



## **Xenon Pharmaceuticals Outlines Key Milestone Opportunities for 2020 and Provides Corporate Update**

January 13, 2020

***Xenon's Proprietary Programs Continue to Advance with Multiple Mid to Late Stage Clinical Trials Anticipated to be Underway in 2020***

***Xenon Eligible for Milestone Payments Based on the Advancement of Partnered Programs***

***Experienced Biotech Executive, Dr. Clarissa Desjardins, Joins Xenon's Board of Directors***

BURNABY, British Columbia, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Xenon Pharmaceuticals Inc. (Nasdaq:XENE), a clinical stage biopharmaceutical company, today provided a corporate update and outlined its key milestone opportunities for 2020.

Dr. Simon Pimstone, Xenon's Chief Executive Officer, said, "Xenon is entering 2020 in a very strong position with an exciting portfolio of proprietary neurology-focused candidates in clinical development, a healthy balance sheet, and valued collaborators advancing partnered programs. We expect to have multiple mid to late stage clinical trials underway in 2020 putting us in a position to generate important clinical data in 2020."

Dr. Pimstone continued, "We anticipate a number of important milestone events in 2020, including the initiation of a Phase 3 clinical trial with XEN496 in patients with KCNQ2-DEE, a severe and rare form of pediatric epilepsy. In addition to the ongoing XEN1101 Phase 2b clinical trial in adult focal epilepsy, where we anticipate top-line data later this year, we are also seeking to expand the clinical development of XEN1101 in 2020 as we evaluate additional potential clinical indications for this novel Kv7 potassium channel modulator. Additionally, we look forward to the results from a physician-led Phase 2 study examining XEN007 in treatment-resistant childhood absence epilepsy."

Dr. Pimstone added, "We are also fortunate to work with great collaborators who continue to advance our partnered programs. Neurocrine has guided that it expects to file an IND in mid-2020 in order to start a Phase 2 clinical trial for XEN901 (now known as NBI-921352) in SCN8A-DEE pediatric patients. Flexion continues to develop its pre-clinical FX301 program focused on peripheral nerve block for control of post-operative pain, and anticipates initiating FX301 clinical trials in 2021."

### **Anticipated Milestones**

#### ***Proprietary Programs***

- XEN1101 is a differentiated Kv7 potassium channel modulator being developed for the treatment of epilepsy and potentially other neurological disorders. A Phase 2b double-blind, placebo-controlled, multicenter clinical trial (called the X-TOLE study) is underway to evaluate the clinical efficacy, safety and tolerability of XEN1101 administered as adjunctive treatment in approximately 300 adult patients with focal epilepsy. The primary endpoint is the median percent change in monthly focal seizure frequency from baseline compared to treatment period of active versus placebo. Patient enrollment for this XEN1101 Phase 2b clinical trial is ongoing in the United States, Canada and Europe. Long term six-and nine-month toxicology studies have now been completed, providing support for the 12-month open label extension for patients enrolled in the Phase 2b clinical trial. Depending upon the rate of enrollment, top-line results are anticipated in the second half of 2020. Xenon continues to explore the development of XEN1101 in other neurological indications.
- XEN496 (active ingredient ezogabine) is a Kv7 potassium channel modulator being developed by Xenon. The U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) for XEN496 as a treatment of KCNQ2 developmental and epileptic encephalopathy (KCNQ2-DEE). A pharmacokinetic (PK) study testing Xenon's proprietary pediatric formulation of ezogabine (XEN496) in healthy adult volunteers is expected to complete in the first quarter of 2020. The FDA previously indicated that it is acceptable to study XEN496 in infants and children up to four years old, and that a single, small pivotal trial may be considered adequate in order to demonstrate XEN496's efficacy in KCNQ2-DEE, provided the study shows evidence of a clinically meaningful benefit in patients with the intended indication. After completion of the XEN496 PK study and discussions with the FDA on a Phase 3 clinical trial design in the first quarter of 2020, Xenon expects to initiate a Phase 3 clinical trial in KCNQ2-DEE.
- XEN007 (active ingredient flunarizine) is a CNS-acting calcium channel modulator that modulates Cav2.1 and T-type calcium channels. Other reported mechanisms include dopamine, histamine and serotonin inhibition. A physician-led, Phase 2 proof-of-concept study has recently been initiated to examine the potential clinical efficacy, safety, and tolerability of XEN007 as an adjunctive treatment in pediatric patients diagnosed with treatment-resistant childhood absence epilepsy. Results from this Phase 2 investigator-led proof-of-concept study are expected in 2020. Depending on the results from the study, CAE may represent a potential orphan indication for future development of XEN007.

