# Xenon Pharmaceuticals Reports Third Quarter 2018 Financial Results and Provides Corporate Update

November 6, 2018

***Robust, Novel Pipeline of Neurology Candidates Advancing in Clinical Development***

***Conference Call at 4:30 pm ET Today***

BURNABY, British Columbia, Nov. 06, 2018 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today reported its financial results for the quarter ended September 30, 2018 and provided a corporate update.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Supported by a strong balance sheet and foundation of leading expertise in ion channel drug development, I believe Xenon has built one of the most exciting neurology pipelines currently in clinical development. As our novel therapeutic candidates advance further into the clinic, we can see the potential to leverage their unique mechanisms of action for new treatments to help epilepsy patients, including strategies to utilize a potential 'precision medicine' approach to address extremely rare and difficult-to-treat pediatric epilepsies such as KCNQ2 epilepsy."

Dr. Pimstone continued, "Looking ahead, we are progressing the development of a pediatric-specific formulation for our XEN496 product and are finalizing the proposed clinical protocol in order to initiate a Phase 3 pivotal trial in approximately mid-2019. We expect to disclose XEN1101 Phase 1 results at the upcoming American Epilepsy Society (AES) meeting and initiate a Phase 2 clinical trial evaluating XEN1101 as a treatment for adult focal seizures in the fourth quarter of this year. Similarly, for XEN901, we anticipate providing an update at AES before year-end and initiating, as soon as feasible thereafter, a Phase 2 clinical trial evaluating XEN901's efficacy as a treatment of either adult or pediatric forms of epilepsy, depending on planned discussions with regulatory agencies in the near term. Additionally, we are evaluating various clinical development strategies for XEN007, including the support of physician-sponsored clinical trials, and we expect to provide further clinical program updates in the coming months."

**Achievements and Anticipated Milestones**

- XEN496 (active ingredient ezogabine) is a Kv7 potassium channel modulator being developed for the treatment of KCNQ2 epilepsy. 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. We believe published case reports where physicians have used ezogabine in infants and young children with KCNQ2 epileptic encephalopathy (KCNQ2-EE, also known as EIEE7), indicate that XEN496 may be efficacious in this often hard-to-treat pediatric patient population.

  Xenon received orphan drug designation (ODD) from the FDA for XEN496 as a treatment of KCNQ2-EE. After consulting with clinical experts and patient advocacy groups, Xenon submitted a pre-IND briefing package to the FDA that outlined the proposed clinical development plans for XEN496. In response, 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 working on a pediatric-specific formulation for XEN496 to support a Phase 3 clinical trial initiation in approximately mid-2019. A steering committee made up of key opinion leaders in the pediatric and KCNQ2 epilepsy fields has been established to help guide the clinical development of XEN496. With input from this steering committee on the proposed trial design, dosing, and endpoints, the protocol development for the XEN496 Phase 3 clinical trial is currently being finalized, and an investigational new drug application is expected to be submitted in the first half of 2019.

- XEN1101 is a Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. Xenon has completed enrollment in its randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate the safety, tolerability and pharmacokinetics of both single ascending doses (SAD) and multiple ascending doses (MAD) using a powder-in-capsule formulation of XEN1101 in healthy subjects. The XEN1101 Phase 1 clinical trial includes a pharmacodynamic read-out from a transcranial magnetic stimulation (TMS) study that is designed to assess XEN1101's ability and potency to modulate cortical excitability, thereby demonstrating activity in the target CNS tissue. Interim Phase 1 clinical trial results presented in May 2018 and August 2018 showed pharmacokinetic data confirming a half-life consistent with once daily dosing, drug exposure levels at doses tested above the $EC_{50}$ in preclinical models, and safety data supporting further development of XEN1101.

