean monthly attack rate: number of attacks/4 weeks.<sup>1</sup>

<sup>†</sup>Adjusted  $P$ -values for multiple testing.<sup>1</sup>

Q2W=every 2 weeks.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Adverse Reactions:** The most commonly observed adverse reactions ( $\geq 10\%$ ) 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.

HELP secondary endpoints

Significant reduction in moderate to severe attacks and attacks requiring acute treatment vs placebo at 6.5 months<sup>1,12</sup>

Attack reduction vs placebo (Adjusted $P < 0.001$ ) <sup>1,12*</sup>	Reduction in moderate or severe attacks	Reduction in attacks requiring acute treatment
TAKHZYRO 300 mg every 2 weeks (n=27)	83%	87%
TAKHZYRO 300 mg every 4 weeks (n=29)	73%	74%



“With my attacks being so unpredictable, I wanted something that could help reduce their frequency and severity. That’s why I’m glad I found TAKHZYRO.”

— Kelly

Real TAKHZYRO patient since 2018

Individuals featured are TAKHZYRO patients as of 2024 and are sharing their own experiences. Individual experiences may vary.

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

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HELP prespecified exploratory endpoints

## SUBGROUP RESULTS FROM THE 300 mg Q4W ARM OF THE HELP STUDY

### Attack History

- 80% reduction in attacks on average vs placebo for patients who had 1 to <2 HAE attacks per month at baseline (n=9)<sup>13\*</sup>
- 77% reduction in attacks on average vs placebo for patients that had 2 to <3 attacks per month (n=5)<sup>13</sup>
- 71% reduction in attacks on average vs placebo for patients that had ≥3 attacks per month (n=15)<sup>13</sup>

### Body Mass Index (BMI)

- 86% reduction in attacks on average vs placebo for patients with a normal BMI (n=6)<sup>13\*\*</sup>
- 70% reduction in attacks on average vs placebo for patients with an overweight BMI (n=5)<sup>13§</sup>
- 74% reduction in attacks on average vs placebo for patients with an obese BMI (n=8)<sup>13¶</sup>

These studies were prespecified exploratory analyses in the pivotal HELP study to evaluate the efficacy and safety of TAKHZYRO compared to placebo in patients of varying BMIs and in patients with different baseline run-in attack rates.

Your patient may be considered for less frequent dosing with TAKHZYRO if they are well controlled (eg, attack free) for more than 6 months.<sup>1</sup>



“My HAE was so bad [that] I had a hard time making plans with my family... I decided I wanted a medication that would help prevent attacks before they happened.”

— Soraya

Real TAKHZYRO patient since 2018

\*In the HELP study, TAKHZYRO provided reductions in monthly attack rates relative to placebo in patients with HAE, regardless of baseline attack rate.<sup>13</sup>

\*\*In the HELP study, TAKHZYRO reduced the HAE attack rate compared with placebo, regardless of patients' BMI.<sup>13</sup>

