Xenon Pharmaceuticals Outlines Key Milestone Opportunities for 2022

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BURNABY, British Columbia, Jan. 10, 2022 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a neurology-focused biopharmaceutical company, today outlined its key milestones for 2022.

Mr. Ian Mortimer, Xenon's President and Chief Executive Officer stated, "We are entering 2022 with an immense amount of positive momentum, building upon the strong efficacy data from our XEN1101 Phase 2b X-TOLE clinical trial announced in the fourth quarter of 2021. We have set clear business objectives for 2022, with a high priority placed on conducting an end-of-Phase 2 meeting with the FDA in the second quarter of 2022, finalizing our XEN1101 clinical development plans, and initiating our XEN1101 Phase 3 program in the second half of 2022 in adult patients with focal epilepsy. In addition, we are evaluating XEN1101 as a treatment for major depressive disorder, both in an investigator-led study with collaborators at Mount Sinai that is currently underway and in a company-sponsored Phase 2 clinical trial that is expected to begin in the first half of this year."

Mr. Mortimer added, "Our team is also focused on continuing to support ongoing patient enrollment in our Phase 3 'EPIK' pediatric clinical trial evaluating XEN496 as a treatment of KCNQ2 developmental and epileptic encephalopathy, which is expected to be completed in the first half of 2023. We also look forward to reporting ongoing progress from our partnered programs and discovery pipeline throughout the year."

Highlights and Anticipated Milestones

Proprietary Programs

XEN1101
XEN1101 is a differentiated Kv7 potassium channel opener being developed for the treatment of epilepsy and major depressive disorder (MDD). 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. The topline data showed all primary and secondary seizure reduction endpoints were statistically significant across all dose groups, including the primary endpoint of median reduction from baseline in monthly seizure frequency and in the key secondary endpoint of patients with at least a 50% reduction in monthly focal seizure frequency from baseline, with p-values of <0.001 for both the 20 mg and 25 mg dose groups. Xenon anticipates participating in an "end-of-Phase 2" meeting with the U.S. Food and Drug Administration (FDA) in the second quarter of this year to support the initiation of its Phase 3 XEN1101 clinical program in adult patients with focal epilepsy, estimated in the second half of the year. The X-TOLE open-label extension, which has been extended to three years, is expected to continue to generate important long-term data for XEN1101. Xenon is also evaluating other potential epilepsy indications for the future development of XEN1101.

In addition, Xenon is collaborating with the Icahn School of Medicine at Mount Sinai to conduct an investigator-sponsored Phase 2 proof-of-concept, multi-site, randomized, parallel-arm, placebo-controlled clinical trial of XEN1101 for the treatment of MDD, with patient enrollment underway. Xenon is also planning a larger company-sponsored clinical study in MDD with XEN1101, which is expected to be initiated in the first half of this year.

XEN496
XEN496, a Kv7 potassium channel opener, is a proprietary pediatric formulation of the active ingredient ezogabine being developed for the treatment of KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE). A Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter clinical trial, called the "EPIK" study, is underway to evaluate the efficacy, safety, and tolerability of XEN496 administered as adjunctive treatment in approximately 40 pediatric patients aged one month to less than six years with KCNQ2-DEE. Xenon anticipates that the EPIK study will be completed in the first half of 2023.

Partnered Programs

NBI-921352
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. Neurocrine Biosciences is conducting a Phase 2 clinical trial evaluating NBI-921352 in adult patients with focal onset seizures, with data expected in 2023. In addition, a Phase 2 clinical trial is underway evaluating NBI-921352 in adolescent patients (aged 12 years and older) with SCN8A developmental and epileptic encephalopathy (SCN8A-DEE). Upon FDA acceptance of a protocol amendment for NBI-921352 in pediatric patients (aged 2-11 years) with SCN8A-DEE, Xenon is eligible to receive an aggregate payment of $15.0 million in the form of 45% cash and a 55% equity investment in Xenon's common shares at a 15% premium to Xenon's 30-day trailing volume weighted average price at that time.

FX301
In November 2021, Pacira BioSciences, Inc. completed its acquisition of Flexion Therapeutics, Inc., which included Flexion's

global rights to develop and commercialize XEN402, a Nav1.7 inhibitor also known as funapide. FX301 consists of XEN402 formulated for extended release from a thermosensitive hydrogel. A Phase 1b proof-of-concept trial is underway evaluating the safety and tolerability of FX301 administered as a single-dose, popliteal fossa block (a commonly used nerve block in foot and ankle-related surgeries) in patients undergoing bunionectomy, with data anticipated in the first quarter of this year. Pursuant to the terms of the agreement, Xenon has the potential to receive certain clinical, regulatory, and commercial milestone payments, as well as future sales royalties.

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 results from clinical trials and pre-clinical development activities, including those related to XEN496, XEN1101, and other proprietary products, and those related to NBI-921352, FX301, and other partnered product candidates; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN1101 and other proprietary and partnered product candidates; the anticipated timing of IND, or IND-equivalent, submissions and the initiation of future clinical trials for XEN496, XEN1101, and other proprietary products, and those related to NBI-921352, FX301, and other partnered candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in the XEN496, XEN1101, and other proprietary development programs; the timing and results of our interactions with regulators; anticipated enrollment in our clinical trials and the timing thereof; the progress and potential of our other ongoing development programs; the potential receipt of milestone payments and royalties from our collaborators; and the timing of potential publication or presentation of future clinical data. 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: the impact of the COVID-19 pandemic on our business, research and clinical development plans and timelines and results of operations, including impact on our clinical trial sites, collaborators, and contractors who act for or on our behalf, may be more severe and more prolonged than currently anticipated; clinical trials may not demonstrate safety and efficacy of any of our or our collaborators' product candidates; 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 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; regulatory agencies may be delayed in reviewing, commenting on or approving any of our or our collaborators' clinical development plans as a result of the COVID-19 pandemic, which could further delay development timelines; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; impact of new or changing laws and regulations; adverse conditions in the general domestic and global economic markets; 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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