Xenon Pharmaceuticals Outlines Key Milestone Opportunities for 2024

January 8, 2024

Completion of Patient Enrollment in XEN1101 Phase 3 X-TOLE2 Clinical Trial in Focal Onset Seizures Anticipated in Second Half of 2024

XEN1101 Phase 3 Program in Major Depressive Disorder Planned for Initiation in 2024

VANCOUVER, British Columbia, Jan. 08, 2024 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today outlined progress within its pipeline programs and key milestones for 2024.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer, stated, "We enter this year well positioned to continue to execute on our broad XEN1101 clinical program, which represents the most advanced potassium channel modulator in clinical development for multiple indications. Most recently, the data we generated in our Phase 2 proof-of-concept X-NOVA clinical trial demonstrated clinically meaningful drug activity in depression, in addition to further supporting XEN1101's highly differentiated profile in epilepsy. With a strong financial position, we are actively planning for late-stage development of XEN1101 in depression and evaluating potential development in additional neurological indications, as we believe this mechanism potentially has broad applicability."

Mr. Mortimer added, "We also remain focused on our goal to improve outcomes for epilepsy patients where there continues to be a significant need for new, differentiated anti-seizure medications. We continue to progress our Phase 3 epilepsy clinical trials and importantly, we anticipate that patient enrollment in X-TOLE2 will be completed in the second half of this year. In addition, the ongoing XEN1101 Phase 2b X-TOLE open label extension epilepsy study has now collected over 500 patient years of data and has been extended from five to seven years. Our interim analyses completed to date have continued to demonstrate compelling efficacy data and seizure freedom rates, while building upon the safety and tolerability profile of XEN1101."

Mr. Mortimer continued, "In addition to our clinical stage programs, we continue to conduct important pre-clinical work that leverages our expertise in ion channel drug development, and we expect multiple drug candidates will enter IND-enabling studies in 2024 and 2025 with a focus on our leadership in the Kv7 space as well as new potential opportunities targeting Nav1.1 for seizure disorders and Nav1.7 for pain. We expect to provide additional updates as these discovery programs advance through IND-enabling studies and into clinical development."

Pipeline Programs and Anticipated Milestones

XEN1101

XEN1101 is a novel, potent Kv7 potassium channel opener being developed for the treatment of epilepsy, major depressive disorder (MDD), and potentially other neurological disorders.

XEN1101 for Epilepsy (Focal Onset Seizures)

Xenon's XEN1101 Phase 3 epilepsy program includes two identical Phase 3 clinical trials, 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 are evaluating the clinical efficacy, safety, and tolerability of 15 mg or 25 mg of XEN1101 administered with food as adjunctive treatment in approximately 360 patients per study with focal onset seizures, or FOS. Xenon anticipates that patient enrollment in X-TOLE2 will be completed in the second half of 2024.

XEN1101 for Epilepsy (Primary Generalized Tonic-Clonic Seizures)

Xenon's Phase 3 X-ACKT clinical trial is intended to support potential regulatory submissions in an additional epilepsy indication of primary generalized tonic-clonic seizures, or PGTCS. This multicenter, randomized, double-blind, placebo-controlled study is evaluating the clinical efficacy, safety, and tolerability of 25 mg of XEN1101 administered with food as adjunctive treatment in approximately 160 patients with PGTCS.

XEN1101 for Epilepsy (Open-Label Extension)

Upon completion of the double-blind period in X-TOLE2, X-TOLE3, or X-ACKT, eligible patients may enter an open-label extension, or OLE, study for up to three years. In addition, the ongoing X-TOLE Phase 2b OLE continues to generate important long-term data for XEN1101.

XEN1101 for Major Depressive Disorder

In November 2023, Xenon reported promising topline results from the Phase 2 proof-of-concept X-NOVA clinical trial, which

evaluated the clinical efficacy, safety, and tolerability of 10 mg and 20 mg of XEN1101 in 168 patients with moderate to severe MDD. Xenon is actively assessing various clinical and regulatory pathways to support late-stage clinical development of XEN1101 in MDD and expects to initiate the Phase 3 clinical program in 2024. Xenon is also evaluating other potential indications for the future development of XEN1101.

In addition, Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to support an ongoing investigator-sponsored Phase 2 proof-of-concept, randomized, parallel-arm, placebo-controlled multi-site study of XEN1101 for the treatment of MDD in approximately 60 subjects.

Partnered Programs

Xenon has an ongoing collaboration with Neurocrine Biosciences to develop treatments for epilepsy. Neurocrine Biosciences has an exclusive license to XEN901, now known as NBI-921352, a selective Nav1.6 sodium channel inhibitor. A Phase 2 clinical trial is underway evaluating NBI-921352 in patients aged between 2 and 21 years with SCN8A developmental and epileptic encephalopathy.

Pre-Clinical Programs

Xenon continues to leverage its extensive ion channel expertise and drug discovery capabilities to identify validated drug targets and develop new product candidates. The near-term focus is on development candidates targeting Kv7, Nav1.1 and Nav1.7 where Xenon expects multiple candidates will enter IND-enabling studies in 2024 and 2025. Additional updates will be provided as these pre-clinical drug candidates advance through IND-enabling studies and into clinical development.

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. 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 in current and anticipated indications, 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 pipeline and 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 of XEN1101 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 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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