§A normal BMI was defined as 18.5 to <25 kg/m<sup>2</sup> (n=35).<sup>13</sup>

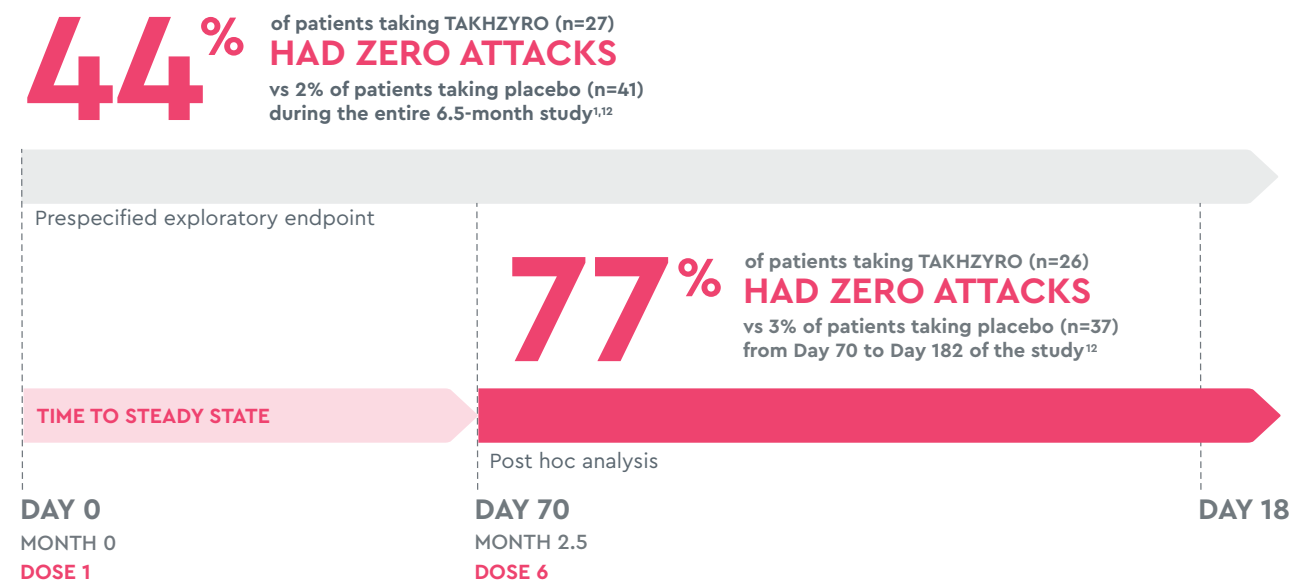
¶An overweight BMI was defined as 25 to <30 kg/m<sup>2</sup> (n=43).<sup>13</sup>

§§An obese BMI was defined as ≥30 kg/m<sup>2</sup> (n=36).<sup>13</sup>

HELP exploratory endpoints

## FREEDOM FROM HAE ATTACKS IN THE HELP STUDY

Many patients taking TAKHZYRO in the study had zero attacks<sup>1,12</sup>



Learn how your patients may experience freedom from HAE attacks for periods of time with TAKHZYRO at [TAKHZYRO.com/hcp](https://www.takeda.com/hcp).<sup>1,12</sup>

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

### IMPORTANT SAFETY INFORMATION (cont'd)

**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](https://www.fda.gov/medwatch).

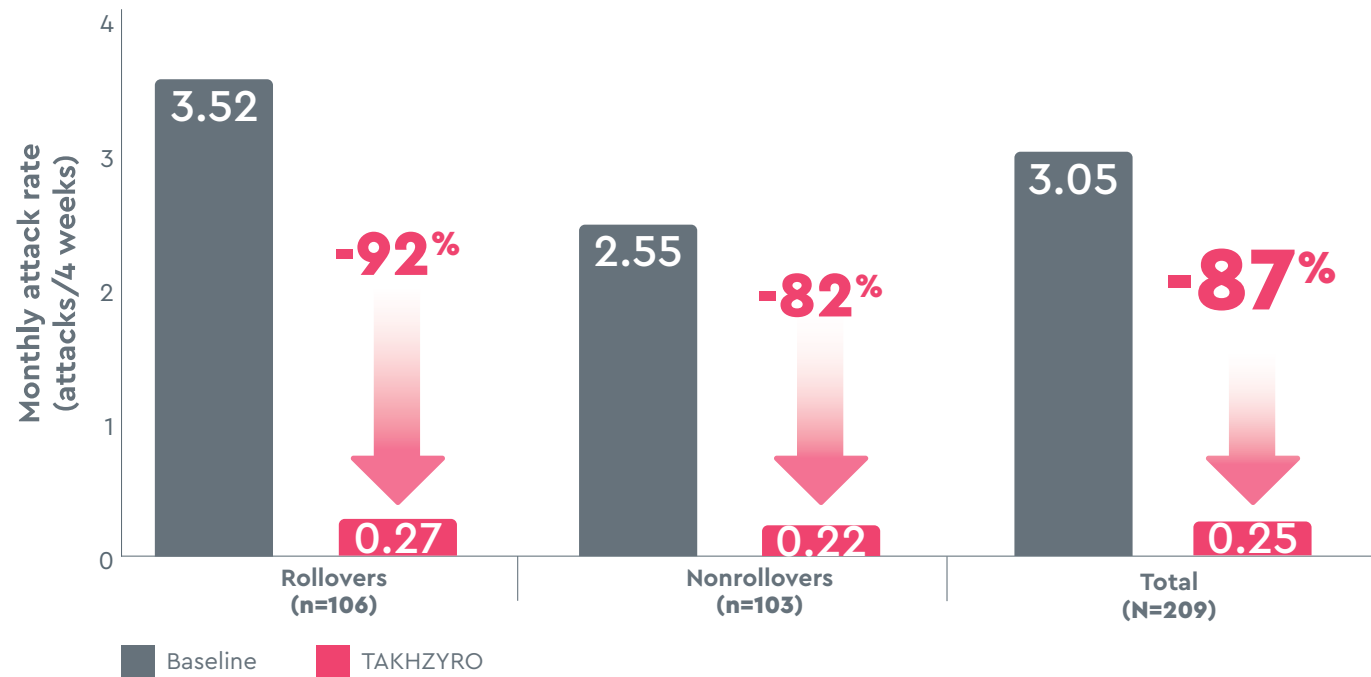
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**TAKHZYRO**<sup>®</sup>  
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HELP OLE secondary endpoints

