November 13, 2020

The Honorable Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
Via email: CDERPASE@fda.hhs.gov

Dear Commissioner Hahn:

I AM ALS and The ALS Association are pleased to share more than 50,000 signatures advocating for the FDA and Amylyx to bring AMX0035 to people with ALS as soon as possible. These signatures represent lives directly impacted by this cruel disease. Together, they are calling for promising ALS treatments like AMX0035 to be made available as soon as possible.

We would like to share a few comments from people living with ALS :

> “I implore the leaders at Amylyx and the FDA to be the bold changemakers we need to work on ‘the ALS clock’ and accelerate access to ALS treatments as quickly as possible. To date there has not been one ALS survivor and it’s time we change that. The results from the AMX0035 trial have given our community great hope and we look to you as the leaders to move forward with urgency. ALS waits for no one and we must be equally as relentless.” – Sandy Morris, Person Living with ALS, and I AM ALS Patient Advisory Council Co-Chair
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> "The ALS community needs immediate access to therapeutics like AMX0035 that have demonstrated safety and efficacy in clinical trials. While we wait, we will say goodbye to many more friends that could have benefitted from this therapy." – Phil Green, Person Living with ALS and I AM ALS Clinical Trials Community Team Co-Chair
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> “I agree with and understand the FDA’s interest in protecting people from harmful or misleading drugs. ALS should be treated differently, however, and the FDA has acknowledged that. People living with ALS are willing to tolerate much greater risk and have expressed this to the FDA for years. I can attest to that. We need the FDA and Amylyx to work together to make AMX0035 available to people with ALS as soon as possible.” – J. Thomas May, Person Living with ALS and Member of The ALS Association National Board of Trustees
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> “The ALS community has united to ask the FDA and Amylyx to make AMX0035 available as soon as possible. Given the promise that AMX0035 shows in slowing progression and its safety record, the community should not have to wait several more years for another clinical trial.

Delaying access means thousands of us who could have been helped will have passed from this devastating disease." – Larry Falivena, Person Living with ALS and Member of The ALS Association National Board of Trustees

We appreciate the strong working relationship between the FDA and the ALS community and request favorable consideration of our petition by the FDA and Amylyx to ensure that people with ALS receive safe and effective treatments as soon as possible.

Danielle Carnival, Ph.D., CEO
I AM ALS

Neil Thakur, Ph.D., Chief Mission Officer
The ALS Association