# PHOENIX Trial of AMX0035 did not meet endpoints

**March 8, 2024 –** Amylyx Pharmaceuticals has announced that the PHOENIX Phase 3 clinical trial of AMX0035 did not meet its primary or secondary endpoints.

The results from the 48-week study, which involved participants from the United States of America and Europe, showed no significant benefit from AMX0035 compared to placebo, as measured by changes in the ALS Functional Rating Scale-Revised (ALSFRS-R) score. AMX0035 was well-tolerated, and the safety profile was found to be consistent with previous studies.

AMX0035, marketed as ALBRIOZA in Canada, was approved by Health Canada under the Notice of Compliance with Conditions (NOC/c) pathway, with conditions depending on the outcome of the PHOENIX trial.

The ALS Society of Canada will work with clinicians, regulators and other key experts to better understand the implications of these results for Canadians living with ALS.

We know that this news is disappointing for the ALS community, and we will continue to provide updates as more information becomes available.

We appreciate Amylyx's commitment to the ALS community, and their responsible and transparent approach to providing clear information about the study results.

The ALS Society of Canada extends its deepest gratitude to all people and families affected by ALS who participated in this trial. Their involvement in the trial has significantly contributed to our understanding of the disease and informs future research.

## Statement from Canadian ALS Research Network on results from the PHOENIX Trial

Members of the **Canadian ALS Research Network (CALS)**, representing the leadership of Canada's multidisciplinary ALS clinics, were disappointed to learn of the negative results from the PHOENIX Phase 3 clinical trial of AMX0035.

The results from the 48-week study, involving participants from the United States of America and Europe, revealed no significant benefit from AMX0035 compared to placebo, as measured by changes in the ALS Functional Rating Scale-Revised (ALSFRS-R) score. AMX0035 was well-tolerated, and the safety profile was consistent with previous studies; however, there was no evidence for slowing of disease progression.

AMX0035, marketed as ALBRIOZA in Canada, was approved by Health Canada under the Notice of Compliance with Conditions (NOC/c) pathway, with conditions depending on the outcome of the PHOENIX trial.

CALS Members understand that these results may be a confusing outcome given the positive findings in a previous Phase 2 trial. The Phase 3 trial, being larger and more rigorous, plays a critical role in confirming or refuting earlier findings, and concluded there was no significant benefit from AMX0035 (ALBRIOZA) compared to placebo.

In light of these findings, CALS physicians recommend discontinuing the use of AMX0035 (ALBRIOZA) for the treatment of ALS at this time. We appreciate the support that Amylyx has given the ALS community, and their responsible approach to providing clear information about the study results.

The negative results of the trial are a frustrating outcome for patients, families, and ALS clinicians. However, we remain hopeful that new treatments for ALS will emerge in the near future.

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