**IN A 2.5-YEAR STUDY WITH OVER 200 PATIENTS, EFFECTIVE PREVENTION SHOWN IN THE LONG TERM<sup>2</sup>**

Patients taking TAKHZYRO for an average of 30 months experienced attack reduction vs baseline<sup>2</sup>



Patients who experienced a reduction in frequency and severity of attacks in the HELP study (rollover patients) were more likely to choose to continue treatment with TAKHZYRO in HELP OLE, which may affect the interpretation of these data.

- 0.25 mean monthly attack rate (N=209; baseline: 3.05)<sup>2</sup>
- 0.05 median monthly attack rate (range: 0.0-4.7; baseline: 2.00)<sup>13</sup>
- 84% reduction in moderate or severe attacks (N=209)<sup>2</sup>
- 93% reduction in attacks requiring acute treatment (n=106)<sup>2</sup>

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

**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](#).

HELP OLE prespecified exploratory endpoints

Freedom from attacks for extended periods of time when taking TAKHZYRO for an average of 30 months (N=209)<sup>2</sup>

**ZERO ATTACKS FOR**

**14.8**

**MONTHS**

ON AVERAGE

Mean duration of attack-free period: 415 days (SD=12.4 months)<sup>2</sup>

**98%**

**OF DAYS ON AVERAGE**

DURING TREATMENT PERIOD\*

(N=209, SD=6%)<sup>2</sup>

**8 OUT OF 10**

**PATIENTS (82%)**

WERE ATTACK FREE FOR AT LEAST A 6-MONTH PERIOD

(N=209)<sup>2</sup>

**NEARLY 7 OUT OF 10**

**PATIENTS (69%)**

WERE ATTACK FREE FOR AT LEAST A 1-YEAR PERIOD

Mean study duration: 29.6 (SD=8.2) months<sup>2</sup>

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

\*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>13</sup>

Long-term, open-label extension data were consistent with the safety profile and efficacy in the pivotal trial.<sup>1,2</sup>

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(lanadelumab-flyo) injection 300mg-150mg

## SPRING study endpoints

# ESTABLISHED EFFECTIVENESS AND SAFETY PROFILE IN PEDIATRIC PATIENTS 2 TO <12 YEARS OF AGE<sup>1</sup>

Use of TAKHZYRO for patients 2 to <12 years of age was supported by extrapolation of efficacy data from the HELP study, with additional pharmacokinetic analyses showing similar drug exposures between adults and pediatric patients, and safety and pharmacodynamic data from the SPRING study.<sup>1</sup>

Lanadelumab-flyo exposures in pediatric patients 2 to <12 years of age receiving TAKHZYRO 150 mg every 2 weeks or every 4 weeks were comparable to those in adult patients receiving TAKHZYRO 300 mg every 2 weeks<sup>15</sup>

- **Pharmacokinetics (Co-primary Endpoint):** Patients aged 2 to <12 years taking TAKHZYRO in the 52-week open-label study experienced systemic exposure to TAKHZYRO<sup>15</sup>

The safety and pharmacokinetics of TAKHZYRO were the co-primary endpoints in the SPRING study.<sup>15</sup>

## IMPORTANT SAFETY INFORMATION (cont'd)

**Adverse Reactions:** The most commonly observed adverse reactions ( $\geq 10\%$ ) 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 [Important Safety Information](#) throughout and full [Prescribing Information](#).

## SPRING study secondary endpoints

### Limitations

Because this was a noncontrolled, open-label study that enrolled 21 pediatric patients and lacked statistical hypothesis testing, these data have less evidentiary value than a double-blind, placebo-controlled study. Further confirmatory studies are required to draw any conclusions from these data.

