

ASTRIA CONNECTION: HAE

Special Edition - March 2024

EXCITING NEWS:

Positive Initial Proof-of-Concept Results from the ALPHA-STAR Phase 1b/2 Trial of STAR-0215 for HAE

Since 2021, Astria has been working to develop a treatment that empowers people living with HAE and their families to live their lives free of the limitations of HAE, focusing their time and energy on what matters most to them. *Today, we're thrilled to share new, positive data that supports this mission.*

Initial results from Astria's Phase 1b/2 ALPHA-STAR trial, which is evaluating **STAR-0215** as a potential preventative therapy for people living with HAE, support **STAR-0215's** target profile as the first-choice, long-acting preventative therapy for HAE dosed subcutaneously (under the skin) once every three and six months. These initial results show a favorable safety and tolerability profile – including no injection site reactions of pain – an average monthly attack rate reduction of 90-96% for up to 6 months of follow up, and support for both three- and six-month dosing regimens. Initial results from **STAR-0215** also showed a reduction in the severity of HAE attacks, with a 92-100% decrease in moderate or severe attacks across all three cohorts and no severe attacks were observed after receiving **STAR-0215**. These initial results support our intention to progress to Phase 3 with trial initiation expected in the first quarter of 2025.

Astria's Chief Medical Officer, Chris Morabito, M.D., shared:

“We are thrilled with these initial results from ALPHA-STAR and believe that STAR-0215 can be a transformative therapy for people living with HAE that greatly reduces their disease and treatment burdens. These results give us conviction that we will be able to deliver STAR-0215 once every three and six months, and we look forward to progressing this program into Phase 3 as quickly as possible.”

Learn more about the Phase 1b/2 ALPHA-STAR trial, its initial results, and our plans for the future below:



alpha-star⁺

1 Trial Design

Cohort 1
Single dose
450 mg once

Cohort 2
600 mg dose
followed by a 300 mg
maintenance dose
three months later

Cohort 3
600 mg dose,
followed by a 600 mg
dose one month later

Phase 1b/2 goals

Collect data demonstrating the ability of STAR-0215 to significantly reduce participants' monthly attack rates, provide proof of concept of STAR-0215 as a durable once every 3- and 6-month treatment, rapidly prevent attacks, and represent favorable safety and tolerability with little to no injection site pain.

2 Initial Results

Favorable safety and tolerability profile

- No injection site reactions of pain

90-96%

average monthly attack rate reduction compared to baseline for up to 6 months of follow up

- 92-100% decrease in moderate or severe attacks
- No severe attacks observed with **STAR-0215**

2 or 4 x

Support for administration 2 or 4 times per year

3 Next Steps

The initial Phase 1b/2 trial results support progressing to Phase 3 with trial initiation expected in Q1 2025 and top-line results expected in Q4 2026. We look forward to working towards our goal of bringing this potential first-choice treatment to people living with HAE as quickly as possible.

HAE Community Perspective:

“As a community, we are blessed to have treatment options that allow us to live a somewhat normal life, but the injection schedules are frequent so it’s always on your mind. The potential to only think about my HAE a few times a year would be huge for my mental health.”

Kim, Living with HAE, Texas, USA



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