A nationwide network of research centers in the Northeast ALS (NEALS) Consortium are partnering with the Sean M. Healey & AMG Center to conduct this first-of-its-kind platform trial for people living with ALS. The mission is to find answers as quickly as possible by testing multiple drugs using a shared platform.

**Trial Highlights:**

- **Multicenter Trial**
  More than 70 sites across the US are participating in the Platform Trial, working together to enroll 160 participants for each regimen.

- **3:1 Active Drug to Placebo Ratio**
  Participants have a 75% chance of receiving active study drug, and a 25% chance of receiving placebo.

- **Open Label Extension (OLE)**
  Upon completion of the 24-week trial, participants may have the option to enroll in the OLE for their regimen. During OLE, participants know with 100% certainty that they are receiving active study drug.

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

healeyalsplatform@mgh.harvard.edu

833-425-8257 (HALT ALS)
What is a platform trial?
The platform trial tests multiple investigational products in different participants using a common master protocol. New investigational products can be added to the platform; this means more opportunities to find groundbreaking therapies in a faster timeframe.

Why use a platform trial approach?
Platform trials are designed to decrease the time it takes to find effective therapies, reduce the number of participants on placebo, and increase access to research by conducting the same trial at multiple locations. The platform trial will remain open until safe and effective treatments are found for all people living with ALS.

What phase is this research trial?
The Platform Trial is a late-stage trial (Phase 2/3), so data derived from the trial, if positive, could be used to support the approval of new medication.

What is meant by the term 'regimen'? A regimen is designed to test the safety and efficacy of one specific investigational product. Participants in the trial are randomly assigned to one regimen, and then randomized to active drug or placebo within that regimen.

What is open label extension? Open Label Extension (OLE) allows participants to receive the active drug for the regimen to which they were assigned after completing the 24-week placebo-controlled trial. The duration of OLE may vary.

Stay Connected to the Platform Trial
Investigational products will be added to the HEALEY ALS Platform Trial through support by pharma, foundation partners, philanthropy, federal, and other fundraising initiatives.

Learn more about what to expect in the trial process:
https://bit.ly/3ExRaI8

Sign up for the ALS Link to receive research news and updates via email:
https://bit.ly/3xC6RXK

Additional questions? Register to attend the Weekly Q&A Webinars:
https://bit.ly/3DvkJTa