Xenon Pharmaceuticals Outlines 2019 Key Milestones

January 6, 2019

Innovative Product Pipeline Includes Multiple Neurology-Focused Products Anticipated to be in Phase 2 or Later Stage Development in 2019

BURNABY, British Columbia, Jan. 06, 2019 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today provided a corporate update and outlined its anticipated key milestone events in 2019.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Xenon is entering 2019 in a strong position, poised to support multiple neurology programs that are expected to be in Phase 2 or later stage development this year. With four distinct therapeutic candidates – XEN496, XEN1101, XEN901 and XEN007 – that are aimed at treating neurological disorders, including epilepsy, we intend to pursue a variety of development strategies, such as those focused on using a 'precision medicine' approach to address rare pediatric disorders including KCNQ2 epilepsy as well as those targeting broader patient populations, including adult patients with focal epilepsy. During 2019, we expect to advance our ongoing XEN1101 Phase 2b clinical trial in adult focal epilepsy, initiate a Phase 3 clinical trial for XEN496 for the treatment of KCNQ2 epilepsy, and initiate a Phase 2 clinical trial for XEN901 in either a pediatric or adult epilepsy indication based on regulatory feedback. In addition, we expect to initiate at least one Phase 2 clinical trial for XEN007 in an orphan neurological indication and continue our drug discovery efforts to identify new therapeutic candidates."

Anticipated Milestones

- XEN496 (active ingredient ezogabine) is a Kv7 potassium channel modulator being developed for the treatment of KCNQ2 epileptic encephalopathy (KCNQ2-EE). Ezogabine was previously approved by the U.S. Food and Drug Administration (FDA), as an anti-epileptic drug (AED) as an adjunctive treatment for adults with focal seizures with or without secondary generalization. Xenon received orphan drug designation (ODD) from the FDA for XEN496 as a treatment of KCNQ2-EE. A steering committee made up of key opinion leaders in the KCNQ2-EE and pediatric epilepsy fields has been established to help guide the clinical development of XEN496. In response to Xenon's pre-IND briefing package submission, the FDA indicated that it was acceptable to study XEN496 in infants and children up to 4 years old, and that a single pivotal trial in approximately 20 patients may be considered adequate in order to demonstrate XEN496's efficacy in KCNQ2-EE. Xenon is currently finalizing a pediatric-specific formulation to complete pre-clinical formulation testing with a final drug product expected in the second quarter of 2019. Xenon expects to file an Investigational New Drug (IND) application in the third quarter of 2019, and, based on regulatory feedback, Xenon expects to initiate a Phase 3 clinical trial thereafter.

- XEN1101 is a Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. Xenon announced final data from its XEN1101 Phase 1 clinical trial and the related transcranial magnetic stimulation (TMS) studies at the American Epilepsy Society (AES) Annual Meeting in December 2018. Based on the encouraging Phase 1 data and TMS results, Xenon has initiated a Phase 2b clinical trial in adult patients with focal epilepsy. A Clinical Trial Application (CTA) has been accepted by Health Canada enabling the start of patient screening, and the first patient in the XEN1101 Phase 2b clinical trial is expected to be enrolled in the near term. Xenon has also submitted regulatory filings to support the clinical development of XEN1101 in other jurisdictions, including the United States and Europe. The XEN1101 Phase 2 clinical trial is designed as a randomized, double-blind, placebo-controlled, multicenter study to evaluate the clinical efficacy, safety and tolerability of XEN1101 administered as adjunctive treatment in adult patients with focal epilepsy. Approximately 300 patients will be randomized in a blinded manner to one of three active treatment groups or placebo in a 2:1:1:2 fashion (XEN1101 25 mg : 20 mg : 10 mg : Placebo). The primary endpoint is the median percent change in monthly focal seizure frequency from baseline compared to treatment period of active versus placebo. Depending upon the rate of enrollment, top-line results from the XEN1101 Phase 2 clinical trial are anticipated in the second half of 2020.

- XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed for the treatment of epilepsy. Xenon announced interim results from its XEN901 Phase 1 clinical trial and the related pilot TMS study at the AES Annual Meeting in December 2018. The next steps for XEN901 include completing the Phase 1 clinical trial and continued planning for Phase 2 clinical development evaluating XEN901 as a treatment for adult focal seizures or for rare, pediatric forms of epilepsy, including SCN8A gain-of-function epilepsy patients, depending on feedback from planned discussions with regulatory agencies. Xenon expects to receive regulatory feedback on advancing XEN901 directly into pediatric SCN8A gain-of-function epilepsy patients in the second quarter of 2019, and pediatric formulation development and juvenile toxicology studies are underway.

- XEN007 (active ingredient flunarizine) is a CNS-acting calcium channel inhibitor that directly modulates the Cav2.1 channel. Flunarizine has been used outside of the U.S. in the prevention of chronic migraine, and in case studies, it has been reported to have clinical benefit in other neurological disorders, including hemiplegic migraine (HM) and alternating

hemiplegia of childhood (AHC). Xenon has received ODD from the FDA for XEN007 for the treatment of HM and AHC. In addition, Xenon entered into key agreements in order to access regulatory files and manufacturing support to potentially enable an accelerated clinical development of XEN007 directly into a Phase 2 clinical trial. Xenon is currently evaluating various development strategies for XEN007, including the support of at least one Phase 2 clinical trial in an orphan neurological indication.

- As of September 30, 2018, cash and cash equivalents and marketable securities were $127.1 million. Based on current assumptions, which include fully supporting the planned clinical development of XEN496, XEN1101, XEN901 and XEN007, Xenon anticipates having sufficient cash to fund operations into 2021, excluding any revenue generated from existing partnerships or potential new partnering arrangements.

About Xenon Pharmaceuticals Inc.

We are a clinical stage biopharmaceutical company committed to developing innovative therapeutics to improve the lives of patients with neurological disorders, including rare central nervous system (CNS) conditions. 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 and Section 21E of the Securities Exchange Act of 1934 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, XEN901, XEN1101, XEN007 and our other product candidates, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN901, XEN1101, XEN007 and our other product candidates, the anticipated timing of IND, or IND equivalent, submissions and the initiation of future clinical trials for XEN496, XEN901, XEN1101, XEN007 and our other product candidates, the efficacy of our clinical trial designs, our ability to successfully develop and achieve milestones in the XEN496, XEN901, XEN1101, XEN007 and other development programs, the timing of results of our interactions with regulators, the potential to advance certain of our product candidates directly into Phase 2 or later stage clinical trials, anticipated enrollment in our clinical trials, the progress and potential of our other ongoing development programs, the sufficiency of our cash to fund operations into 2021, 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: 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 not permit certain of our product candidates to advance directly into a Phase 2 or later clinical trials or may delay the initiation thereof; the impact of competition; the impact of expanded product development and clinical activities on operating expenses; 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.

Investor/Media Contact:
Jodi Regts
Xenon Pharmaceuticals Inc.
Phone: (604) 484-3353
Email: investors@xenon-pharma.com

XENON

Xenon Pharmaceuticals Inc.