Xenon Pharmaceuticals Announces Launch of XEN1101 Phase 3 Program with Initiation of X-TOLE2 Clinical Trial in Patients with Focal Onset Seizures

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BURNABY, British Columbia, Nov. 03, 2022 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today announced the launch of its XEN1101 Phase 3 program with the initiation of the X-TOLE2 clinical trial, which will examine XEN1101 administered as an adjunctive treatment for adult patients with focal epilepsy.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer, stated, "We are thrilled to announce the launch of our XEN1101 Phase 3 program with the initiation of our X-TOLE2 clinical trial. We have ambitious clinical development plans for XEN1101, including our X-TOLE2 and X-TOLE3 clinical trials in focal onset seizures, as well as our Phase 3 X-ACKT clinical trial in primary generalized tonic clonic seizures. We continue to hear from key opinion leaders and prescribing physicians that novel mechanisms are needed to provide new therapeutic options that are clearly differentiated from the anti-seizure medications currently available. Backed by a strong scientific rationale and compelling Phase 2b clinical data, we are focused on advancing XEN1101 through its late-stage clinical development towards commercialization, with the goal of providing new therapies for epilepsy patients in need."

About XEN1101
XEN1101 is a differentiated Kv7 potassium channel opener being developed for the treatment of epilepsy and major depressive disorder. In October 2021, Xenon announced positive results from its Phase 2b X-TOLE clinical trial, which evaluated the clinical efficacy, safety and tolerability of XEN1101 administered as an adjunctive treatment for adult patients with focal epilepsy. In June 2022, Xenon announced the successful completion of an End-of-Phase 2 meeting with the U.S. Food & Drug Administration (FDA). Based on the EOP2 meeting, Xenon and the FDA aligned on key elements of the Phase 3 program to support a New Drug Application (NDA) submission. Xenon plans to submit an NDA upon completion of the first XEN1101 Phase 3 clinical trial (X-TOLE2), if successful, and use the existing data package from the Phase 2b X-TOLE clinical trial along with additional safety data from other clinical trials to meet regulatory requirements.

About the XEN1101 Phase 3 Program
Xenon has initiated its XEN1101 Phase 3 development program, which includes two identical Phase 3 clinical trials to be run in parallel, called X-TOLE2 and X-TOLE3, that are designed closely after the Phase 2b X-TOLE clinical trial. These multicenter, randomized, double-blind, placebo-controlled trials will evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 360 patients per study with focal onset seizures (FOS). The primary efficacy endpoint is the median percent change (MPC) in monthly seizure frequency from baseline through the double-blind period (DBP) of XEN1101 compared to placebo. On completion of the DBP in X-TOLE2 and X-TOLE3, eligible patients may enter an open-label extension (OLE) study for up to three years. In addition, the ongoing X-TOLE OLE also continues to generate important long-term data for XEN1101 in FOS. Xenon also intends to initiate a Phase 3 clinical trial, called X-ACKT, to support potential regulatory submissions in an additional epilepsy indication of primary generalized tonic clonic seizures (PGTCS). This multicenter, randomized, double-blind, placebo-controlled study will evaluate the clinical efficacy, safety, and tolerability of XEN1101 administered as adjunctive treatment in approximately 160 patients with PGTCS. The primary efficacy endpoint is the MPC in monthly PGTCS frequency from baseline through the DBP of XEN1101 compared to placebo. On completion of the DBP in X-ACKT, eligible patients may enter an OLE study for up to three years.

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 timing of and potential results from clinical trials; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of our and our partners' product candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in our XEN1101 and other development programs; the timing and results of our interactions with regulators; our ability to successfully develop and obtain regulatory approval of XEN1101 and our other product candidates; and anticipated enrollment in our clinical trials and the timing thereof. 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 the ongoing COVID-19 pandemic 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, may be more severe and more prolonged than currently anticipated; the impact of the COVID-19 pandemic on our business; 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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