Transcript Details
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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Effective Prevention for Hereditary Angioedema Attacks

Announcer:
Welcome to ReachMD. This medical industry feature titled, “Effective Prevention for Hereditary Angioedema Attacks,” is sponsored by Takeda. Here’s your host, Dr. Jennifer Caudle.

Dr. Caudle:
Hereditary angioedema, commonly referred to as HAE, is a rare, genetic disease that can cause recurrent, unpredictable, and potentially life-threatening attacks of swelling in the body. The disease impacts about 1 in 50,000 people worldwide and can affect both children and adults.[1] Swelling attacks can be both painful and debilitating, which is why prevention is so important.[2] So, what are the treatment options available that can help prevent and treat HAE attacks?

This is ReachMD, and I’m your host, Dr. Jennifer Caudle, and joining me today to discuss the importance of long-term prevention for HAE is Dr. William Lumry, who’s a specialist in Allergy and Immunology and Clinical Professor of Internal Medicine at the University of Texas Southwestern Medical School. Dr. Lumry, welcome to the program.

Dr. Lumry:
Thanks for having me, Dr. Caudle.

Dr. Caudle:
Well we’re excited that you’re here, so to start us off, can you tell us about the different types of treatment approaches for people living with HAE?

Dr. Lumry:
Sure. There are two main types of treatment for HAE: on-demand and preventive. On-demand, or acute treatment, is used to treat the symptoms of an HAE attack as they are beginning. It’s important to have on-demand treatment available, even if a patient is taking a preventive treatment, because everyone with HAE is at risk of an attack. Attacks at any location should be treated as soon as they are recognized.[3] Preventive, or prophylactic treatments, help reduce the frequency and severity of HAE attacks. This can be done by taking medication on a regular schedule on either a long- or short-term basis.[3] When it comes to applying these two types of treatment, it’s important to know that HAE is a lifelong, debilitating and potentially life-threatening disease, but it affects everyone differently. So open and honest communication between patients and healthcare providers is critical to finding an individualized management plan based on the patient’s frequency and severity of HAE attacks and the burden these attacks place on the patient and family.[3]

Dr. Caudle:
And what are some of the treatment options that are currently available?

Dr. Lumry:
There are currently several therapies approved by the U.S. Food and Drug Administration for the prevention or treatment of HAE attacks.[3] Today we will only discuss one of them. One of the available therapies for long-term prevention is Takeda’s TAKHZYRO, or lanadelumab-flyo, which was approved by the FDA in 2018.

Announcer:
TAKHZYRO is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older. It’s administered subcutaneously only every 2 weeks in patients 12 years of age and older. [3,4] A four-week interval may be considered if the patient is attack-free for more than 6 months or for patients 2 to less than 6

years of age.[4]

Now, back to Dr. Lumry.

Dr. Lumry:
Hypersensitivity reactions have been observed with TAKHZYRO. In case of a severe hypersensitivity reaction, TAKHZYRO should be discontinued and appropriate treatment instituted.[4] Please continue listening until the end of the program for additional important safety information about TAKHZYRO.

In February 2022, the FDA approved a single-dose prefilled syringe, which is ready to use and shortens the treatment experience with fewer steps, fewer supplies and less waste than the vial-based injection.[4]

Announcer:
Since launch of program, TAKHZYRO® is now approved as a routine prophylaxis treatment for children 2 to <12 years of age.

Dr. Lumry:
As a physician, it's encouraging to see how the treatment landscape has evolved over the past decade and that we now have options that can help reduce the frequency and severity of attacks. In fact, due to the number of therapies that entered the U.S. market in the recent years and other clinical advancements in HAE research, the U.S. Hereditary Angioedema Association, or HAEA, Medical Advisory Board published 2020 guidelines to assist physicians in creating care plans.[3]

Dr. Caudle:
With that being said, Dr. Lumry, what do these guidelines tell us about the prevention of HAE attacks?[7]

Dr. Lumry:
When it comes to preventing HAE attacks long-term, the HAEA recommends a preventive treatment for appropriate HAE patients. The decision on when to use long-term prophylactic treatment cannot be made on rigid criteria but should reflect the needs of the individual. Decisions regarding which patients should be considered for long-term prophylaxis should take into account the patient's lifestyle, disease burden, and treatment preferences in the context of attack frequency, attack severity, comorbid conditions, and access to emergent treatment.[3]

We know HAE can take a toll on patients' lives. For example, many patients often live with the fear of an impending attack, and certain day-to-day activities and events can trigger HAE attacks, such as:[3,5,6]

- Emotional stress
- Minor trauma, surgery, or dental procedures
- Infection
- Hormonal influences, like menstruation or using a contraceptive containing estrogen
- And mechanical pressure from physical activities, like mowing the lawn or using scissors

