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President and CEO
Calaneet Balas

November 18, 2021

Patrizia Cavazzoni, M.D.
Director
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Dear Dr. Cavazzoni,

On behalf of the ALS community, we call on the U.S. Food and Drug Administration (FDA) to conduct a Priority Review of the New Drug Application (NDA) for AMX0035 and then provide approval of the drug for the treatment of ALS. People with ALS and their families cannot wait the extra months that a Standard Review process would take.

According to information shared with The ALS Association and publicly, AMX0035 demonstrated a significant slowing of functional decline in the Phase 2 CENTAUR trial, lowering risk of death by over 40%, and increasing survival by at least 6 months. The positive data on both function and survival along with a good safety profile of the drug give tremendous hope to people living with ALS and their families and caregivers.

You have heard directly from our community, including through the petition signed by over 50,000 people and in the May 25, 2021 "We Can't Wait" action meeting, that people living with ALS and their caregivers want access to safe therapies that have shown positive effect, even if that benefit is modest. Incremental effects can mean the opportunity for more time with loved ones, more time to walk, to talk or to feed oneself, and more time to potentially benefit from a next therapy. We are heartened that you listened to our community's pleas to exercise regulatory flexibility resulting in an NDA submission by Amylyx Pharmaceuticals. For people living with ALS, time is the most important resource.

We implore you to 1) provide a Priority Review designation to AMX0035 so that valuable time is not wasted during the Standard Review process, and 2) review and approve AMX0035 for the treatment of ALS as soon as possible. People with ALS typically have two to five years to live after diagnosis. Your actions and involvement must meet that urgency. Your decision will deeply impact the lives of thousands of people with ALS and their loved ones. Please listen to their calls for swift approval of AMX0035.

Sincerely,



Calaneet Balas
President & CEO
The ALS Association



OUR VISION: Create a world without ALS.

OUR MISSION: To discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest.

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