Patients aged 2 to <12 years taking TAKHZYRO in the 52-week open-label study experienced attack reduction vs baseline<sup>1,15</sup>

### Secondary Endpoints

- **95%** reduction in attacks on average vs baseline (N=21)<sup>15</sup>
  - Mean monthly attack rate at baseline (during observation period): 1.84 (N=21)<sup>15</sup>
  - Mean monthly attack rate on treatment: 0.08 (N=21)<sup>15</sup>
- **76%** of patients experienced freedom from attacks for the entire 52-week study (n=16)<sup>15</sup>
- **99.5%** of days on average with zero attacks during the entire treatment period (N=21)<sup>15</sup>



All data presented are for the total population of pediatric patients taking TAKHZYRO 150 mg every 2 or every 4 weeks.

TAKHZYRO<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg



## HELP safety results

# SAFETY PROFILE ESTABLISHED IN THE LARGEST PIVOTAL TRIAL PREVENTION STUDY IN HAE<sup>1,9-11</sup>

Most common ARs (≥10%) observed in the pivotal trial <sup>1,12*</sup>	TAKHZYRO every 2 weeks (n=27)	TAKHZYRO every 4 weeks (n=29)	Placebo (n=41)
Injection site reactions <sup>†</sup>	56%	45%	34%
• Pain	52%	31%	29%
• Erythema	7%	7%	2%
• Bruising	4%	7%	0%
Upper respiratory infection <sup>‡</sup>	44%	31%	32%
Headache <sup>§</sup>	33%	21%	22%
Rash <sup>¶</sup>	4%	10%	5%
Dizziness	4%	10%	0%
Diarrhea	4%	0%	5%
Myalgia	11%	0%	0%

Hypersensitivity reactions have been observed. In case of a severe hypersensitivity reaction, discontinue TAKHZYRO administration and institute appropriate treatment.<sup>1</sup>

No incidence of anaphylaxis in the pivotal trial.<sup>1</sup>

Injection site reactions were the most common adverse reactions (ARs).<sup>1</sup>

\*≥10% in any TAKHZYRO group that also occurred at a higher rate than placebo group.<sup>1</sup>

<sup>†</sup>Additional injection site reactions included hematoma, hemorrhage, pruritus, swelling, induration, paresthesia, reaction, warmth, edema, and rash.<sup>1</sup>

<sup>‡</sup>Includes upper respiratory infection, viral upper respiratory infection.<sup>1</sup>

<sup>§</sup>Includes headache, tension headache, sinus headache.<sup>1</sup>

<sup>¶</sup>Includes rash, rash maculopapular, rash erythematous.<sup>1</sup>

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## HELP OLE safety results

# CONSISTENT SAFETY PROFILE SEEN IN 212 PATIENTS IN THE OPEN-LABEL EXTENSION STUDY<sup>1</sup>

## Safety data of patients taking TAKHZYRO for an average of 30 months<sup>2</sup>

Most common ARs (≥10%) observed in the HELP open-label study <sup>2</sup>	TAKHZYRO every 2 weeks (N=212)
Injection site pain	47%
Viral upper respiratory tract infection	42%
Upper respiratory tract infection	26%
Headache	25%
Injection site erythema	17%
Arthralgia	13%
Injection site bruising	12%
Back pain	12%
Diarrhea	11%
Sinusitis	11%
Influenza	10%
Nausea	10%
Urinary tract infection	10%

Hypersensitivity reactions (2%, n=4) were reported in the study.<sup>2#</sup>

Six patients discontinued due to treatment-emergent adverse events (TEAEs).<sup>2</sup>

- Three patients discontinued due to hypersensitivity reactions<sup>2</sup>
- One hypersensitivity event was considered related to the study drug and led to discontinuation<sup>2</sup>
- No discontinuations due to injection site reactions, and most injection site reactions resolved within 1 hour (70.2%) or 1 day (92.6%)<sup>2</sup>

No treatment-related serious adverse events or anaphylaxis were observed.<sup>2</sup>