Within the guidelines, TAKHZYRO is recommended as one of the first-line therapies for long-term prevention.[3] It's worth noting that the HAEA guidelines also recommend all patients with laboratory confirmed HAE should have access to at least two standard doses of an FDA-approved on-demand medication for treatment of acute attacks.[3] The guidelines also note that management plans may need to be adjusted over time due to changes in HAE symptoms or other factors.[3]

Dr. Caudle:
For those of you who are just tuning in, you're listening to ReachMD. I'm your host Dr. Jennifer Caudle, and today I'm speaking with Dr. William Lumry about TAKHZYRO, a treatment to help prevent attacks of hereditary angioedema, or HAE for short, in patients 12 years of age or older. As a quick safety reminder, hypersensitivity reactions have been observed with TAKHZYRO. In case of a severe hypersensitivity reaction, TAKHZYRO should be discontinued, and appropriate treatment instituted. Please continue listening until the end of the program for additional important safety information about TAKHZYRO.

Now Dr. Lumry, considering how important preventive treatment options can be for managing HAE, what can you tell us about long-term data published about TAKHZYRO?

Dr. Lumry:
First, I'd like to provide some information about the Phase 3 HELP study, or Hereditary Angioedema Long-term Prophylaxis study, which was the pivotal trial and established the safety and efficacy profile for TAKHZYRO. This study enrolled 125 people with HAE types I and

II, 12 years old and older, who were randomized to receive different doses of TAKHZYRO or placebo.[7] The 27 people who took TAKHZYRO 300 mg subcutaneously every two weeks experienced an 87% reduction in mean attack rate versus the 41 people in the placebo group over the 6.5 months of the trial.[7] In addition, 44% of these patients were attack-free for the entire 6.5 month treatment period.[7]

Announcer:
The most common side effects (occurring in ≥10% of people) seen in the HELP study were injection site reactions, which included pain, redness, bruising; upper respiratory tract infection; headache; rash; dizziness; diarrhea; and myalgia.[4]

Now, back to Dr. Lumry.

Dr. Lumry:
Following completion of the randomized clinical trial about 97 percent of patients in the HELP study enrolled in the open label extension study. The study's primary goal was to evaluate the safety of TAKHZYRO for up to 2.5 years in patients with HAE type I or II who were 12 years of age or older.[8] The results of the open label extension were published in July 2021. As one of the study's investigators and authors, I'm excited that these results are available to the broader HAE and healthcare community.

Dr. Caudle:
So with that background on this study in mind, can you tell us a bit more about the key findings?

Dr. Lumry:
I'm happy to. First, the long-term, open-label extension data were consistent with the safety profile and efficacy in the pivotal trial.[8] The most common treatment-related adverse events in the open-label extension were injection site pain, viral upper respiratory tract infection, upper respiratory tract infection and headache.[8] Results from the open label extension showed that preventive treatment with TAKHZYRO reduced the frequency of HAE attacks by 87.4 percent overall compared to baseline over the course of about 2.5 years.[8] In fact, 8 out of 10 patients experienced zero attacks for at least a 6-month period.[8] As a physician, I seek to help my HAE patients navigate this unpredictable disease and often highlight the importance of sustained prevention in my discussions with eligible patients. Please stay tuned to hear the Important Safety Information and visit TAKHZYRO.com/HCP to learn more.

Dr. Caudle:
One final question, Dr. Lumry, do you have any further thoughts about your work treating HAE or your experiences working with this community?

Dr. Lumry:
As a physician and advocate for the HAE community, I'm excited to continue to support individuals at every step of their journey. I hope to empower more people to find the right management plan for their unique needs. If you'd like to learn more about HAE diagnosis, prevention and treatment options, I encourage you to visit the Hereditary Angioedema Association's website, HAEA.org. There, you can find the latest HAEA treatment guidelines, recent updates on treatments and scientific advances, educational resources and research opportunities.

Dr. Caudle:
Now, let's review some important safety information for TAKHZYRO.

Announcer:
TAKHZYRO® (lanadelumab-flyo) is indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients ≥2 years of age.

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

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.

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 full Prescribing Information at www.takhzyro.com/hcp.

Dr. Caudle:
Well as that brings us to the end of today's program, I'd like to thank my guest, Dr. William Lumry, for helping us better understand the importance of long-term prevention for HAE and the data for one option, TAKHZYRO. Dr. Lumry, it was great speaking with you today.

Dr. Lumry:
Thank you so much. It was my pleasure.

Announcer:
This medical industry feature was sponsored by Takeda. To visit any part of this discussion, visit ReachMD.com/industryfeature. This is ReachMD. Be Part of the Knowledge.

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