



Xenon Pharmaceuticals Announces Publication of Results from XEN1101 Phase 2b “X-TOLE” Clinical Trial in Peer-Reviewed Journal Article in *JAMA Neurology*

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VANCOUVER, British Columbia, Oct. 09, 2023 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today announced the medical journal *JAMA Neurology* has published peer-reviewed efficacy and safety results from the X-TOLE Phase 2b randomized clinical trial of XEN1101, a novel potassium channel opener, in adults with focal epilepsy. Importantly, the efficacy and safety findings of this clinical trial supported the further clinical development in epilepsy of XEN1101, which is currently being evaluated in Phase 3 clinical trials in patients with focal onset seizures (FOS) and primary generalized tonic-clonic seizures.

Mr. Ian Mortimer, Xenon’s President and Chief Executive Officer, stated, “We are pleased to report that the peer-reviewed results from our Phase 2b X-TOLE study of XEN1101 in adults with focal epilepsy have been published in the prestigious *JAMA Neurology* journal. With a cohort of patients now on drug for more than four years as we continue to gather data from our ongoing open-label extension study, XEN1101 continues to demonstrate its efficacy through sustained seizure reduction and a compelling product profile with once-daily dosing with food and no titration required. Based on the need for new, efficacious, and well-tolerated antiseizure medications, we continue to advance the Phase 3 development of XEN1101 in our X-TOLE2, X-TOLE3 studies (in focal onset seizures) and the X-ACKT study (in primary generalized tonic-clonic seizures). We look forward to presenting additional longer-term data from the X-TOLE open-label extension study at AES 2023, the upcoming annual meeting of the American Epilepsy Society in December.”

In the XEN1101 Phase 2b X-TOLE study, the primary efficacy endpoint was the median percent change from baseline in monthly FOS frequency. Treatment-emergent adverse events (TEAEs) were recorded, and comprehensive laboratory assessments were made. A total of 325 patients who were randomized and treated were included in the safety analysis; 285 completed the 8-week double-blind phase. In the 325 patients included, mean (SD) age was 40.8 (13.3) years, 168 (51.7%) were female, and 298 (91.7%) identified their race as White. Treatment with XEN1101 was associated with seizure reduction in a robust dose-response manner. The median (IQR) percent reduction from baseline in monthly FOS frequency was 52.8% ($P < .001$ vs placebo; IQR, -80.4% to -16.9%) for 25 mg, 46.4% ($P < .001$ vs placebo; IQR, -76.7% to -14.0%) for 20 mg, and 33.2% ($P = .04$ vs placebo; IQR, -61.8% to 0.0%) for 10 mg, compared with 18.2% (IQR, -37.3% to 7.0%) for placebo. XEN1101 was generally well tolerated and TEAEs were similar to those of commonly prescribed ASMs, and no TEAEs leading to death were reported.

The article entitled “Efficacy and Safety of XEN1101, a Novel Potassium Channel Opener, in Adults With Focal Epilepsy A Phase 2b Randomized Clinical Trial” was posted today on the [JAMA Neurology website](#).

About Xenon Pharmaceuticals Inc.

Xenon Pharmaceuticals (NASDAQ:XENE) is a clinical stage biopharmaceutical company committed to developing innovative therapeutics to improve the lives of patients with neurological disorders. We are advancing a novel product pipeline of neurology therapies to address areas of high unmet medical need, with a focus on epilepsy. For more information, please visit www.xenon-pharma.com.

Safe Harbor Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and the Private Securities Litigation Reform Act of 1995 and Canadian securities laws. These forward-looking statements are not based on historical fact, and include statements regarding the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN1101; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in our XEN1101 development program; our intention to publish data from the ongoing open-label extension study, and our ability to successfully develop and obtain regulatory approval of XEN1101. These forward-looking statements are based on current assumptions that involve risks, uncertainties and other factors that may cause the actual results, events, or developments to be materially different from those expressed or implied by such forward-looking statements. These risks and uncertainties, many of which are beyond our control, include, but are not limited to: clinical trials may not demonstrate safety and efficacy of any of our or our collaborators’ product candidates; promising results from pre-clinical development activities or early clinical trial results may not be replicated in later clinical trials; our assumptions regarding our planned expenditures and sufficiency of our cash to fund operations may be incorrect; our ongoing discovery and pre-clinical efforts may not yield additional product candidates; any of our or our collaborators’ product candidates, including XEN1101, may fail in development, may not receive required regulatory approvals, or may be delayed to a point where they are not commercially viable; we may not achieve additional milestones in our proprietary or partnered programs; regulatory agencies may impose additional requirements or delay the initiation of clinical trials;

the impact of competition; the impact of expanded product development and clinical activities on operating expenses; the impact of new or changing laws and regulations; the impact of pandemics, epidemics and other public health crises on our research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, regulatory agencies and related review times, and contractors who act for or on our behalf; the impact of unstable economic conditions in the general domestic and global economic markets; adverse conditions from geopolitical events; as well as the other risks identified in our filings with the Securities and Exchange Commission and the securities commissions in British Columbia, Alberta, and Ontario. These forward-looking statements speak only as of the date hereof and we assume no obligation to update these forward-looking statements, and readers are cautioned not to place undue reliance on such forward-looking statements.

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