Mean study duration: 29.6 (SD=8.2) months.<sup>2</sup>

<sup>#</sup>Related, treatment-emergent hypersensitivity reactions.<sup>2</sup>

**TAKHZYRO**<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg

SPRING safety results

# SAFETY PROFILE SEEN IN PATIENTS AS YOUNG AS 2 YEARS OF AGE

## Safety data of 21 pediatric patients taking TAKHZYRO for 52 weeks<sup>1</sup>

Most common related TEAEs <sup>15*</sup>	TAKHZYRO 150 mg every 2 or 4 weeks (N=21)
Injection site pain	29%
Injection site erythema	14%
Injection site swelling	5%
Administration site pain	5%
Injection site reaction	5%

The profile of related TEAEs was similar between the every-2-weeks and every-4-weeks dosing treatment groups.<sup>15</sup>

No deaths, serious TEAEs, hospitalizations, or discontinuations due to TEAEs were observed.<sup>15</sup>

No new safety signals were observed in these patients. Overall, the safety was similar between adult patients and pediatric patients (2 to <18 years of age).<sup>1</sup>

\*TEAEs reported by  $\geq 3$  patients are presented.<sup>15</sup>

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TAKHZYRO<sup>®</sup>  
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HR-QoL prespecified exploratory endpoint

## THE BURDEN OF HAE GOES BEYOND THE ATTACK

The unpredictable nature of HAE can affect various facets of a patient's life.<sup>3</sup>

### In the HELP study, quality of life (QoL) measures were evaluated using the AE-QoL and EQ-5D-5L questionnaires<sup>16</sup>

**Limitations:** These results should be interpreted with caution as they are based on patient recall and are observational/descriptive in nature. These data were also from an exploratory objective and had less evidentiary value than the primary and secondary objectives. The AE-QoL was administered to 10 adolescent patients in the study, an age group for which the instrument was not validated.<sup>16</sup>

For the EQ-5D-5L questionnaire, an instrument used to measure health status on a given day, no differences were observed. The nondisease-specific EQ-5D-5L questionnaire was administered on days 0, 98, and 182.<sup>16</sup>

Significantly more patients taking TAKHZYRO vs placebo experienced improvements in AE-QoL in the 6.5-month HELP study<sup>16</sup>:

- 81% of patients receiving TAKHZYRO 300 mg Q2W (95% CI, 61-93; n=26) experienced improvement in AE-QoL total score vs 37% of patients taking placebo ( $P<0.05$ ; 95% CI, 22-54; n=38)<sup>16</sup>
- Patients receiving TAKHZYRO 300 mg Q2W were 7.2 times more likely to achieve improvement in AE-QoL total score vs patients taking placebo ( $P<0.01$ )<sup>16</sup>

**Definitions:** The AE-QoL is a validated, angioedema-specific questionnaire in adults that was administered monthly, consisting of **4 domains (functioning, fatigue/mood, fears/shame, nutrition)** and total scores. The minimal clinically important difference (MCID) is the minimum change in score that is meaningful to patients. For the AE-QoL total score, the predefined MCID is a reduction of 6 points.<sup>16-18</sup>

AE-QoL=Angioedema Quality of Life Questionnaire; EQ-5D-5L=5-level EuroQol 5-dimensional; HR-QoL=health-related quality of life.

### IMPORTANT SAFETY INFORMATION (cont'd)

**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.

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**TAKHZYRO**<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg

For adult and adolescent patients ≥12 years of age

## FREEDOM FROM DAILY DOSING

Ready-to-use self-injection that allows control of injection speed<sup>1</sup>



≤1

**MINUTE TO SELF-INJECT**  
for most people in the clinical studies<sup>\*</sup>

2

**EVERY-2-WEEKS DOSING<sup>1</sup>**

3

**CHOICES FOR INJECTION SITE**  
abdomen, thigh, or upper arm<sup>1</sup>

27-gauge,  
0.5-inch needle



Not actual size.

