INTRODUCTION

Despite the availability of several antiseizure medications (ASMs), 37% of patients with focal onset seizures (FOS) do not achieve ≥1 year of seizure freedom after a trial of 2 ASMs; the incremental likelihood of achieving seizure control decreases with each subsequent ASM.1 XEN1101 is a novel, selectivity, XEN1101[2] K2[2,7,17] potassium channel opener in development for the treatment of FOS, primary generalized tonic-clonic seizures, and major depressive disorder.2

X-TOLE is a phase 2b, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging, multicenter study with an optional 5-year open-label extension (OLE) evaluating the efficacy, safety, and tolerability of XEN1101 administered as fixed adjunctive treatment in adults with FOS.

In the double-blind period (DBP), XEN1101 treatment yielded a dose-dependent, consistent, range, multicenter study with an optional 5-year open-label extension (OLE) evaluating the⋅

METHODS

▪ XEN1101 was generally well tolerated with a low incidence of serious adverse events (SAEs), and no cardiovascular safety signals were identified.2

▪ The results presented here are interim data (cutoff date September 22, 2022) from the OLE of x-TOLE, in which patients received open-label XEN1101 at a dose of 20 mg once daily (QD) with food.

RESULTS

Patients

- Of the 285 patients who completed the DBP, 275 (96.5%) enrolled in the OLE study.
- At the analysis cutoff (September 22, 2022), 168 patients were progressed to 10 mg QD, 47 to 15 mg QD, 16 to 20 mg QD, and 15 to 25 mg QD.

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- The percentage of patients continuing XEN1101 at 6 months maintained at 80%–90% in OLE study months 14–20 (Figure 3).
- XEN1101 yielded long-term efficacy in this interim analysis with 68% retention at 12 months.

- During our study months 14–16, there was a sustained monthly reduction in seizure frequency (68%-90%) with XEN1101, and no new safety signals were identified.

- Seizure freedom for 6-month and 12-month cumulative durations was achieved in 17.5% and 30.5% of patients, respectively.

- XEN1101 continues to be generally well-tolerated in the OLE with AEIs consistent with prior results and other ASMs; no new safety signals were identified.

CONCLUSIONS

- XEN1101 yielded long-term efficacy in this interim analysis with 68% retention at 12 months.

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DISCLOSURES

The following authors report relationships with pharmaceutical companies: Michael A. Rogawski (consultant, advisory boards, medical writing); John Lynch (as an employee, consultant, and on the scientific advisory board, including Xenon Pharmaceuticals); and Michaela M. Hahnel (employee, consultant, scientific advisory board, and on the editor's board, including Xenon Pharmaceuticals). The following authors report no relationships with pharmaceutical companies: Jacqueline French, Roger Porter, Emilio Perucca, Martin Brodie, Michael A. Rogawski, Cynthia Harden, Jenny Qian, Constanza Luzon Rosenblut, Christopher Kenney, Gregory N. Beach.