## **Partnered Programs**

- In December 2019, Xenon entered into a license and collaboration agreement with Neurocrine Biosciences, Inc. (Nasdaq:NBIX) to develop first-in-class treatments for epilepsy. Neurocrine Biosciences has an exclusive license to XEN901, now known as NBI-921352, a clinical stage selective Nav1.6 sodium channel inhibitor for epilepsy. In addition, Neurocrine Biosciences gained an exclusive license to pre-clinical compounds for development, including selective Nav1.6 inhibitors and dual Nav1.2/1.6 inhibitors. The agreement also included a multi-year research collaboration to discover, identify and develop additional novel Nav1.6 and Nav1.2/1.6 inhibitors. Neurocrine Biosciences anticipates filing an IND application with the FDA in mid-2020 in order to start a Phase 2 clinical trial in SCN8A developmental and epileptic encephalopathy patients in the second half of 2020. Xenon is eligible to receive up to \$25 million upon the FDA acceptance of an IND for NBI-921352, with 55% of the amount in the form of an equity investment in Xenon at a 15% premium to Xenon's 30-day trailing volume weighted average price at that time.
- In September 2019, Xenon entered into an agreement with Flexion Therapeutics, Inc. (Nasdaq:FLXN) that provides Flexion with the global rights to develop and commercialize XEN402, a Nav1.7 inhibitor. Flexion's pre-clinical program, known as FX301, consists of XEN402 formulated for extended release from a thermosensitive hydrogel. The initial development of FX301 is intended to support administration as a peripheral nerve block for control of post-operative pain. Flexion has indicated that it anticipates initiating FX301 clinical trials in 2021.

## **Corporate Updates**

- Effective immediately, Dr. Clarissa Desjardins has been appointed to Xenon's Board of Directors and will also serve on the Compensation Committee. An award-winning entrepreneur with over 25 years of biotechnology experience, Dr. Desjardins has a doctorate in neurology and neurosurgery from McGill University's Faculty of Medicine. In 2011, Dr. Desjardins founded Clementia Pharmaceuticals, a publicly traded biotechnology company focused on rare bone disorders that was acquired by Ipsen S.A. in 2019 for up to \$1.3 billion. Dr. Richard Scheller will resign from Xenon's Board effective January 14, 2020 after serving as an independent director since 2015.

Dr. Pimstone stated, "I am pleased to welcome Clarissa Desjardins to our Board of Directors. With her extensive biotechnology, entrepreneurial, and neuroscience background, Clarissa is a superb addition to Xenon's Board. I expect her contributions will be invaluable as we continue to advance our clinical programs and strive to develop new therapeutics for patients in need. I also wish to thank Richard for his esteemed counsel and service on our Board of Directors. The Xenon team wishes him well in all of his future endeavors."

## **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](http://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 the timing of and results from clinical trials and pre-clinical development activities, including those related to XEN496, XEN1101, XEN007, and other proprietary products, and those related to NBI-921352, FX-301, and other partnered product candidates; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN496, XEN1101, XEN007 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, XEN007, and other proprietary products, and those related to NBI-921352, FX-301, and other partnered candidates; the efficacy of our clinical trial designs; our ability to successfully develop and achieve milestones in the XEN496, XEN1101, XEN007 and other proprietary development programs; the timing and 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 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: 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, 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; 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” and the Xenon logo are registered trademarks or trademarks of Xenon Pharmaceuticals Inc. in various jurisdictions. All other trademarks belong to their respective owner.

**Investor/Media Contact:**

Jodi Regts

Xenon Pharmaceuticals Inc.

Phone: 604.484.3353

Email: [investors@xenon-pharma.com](mailto:investors@xenon-pharma.com)



Source: Xenon Pharmaceuticals Inc.