The TAKHZYRO prefilled syringe is a smaller gauge than other subcutaneous injections, such as those used for<sup>1,19,20</sup>

- Vaccinations (22-25 gauge, 1-1.5 inches)<sup>19</sup>
- FIRAZYR (icatibant [25 gauge, 0.625 inch])<sup>19,20</sup>

- TAKHZYRO has a half-life of ~14 days; therefore, it takes ~10 weeks (ie, 6 doses) to reach **steady state** and ~2 weeks until 50% of TAKHZYRO is eliminated from the body<sup>1,21</sup>
- 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>
- **The TAKHZYRO prefilled syringe does not require reconstitution<sup>1</sup>**

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

<sup>\*</sup>In clinical studies, the majority of patients self-administered TAKHZYRO within 10 to 60 seconds. These injection times are based on vial administration.<sup>1</sup>

### 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](#).

For pediatric patients 2 to <12 years of age

## A LOWER DOSE FOR YOUNGER PATIENTS

Age-based dosing interval of every 2 or 4 weeks<sup>1</sup>

AGES	NUMBER OF DOSES PER MONTH
2 TO <6 YEARS	<b>1</b> 150 mg/1 mL SUBCUTANEOUS INJECTION (1 INJECTION EVERY 4 WEEKS) <sup>1</sup>
6 TO <12 YEARS	<b>2</b> 150 mg/1 mL SUBCUTANEOUS INJECTIONS (1 INJECTION EVERY 2 WEEKS) <sup>1</sup>  A dosing interval of 150 mg every 4 weeks may be considered if the patient is well-controlled (eg, attack free) for more than 6 months. <sup>1</sup>

Remind your patients and their caregivers to always have acute treatment on hand and periodically check the date to ensure it hasn't expired.

One month is defined as 28 days.

TAKHZYRO<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg

# TWO DOSING OPTIONS PROVIDE FLEXIBILITY TO HELP MEET PATIENTS' CHANGING HAE NEEDS

Total doses per month for adult and adolescent patients ≥12 years of age

<p>Q2W DOSING <b>TAKHZYRO<sup>1*</sup></b></p> <p><b>2</b></p> <p>SUBCUTANEOUS INJECTIONS VIA PREFILLED SYRINGE</p> <p>one 300 mg/2 mL injection every 2 weeks</p>	OR	<p>Q4W DOSING <b>TAKHZYRO<sup>1*</sup></b></p> <p><b>1</b></p> <p>SUBCUTANEOUS INJECTION VIA PREFILLED SYRINGE</p> <p>one 300 mg/2 mL injection every 4 weeks if well controlled (eg, attack free) for 6 months</p>
<p>C1 ESTERASE INHIBITOR (HUMAN)</p> <p><b>7</b></p> <p>INTRAVENOUS INFUSIONS 1000 IU every 3 or 4 days</p> <p>OR</p> <p>SUBCUTANEOUS INJECTIONS one injection twice weekly; every 3 or 4 days</p>		<p>ORAL PLASMA KALLIKREIN INHIBITOR</p> <p><b>28</b></p> <p>CAPSULES one 150 mg capsule daily</p>

This presentation is not intended to compare the relative safety or efficacy of these treatments. Please refer to each product's full Prescribing Information.

One month is defined as 28 days.

\*The recommended starting dosage in adult and pediatric patients 12 years of age and older is 300 mg every 2 weeks. A dosing interval of 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>

## 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 [Important Safety Information](#) throughout and full [Prescribing Information](#).

## Total doses per month for pediatric patients

AGES	TAKHZYRO <sup>1</sup>	C1 ESTERASE INHIBITOR (HUMAN) <sup>9,10</sup>	ORAL PLASMA KALLIKREIN INHIBITOR <sup>11</sup>
2 TO <6 YEARS	<b>1</b> SUBCUTANEOUS INJECTION one 150 mg/1 mL injection via prefilled syringe every 4 weeks <sup>1*</sup>	No approved options	No approved options
6 TO <12 YEARS	<b>2</b> SUBCUTANEOUS INJECTIONS one 150 mg/1 mL injection via prefilled syringe every 2 weeks <sup>1*</sup>  OR <b>1</b> SUBCUTANEOUS INJECTION one 150 mg/1 mL injection via prefilled syringe every 4 weeks if well controlled (eg, attack free) for 6 months <sup>1*</sup>	<b>7</b> INTRAVENOUS INFUSIONS 1000 IU every 3 or 4 days OR SUBCUTANEOUS INJECTIONS one injection twice weekly; every 3 or 4 days	No approved options

This presentation is not intended to compare the relative safety or efficacy of these treatments. Please refer to each product's full Prescribing Information.

TAKHZYRO is the only approved HAE preventive treatment indicated for pediatric patients 2 to <6 years of age.

One month is defined as 28 days.

