Shionogi Inc.

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Dear Members of the U.S. Fragile X Syndrome Community,

Thank you all for your participation in and support of the EXPERIENCE (**E**valuation of Fragile **X** Ex**perien**ce in **C**ognition **E**xpression) clinical development program in the U.S. We understand you have been patiently waiting for an update on the findings.

As previously shared in October 2025, we are reporting results from EXPERIENCE-301, the adult study in ages 18–45 and EXPERIENCE-204, the adolescent study in ages 9–17 at the same time. This approach allows us to consider the results from both studies together, helping us to more clearly understand what they mean for zatolmilast in FXS.

The respective primary endpoints were not met in the EXPERIENCE-301[1] (adult) or in the EXPERIENCE-204[2] (adolescent) studies evaluating zatolmilast in Fragile X syndrome in the U.S.[3] In both studies, treatment with zatolmilast was generally well-tolerated, and no new safety concerns were identified.

In EXPERIENCE-301 (adult study), significant differences were observed in FXS-Numerical Rating Scale (NRS) language/communication and daily function. FXS-NRS is a caregiver assessment that captures personalized changes in FXS. These findings are suggestive of an efficacy signal[4] but are not considered conclusive since the primary endpoint was not met.

We continue to work diligently to gain a comprehensive understanding of the clinical trial data so we can fully characterize the safety and efficacy of zatolmilast in individuals with FXS, particularly in the context of zatolmilast's well-established mechanism of action and the promising results of the earlier Phase 2 study. This will include additional exploratory analyses of EXPERIENCE-301 and -204, plus analysis of EXPERIENCE-302 (the open label extension study).

At this time, the U.S.-based open-label extension study, EXPERIENCE-302, will continue for previously enrolled participants who wish to continue. We plan to analyze the results of this study and continue to engage with the FDA before providing an update to the community in the second half of 2026.

We invite the community to join Shionogi, FRAXA, and the National Fragile X Foundation for a conversation about this update on May 19 at 12:00 pm EDT. As we continue to analyze the results, we will not be able to answer every question, but we will do our best to share available and relevant information with the community.

Please register for the Zoom webinar here and submit your questions in advance; the earlier a question is submitted, the more likely it is to be addressed during the conversation.

We extend our sincere gratitude to the individuals, families, and caregivers who participated in these studies, and the investigators, site teams, and advocacy partners whose collaboration made these trials possible. The commitment and contributions of the community are deeply appreciated and have meaningfully supported our research.

With my deep respect and appreciation,

Juan Carlos Gomez, MD

Chief Medical Officer

Shionogi & Co., Ltd.

1. In EXPERIENCE-301 (adult study), the primary endpoint National Institutes of Health Total Cognitive Battery Crystallized Cognition Composite (NIH-TCB-CCC), a measure of cognition, was not met.
2. In EXPERIENCE-204 (adolescent study), the primary endpoints FXS-NRS language/communication and daily function were not met. The key secondary endpoint, Clinician Global Impression of Improvement (CGI-I) of Language was not met.
3. An endpoint is an outcome or event in a clinical trial that is measured to determine the effectiveness or safety of a drug being studied.
4. A "signal" means we may be seeing an early pattern that suggests the treatment could have an effect, but more research is needed to be sure what it means.