# Amylyx Pharmaceuticals, Inc.

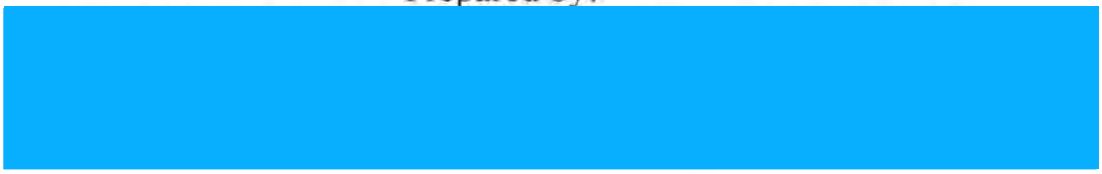
# Integrated Analysis of Protocols # AMX3500 and AMX3500-OLE Evaluation of the Safety, Tolerability, Efficacy and Activity of AMX0035, a Fixed Combination of Phenylbutyrate (PG) and Taurursodiol (TURSO), for Treatment of Amyotrophic Lateral Sclerosis (ALS)

**Version 1.0**

**Addendum to Statistical Analysis Plan for Survival**

August 26, 2020

Prepared by:



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By signing below, all parties accept that the analysis methods and data presentations are acceptable and that this document is final.

Prepared By:

[redacted]

08/28/2020
Date

Aug 28, 2020
Date

Reviewed/Approved By:

[redacted]

August 28, 2020
Date

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# 1. Introduction

This addendum to the survival statistical analysis plan (SAP) contains details of differences between the initial interim survival analysis (interim analysis 1) and the present analysis (interim analysis 2). The initial interim analysis was designed to provide the FDA with survival information in support of the initial data generated from AMX3500. The second interim analysis, of which relevant differences are outlined below, is required to provide survival data corresponding to the first 24 weeks of the AMX open label extension (OLE) data (AMX3500OLE). We anticipate a final follow-up analysis (described at a later date) will be required once the last patient completes the OLE. This is not a stand-alone document but should be read together with the protocol (AMX3500 v7) and the AMX3500 survival SAP (v1.0).

# 2. Analysis Addendum

The survival analysis outlined in AMX3500 survival SAP (v1.0) will be performed with the following changes.

1) The cutoff date for the present analysis will be changed from February 29, 2020 (AMX3500 interim analysis 1) to July 20, 2020 (AMX3500 OLE interim analysis 2).
2) The [redacted] data at the cut-off outlined above will be used for all individuals in the study, with the exception of two individuals. These individuals were identified to be out of the country and do not have [redacted] data available, thus EDC data will be used for these individuals and the last EDC date available will be used as the censoring cutoff date.

# Modification History

| Unique Identifier for this Version | Date of the Document Version | Author | Significant Changes from Previous Authorized Version |
|---|---|---|---|
| **1.0** | **26 August 2020** | | **Not Applicable – First Version** |