<sup>1</sup>The recommended dosage in pediatric patients 2 to less than 6 years of age is 150 mg administered subcutaneously every 4 weeks.<sup>1</sup>

<sup>1</sup>The recommended starting dosage in pediatric patients 6 to less than 12 years of age is 150 mg administered subcutaneously every 2 weeks. A dosing interval of 150 mg every 4 weeks may be considered if the patient is well-controlled (eg, attack free) for more than 6 months.<sup>1</sup>

**TAKHZYRO**<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg

## LONG-TERM PREVENTION. LONG-TERM SUPPORT.

### Helping your patients stay on track with treatment

Whether you currently treat patients with HAE or have prescribed TAKHZYRO recently, it's important to help you and your patients plan for the long term.

In addition to the established safety profile and clinically proven efficacy of TAKHZYRO, evaluated across 2 studies of adult and adolescent patients ≥12 years of age, Takeda has:



in treating and providing access and product support for patients with HAE<sup>1,2</sup>

Think of a patient taking TAKHZYRO—where are they on their treatment journey?

### IMPORTANT SAFETY INFORMATION (cont'd)

**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](http://www.fda.gov/medwatch).

## STARTING OFF RIGHT WITH TAKHZYRO

### Establishing treatment expectations and goals



- HAE is a genetic, unpredictable, and lifelong condition, and it's important to set specific goals for therapy<sup>3</sup>
- Choosing effective prevention with TAKHZYRO means **working together with your patients to help prevent and reduce the severity of their HAE attacks**—which may align with their treatment goals<sup>3</sup>

Create a regular check-in schedule to review progress and treatment goals—as routine monitoring is recommended by the 2020 US HAEA guidelines.<sup>3</sup>

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).

**TAKHZYRO**<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg



# Tailored product support for your patients prescribed HAE therapy

Supporting patients with HAE and prescribers for over 16 years



## Our services include:

- **Benefits investigation** to help determine your patient's insurance benefits and eligibility for certain services
- **Enrollment** in the **Takeda Patient Support Co-Pay Assistance Program**, if they qualify\*
- **Information** about financial assistance options, if they're eligible\*
- **Specialty pharmacy** (or site of care) triage and coordination
- **Arrange** for Takeda **product administration training** (at home, if requested by your office) and **education for your patient**

To learn more about Takeda Patient Support, visit [www.takedapatientssupport.com](http://www.takedapatientssupport.com) or scan to get started.

You can also call 1-866-888-0660 Monday through Friday, 8:30 AM to 8 PM ET.

\*To be eligible, your patient must be enrolled in Takeda Patient Support and have commercial insurance. Other terms and conditions apply. Contact us for more details.

Please see [Important Safety Information](#) throughout and full [Prescribing Information](#).



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# THE **#1 PRESCRIBED** HAE PREVENTIVE TREATMENT\*

Imagine what the TAKHZYRO experience can mean for all of your patients aged 2 years and older<sup>1</sup>

- Studied in the broadest range of patients aged 2 years and older<sup>1,9-11</sup>
- Long-term freedom from attacks for an average of 14.8 months for adult and adolescent patients<sup>2†</sup>
- Freedom from daily dosing with every-2-weeks or every-4-weeks administration based on age<sup>1</sup>
  - See full Prescribing Information for additional details

The 6.5-month HELP clinical trial of 125 patients led to the 2018 FDA approval of TAKHZYRO

Studied for

**11**

YEARS IN US CLINICAL AND REAL-WORLD STUDIES<sup>13</sup>

Studied in over

**800**

PATIENTS GLOBALLY ACROSS 15 STUDIES<sup>13\*</sup>

Prescribed to over

**4000**

US PATIENTS SINCE 2018<sup>§</sup>

\*Based on total patients on HAE preventive treatments according to US third-party industry healthcare data.

†Mean duration of the attack-free period in the open-label extension study was 14.8 (SD=12.4) months (N=209).<sup>2</sup>

\*Includes clinical and real-world evidence studies.

§Based on third-party US specialty pharmacy data.

Enroll your patients online today at [TAKHZYRO.com/hcp/quick-start](https://TAKHZYRO.com/hcp/quick-start).

## INDICATION

TAKHZYRO is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients  $\geq 2$  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.

Please see additional [Important Safety Information](#) throughout and full [Prescribing Information](#).



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**TAKHZYRO**<sup>®</sup>  
(lanadelumab-flyo) injection 300mg-150mg