INVESTIGATIONAL TREATMENTS:

How Do They Get from the Lab to the Pharmacy?

An investigational treatment has a long journey before becoming something that you can get at your local pharmacy—**it takes years of research to confirm its safety and effectiveness.**

With our recent announcement about the FDA's clearance of our IND, **let's learn more about the drug development process and where we are with STAR-0215 for the treatment of HAE!**

Preclinical Studies:

Before an investigational treatment can be evaluated in people (clinical trials), it is evaluated in animals (preclinical studies) to gather basic information on safety, the effects of the investigational treatment on the body (pharmacodynamics), and the movement of the investigational treatment within the body (pharmacokinetics).

Investigational New Drug (IND) Application and Review:

With the results of these preclinical studies in hand, the company submits a request to a government authority to evaluate the investigational treatment in people. In the United States, that request is called an IND, and it's submitted to the US Food and Drug Administration (FDA). The government authority reviews the request to ensure participants' safety will be protected and decides whether to clear the IND to move to clinical trials.

Clinical Trials:

This stage in the development process is made possible by people who volunteer to participate in clinical trials. We are grateful to all those who consider participating as these trials can result in new and better treatments.

PHASE 1

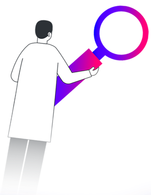
This phase focuses on evaluating the safety and side effects of the investigational treatment. The number of participants is usually small and made up of healthy volunteers or people with the disease.

PHASE 2

This phase evaluates both the safety and effectiveness of the investigational treatment in participants with the disease.

PHASE 3

This phase is focused on confirming the previous findings of safety and effectiveness in a much larger group of participants with the disease.



If the data generated during all 3 phases supports the safety and effectiveness of the investigational treatment, the company submits an application to a government authority for marketing approval. In the US, this application is submitted to FDA. The government authority reviews the data generated and approves, rejects, or asks for more information to further support the application. Once approved, the treatment can then be made available for the specific condition for which it is approved. This is when your healthcare provider can write you a prescription.

Where is STAR-0215 in this process?

With STAR-0215, our team is committed to providing an effective preventative treatment, dosed once every 3 months or longer, to decrease the burden of disease and treatment for people living with HAE.

STAR-0215's IND was cleared by the FDA in July 2022, and we have since announced the start of a Phase 1a clinical trial in healthy volunteers.

The results will provide data related to safety, tolerability, pharmacodynamics, and pharmacokinetics. We anticipate preliminary results from this trial by the end of 2022. Following this, and provided the data from the Phase 1a trial is favorable, we anticipate initiating a Phase 1b/2 trial in people living with HAE in 2023.

We'll continue to keep you updated along the way as our work progresses.

Upcoming Events from HAEA/HAEi

CLICK EVENT FOR DETAILS

August 9
HAEA Virtual Round Table for Young Adults

August 16
August Virtual HAEA Meet & Greet

August 18
HAE Treatment Education Series Webinar: A deeper dive into HAE types. Let's talk about it.

August 23
Virtual Webinar for Women With HAE: Menopause and Aging

September 14
In-Person Chicago HAEA Meet & Greet

September 20
September Virtual HAEA Meet & Greet

October 6-9
In-Person HAEi Global Leadership Workshop

October 18
October Virtual HAEA Meet & Greet

November 15
November Virtual HAEA Meet & Greet

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The information provided here is for those affected by HAE and caregivers.
STAR-0215 is in early-stage clinical development and not approved in any territory.

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