Xenon Pharmaceuticals Outlines Key Milestones for 2018

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BURNABY, British Columbia, Jan. 08, 2018 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical-stage biopharmaceutical company, today provided a corporate update and outlined its anticipated key corporate milestones for 2018.

Dr. Simon Pimstone, Xenon's President and Chief Executive Officer, said, “Xenon is entering 2018 with a sharp focus on advancing our proprietary pipeline of novel anti-epileptic drugs, including XEN1101, a next-generation Kv7 potassium channel opener, and XEN901, a Nav1.6 sodium channel inhibitor, to treat both adult and orphan pediatric forms of severe epilepsy, such as EIEE7 and EIEE13. Looking ahead to key clinical data points, we expect to have the ongoing XEN1101 Phase 1 clinical trial completed by mid-year, including a pharmacodynamic read-out from the Phase 1b transcranial magnetic stimulation (TMS) study. In the second half of this year, we anticipate having completed the XEN901 Phase 1 clinical trial. We anticipate that both XEN1101 and XEN901 could be in Phase 2 development by the end of this year. In addition, we will work towards expanding our pipeline of novel ion channel modulators through both our internal research efforts and our ongoing assessment of promising external product opportunities.”

Anticipated Milestones

- XEN1101 is a Kv7 potassium channel opener being developed for the treatment of epilepsy and potentially other neurologic disorders. Pre-clinically, XEN1101 has demonstrated improved pharmacokinetics, selectivity, potency and efficacy over ezogabine, an earlier generation potassium channel modulator. Xenon has initiated a Phase 1 first-in-human clinical trial to evaluate the safety, tolerability and pharmacokinetics of both single ascending doses and multiple ascending doses of XEN1101 in healthy subjects. The XEN1101 Phase 1 clinical trial includes a pharmacodynamic read-out incorporating a TMS model, which is designed to demonstrate activity of XEN1101 in the central nervous system by observing a change in an EEG (otherwise known as an electroencephalogram) or an EMG (otherwise known as an electromyogram) signal. By mid-year, we expect to have Phase 1 clinical results. A Phase 2 proof-of-concept trial evaluating XEN1101’s efficacy as a treatment for adult focal seizures is anticipated to begin in the second half of 2018, with a parallel plan to advance XEN1101 as soon as feasible thereafter into rare, pediatric forms of epilepsy, such as EIEE7, an early infantile epileptic encephalopathy associated with mutations in the KCNQ2 gene causing a loss-of-function in the Kv7.2 potassium channel. XEN1101 potentially addresses the primary cause of this severe encephalopathy by augmenting the defective Kv7.2 channel. Other potential indications for XEN1101 include tinnitus and ALS.

- XEN901 is a potent, selective Nav1.6 sodium channel inhibitor being developed for the treatment of epilepsy, including adult focal seizures and rare, pediatric forms of epilepsy, such as EIEE13, an early infantile epileptic encephalopathy associated with mutations in the SCN8A gene that cause a gain-of-function in the Nav1.6 sodium channel. XEN901 has demonstrated efficacy against seizures in an animal model of Nav1.6 gain-of-function epilepsy as well as animal models that support the treatment of adult focal seizures including the Maximal Electric Shock (MES) model. By selectively targeting Nav1.6, it is anticipated that XEN901 may achieve efficacy conferred by this well validated epilepsy target, but with an improved therapeutic index compared with currently available non-selective sodium channel inhibitors. Xenon recently filed a Clinical Trial Application (CTA) for XEN901 with the Medicines & Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK). It is anticipated that a Phase 1 clinical trial in the UK will begin in the first quarter of 2018, with a Phase 1 read-out expected in the second half of 2018. A Phase 2 proof-of-concept trial evaluating XEN901’s efficacy as a treatment for adult focal seizures is anticipated to begin by year-end.

- Xenon has an ongoing collaboration with Genentech focused on developing novel inhibitors of Nav1.7 for the treatment of pain, as well as a second collaboration centered on pain genetics. Genentech has completed a Phase 1 clinical trial for GDC-0310, which is an oral, selective Nav1.7 small-molecule inhibitor developed for the potential treatment of pain. Guidance around the future clinical development of GDC-0310 will be updated once ongoing pre-clinical studies are completed and the final results are analyzed by Genentech.

- Xenon intends to continue to leverage its drug discovery capabilities to identify genetically validated drug targets and develop new ion channel therapeutic candidates, and expects to provide updates as new drug discovery programs advance in 2018.

- In December 2017, Xenon entered into a Loan and Security Agreement with Silicon Valley Bank that provided for up to $15 million debt facility, $7 million of which was immediately available and drawn-down by Xenon.

- As of December 31, 2017, cash and cash equivalents and marketable securities were $43.7 million. Based on current assumptions, which include fully supporting the planned clinical development of XEN1101 and XEN901, Xenon anticipates having sufficient cash to fund operations into mid-2019, excluding any revenue generated from existing partnerships or

potential new partnering arrangements.

About Xenon Pharmaceuticals Inc.

Xenon is a clinical stage biopharmaceutical company focused on developing innovative therapeutics to improve the lives of patients with neurological disorders. Building upon our extensive knowledge of human genetics and diseases caused by mutations in ion channels, known as channelopathies, we are advancing – both independently and with our pharmaceutical collaborators – a novel product pipeline of ion channel modulators to address therapeutic areas of high unmet medical need, such as pain and 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 our ability to achieve milestones in both our proprietary and partnered development programs, our expectations regarding the sufficiency of our cash to fund operations into mid-2019, the anticipated timing of IND or IND equivalent submissions with regulatory agencies, the initiation of future clinical trials, the timing of and results from our and our collaborators' ongoing clinical trials and pre-clinical development activities, the plans of our collaboration partners and their interactions with regulatory agencies, the potential efficacy, future development plans and commercial potential of our and our collaborators' product candidates and the progress and potential of ongoing development programs. 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 discovery platform or ongoing collaborations 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 pursuant to our collaboration agreements; 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.

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