  In August 2018, Xenon disclosed data from the completed XEN1101 Phase 1b TMS study that demonstrated XEN1101 has an ability to inhibit cortical excitability, an important CNS effect observed with certain approved AEDs. The completed Phase 1b TMS study was a double-blind, placebo-controlled, randomized cross-over study in 20 healthy male subjects and

was initiated based on positive results from a Phase 1a pilot TMS study in 8 healthy subjects. Consistent with the Phase 1a TMS pilot study, in the Phase 1b TMS study, XEN1101 reduced corticospinal excitability, as demonstrated by a concentration dependent elevation in resting motor threshold (RMT), the key TMS-EMG measure. In the TMS-EEG portion of the study, XEN1101 statistically significantly modulated TMS-evoked potentials (TEPs) in a manner consistent with reductions in cortical excitability, potentially showing a unique "fingerprint" of activity as anticipated based on studies with other AEDs. XEN1101 has been shown to be generally well tolerated with all adverse events (AEs), reported as mild or moderate and reversible. There were no withdrawals, serious AEs, or deaths. Xenon plans to publish the complete XEN1101 Phase 1 clinical trial results at the upcoming AES meeting held from November 30, 2018 to December 4, 2018, and anticipates initiating a Phase 2 clinical trial evaluating XEN1101 as a treatment for adult focal seizures in the fourth quarter of 2018.

- XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed for the treatment of epilepsy. In February 2018, Xenon initiated a randomized, double-blind, placebo-controlled Phase 1 clinical trial to evaluate XEN901's safety, tolerability and pharmacokinetics in both SAD and MAD cohorts. Interim results disclosed in May 2018 and August 2018 demonstrate a favorable pharmacokinetic data that showed dose proportionality and supported twice daily or better dosing. The multiple dose levels tested yielded drug exposure above the efficacy range required to achieve $EC_{70}$ in pre-clinical models. Based on experience with TMS in the XEN1101 studies, Xenon, along with its collaborators at King's College, are exploring the use of the TMS assay in a small subset of subjects in the ongoing XEN901 Phase 1 clinical trial. An update of the XEN901 Phase 1 clinical trial is anticipated in the fourth quarter of 2018 at the upcoming AES meeting, and a Phase 2 clinical trial evaluating XEN901's efficacy as a treatment for adult focal seizures or for rare, pediatric forms of epilepsy is expected to be initiated as soon as feasible thereafter depending on planned discussions with regulatory agencies in the near term.

- XEN007 (active ingredient flunarizine) is a CNS-acting calcium channel inhibitor that directly modulates Cav2.1. 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). Xenon has received ODD from the FDA for XEN007 for the treatment of HM. In addition, Xenon entered into key agreements in order to access regulatory files and manufacturing support to potentially enable the 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 physician-sponsored clinical trials in different neurological disorders.

**Third Quarter 2018 Financial Results**

Cash and cash equivalents and marketable securities as of September 30, 2018 were $127.1 million, compared to $43.7 million as of December 31, 2017. There were 25,187,441 common shares and 1,568,000 Series 1 Preferred Shares, which Series 1 Preferred Shares are convertible into common shares on a one-for-one basis at the option of the holder, subject to certain limitations, outstanding as of September 30, 2018.

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.

Research and development expenses for the quarter ended September 30, 2018 were $6.2 million, compared to $7.2 million for the same period in 2017. The decrease of $0.9 million was primarily attributable to decreased spending on pre-clinical, discovery and other internal program expenses, partially offset by increased spending on XEN1101, which was acquired in April 2017.

General and administrative expenses for the quarter ended September 30, 2018 were $1.9 million, compared to $1.7 million for the same period in 2017. The increase of $0.2 million was primarily attributable to increased stock-based compensation, corporate affairs and intellectual property expenses.

Other operating expenses for the quarter ended September 30, 2018 were $6.0 million due to a one-time payment to Valeant Pharmaceuticals Luxembourg S.a.r.l. and Valeant Pharmaceuticals Ireland Limited, or together, Bausch Health, for the buy-out of all future milestone payments and royalties owed to Bausch Health with respect to the XEN1101 program.

Other expenses for the quarter ended September 30, 2018 were $0.2 million, compared to other income of $0.9 million for the same period in 2017. The decrease in other income was primarily driven by interest expense incurred on a term loan and a change in foreign exchange gains and losses arising largely from the translation of cash and cash equivalents and marketable securities denominated in Canadian dollars to U.S. dollars.

