Healey & AMG Center

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at Massachusetts General Hospital

NEALS Northeast Amyotrophic Lateral Sclerosis Consortium®

HEALEY ALS Platform Trial

Regimen F

ABBV-CLS-7262

Developed by Calico Life Sciences LLC in collaboration with AbbVie Inc.

Investigational products included in the HEALEY ALS Platform Trial are selected by a team of experts after careful review of the study drug and the science supporting its treatment potential in Amyotrophic Lateral Sclerosis (ALS). Regimen F is testing an experimental medication called ABBV-CLS-7262, and the trial will involve in-person study visits every 4 to 8 weeks (about 6 visits total over the course of 24 weeks).

Please discuss the possible benefits and risks of this investigational product with your study team.

Visit our website to learn more about what to expect in the trial process:

https://bit.ly/3ExRal8

About Regimen F:

Regimen F is a Phase 2/3 trial enrolling approximately 240 participants to evaluate the safety and efficacy of ABBV-CLS-7262 as a potential treatment for ALS. This regimen involves biomarker analysis and cerebrospinal fluid collection via lumbar punctures to assess the effects of ABBV-CLS-7262.

3:1 Active Drug to Placebo Ratio:
Participants who enroll in this trial have a 3 in 4 (75%) chance of being assigned to active study drug and a 1 in 4 (25%) chance of being assigned to placebo during the initial 24-week randomized controlled trial (RCT) period.

Active Treatment Extension (ATE):
Participants will continue into the ATE for ABBV-CLS-7262 after completing the 24-week RCT. During ATE, all participants will receive the active study drug.

To see if you may qualify, please review the list of eligibility criteria:

https://bit.ly/30ctynm

For general questions about the HEALEY ALS Platform Trial,
Contact the Patient Navigator:

healeyalsplatform@mgh.harvard.edu
833-425-8257 (HALT ALS)

Q&A for Regimen F:

Q: How is this drug administered?

A: ABBV-CLS-7262 is taken by mouth once daily. The study drug is stored in small packets (sachets) and has a granular texture similar to coarse sugar, so it should be swallowed with sips of water.

Q: What does this drug do?

A: ABBV-CLS-7262 aims to restore function in cells affected by ALS by normalizing protein production and preventing further buildup of TDP-43, thereby protecting neurons, and possibly slowing ALS progression. ABBV-CLS-7262 activates the protein complex eIF2B, which is a key regulator of the integrated stress response (ISR). Studies suggest that the ISR is chronically activated in people with ALS. It is thought that TDP-43 aggregates, a hallmark of ALS, may form as a result of chronic ISR activation. Binding of ABBV-CLS-7262 desensitizes eIF2B to stress and decreases the ISR, which may prevent motor neuron injury in ALS.

Q: Has this drug been studied before?

A: Yes. A first-in-human study of ABBV-CLS-7262 showed that this drug was well-tolerated by participants, and crossed the blood brain barrier at concentrations predicted to be effective in ALS. The study showed that ABBV-CLS-7262 increased eIF2B enzymatic activity and suppressed the ISR in blood cells (indicating successful target engagement). ABBV-CLS-7262 is currently being studied in a Phase 1b trial in people with ALS (NCT04948645).

Additional Questions?

Register to attend the Weekly Platform Trial Q&A Webinars:

https://bit.ly/3DvkJTa

Stay Connected to the Platform Trial

More investigational products are anticipated to be added to the HEALEY ALS Platform Trial through support by pharma, foundation partners, philanthropy, federal, and other fundraising initiatives.

Visit our website to learn more about current and future regimens:

https://bit.ly/31EKT98

View map and contact info for participating research centers:

https://bit.ly/3IICv9t

Sign up for the ALS Link to hear about ALS news and research:

https://bit.ly/3EH2eMT