Net loss for the quarter ended September 30, 2018 was $14.4 million, compared to $7.7 million for the same period in 2017. The change was primarily attributable to higher research and development and interest expense, foreign exchange losses in the current quarter, as well as a decrease in collaboration revenue.

**Conference Call Information**

Xenon will host a conference call and live audio webcast today at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time) to discuss its third quarter 2018 financial results and to provide a business update. To participate in the call, please dial (855) 779-9075, or (631) 485-4866 for international callers, and provide conference ID number 2982939. The webcast will be broadcast live on the

“Investors” section of Xenon's website at www.xenon-pharma.com and will be available for replay following the call for 30 days.

**About Xenon Pharmaceuticals Inc.**

We are 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 collaborators – a novel product pipeline of neurology therapies to address areas of high unmet medical need, such as epilepsy, migraine and pain. 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 and supporting assumptions are not based on historical fact, and include statements regarding our expectations regarding the sufficiency of our cash to fund operations into 2021, the timing of and results from clinical trials and pre-clinical development activities, including those related to XEN496, XEN901, XEN1101 and our other product candidates, the plans of our collaboration partners, the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN901, XEN1101 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 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 and other development programs, the potential addition of new programs to our pipeline, the potential to advance our product candidates directly into a Phase 2 or later clinical trial, the anticipated benefits of the unique mechanisms of action of XEN901 and XEN1101, the design of our clinical trials and anticipated enrollment, the progress and potential of our other ongoing development programs, and the timing of our public presentation and potential publication 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 efforts to expand our current pipeline may not be successful; 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 our product candidates to advance directly into a Phase 2 or later clinical trial; 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.



XENON PHARMACEUTICALS INC.
Condensed Consolidated Balance Sheets
(Expressed in thousands of U.S. dollars)

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents and marketable securities | $ 127,128 | $ 43,667 |
| Other current assets | 2,365 | 1,154 |
| Other assets | 962 | 1,300 |
| **Total assets** | $ 130,455 | $ 46,121 |
| | | |
| **Liabilities** | | |
| Current liabilities: | | |
| Accounts payable and accrued expenses | 4,413 | 3,383 |
| Loan payable, current portion | — | 700 |
| Loan payable, long-term | 14,886 | 6,104 |
| **Total liabilities** | $ 19,299 | $ 10,187 |

| | | | | |
|---|---|---|---|---|
| **Shareholders' equity** | $ | 111,156 | $ | 35,934 |
| **Total liabilities and shareholders' equity** | $ | 130,455 | $ | 46,121 |

XENON PHARMACEUTICALS INC.
Condensed Consolidated Statements of Operations
(Expressed in thousands of U.S. dollars except share and per share amounts)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Revenue: | | | | |
| Collaboration revenue | $ — | $ 264 | $ — | $ 295 |
| Operating expenses: | | | | |
| Research and development | 6,240 | 7,164 | 17,228 | 19,176 |
| General and administrative | 1,938 | 1,744 | 6,354 | 5,643 |
| Buy-out of future milestones and royalties | 6,000 | - | 6,000 | - |
| Total operating expenses | 14,178 | 8,908 | 29,582 | 24,819 |
| Loss from operations | (14,178) | (8,644) | (29,582) | (24,524) |
| Other income (loss) | (205) | 902 | 3,643 | 1,885 |
| Net loss | (14,383) | (7,742) | (25,939) | (22,639) |
| Net loss attributable to preferred shareholders | (1,621) | — | (2,506) | — |
| Net loss attributable to common shareholders | $ (12,762) | $ (7,742) | $ (23,433) | $ (22,639) |
| Net loss per common share: | | | | |
| Basic | $ (0.63) | $ (0.43) | $ (1.34) | $ (1.26) |
| Diluted | $ (0.63) | $ (0.43) | $ (1.34) | $ (1.27) |
| Weighted-average common shares outstanding: | | | | |
| Basic | 20,306,298 | 17,998,420 | 17,472,403 | 17,980,608 |
| Diluted | 20,306,298 | 18,009,979 | 17,472,403 | 18,000,066 |

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