

Neurocrine Biosciences and Xenon Pharmaceuticals Announce Agreement to Develop First-in-Class Treatments for Epilepsy

December 2, 2019

Neurocrine Biosciences Gains Rights to XEN901, a Clinical Stage Selective Nav1.6 Sodium Channel Inhibitor, Being Developed for the Treatment of Epilepsy

Xenon Receives \$50 Million Upfront and Up to \$1.7 Billion in Potential Development, Regulatory and Commercial Milestone Payments Across All Licensed Products, as well as Option to Co-Fund XEN901

SAN DIEGO and BURNABY, British Columbia, Dec. 2, 2019 /PRNewswire/ -- Neurocrine Biosciences, Inc. (Nasdaq: NBIX) and Xenon Pharmaceuticals Inc. (Nasdaq: XENE) announced a license and collaboration agreement to develop first-in-class treatments for epilepsy.

Neurocrine Biosciences gains an exclusive license to XEN901, a clinical stage selective Nav1.6 sodium channel inhibitor with potential in SCN8A developmental and epileptic encephalopathy (SCN8A-DEE) and other forms of epilepsy, including focal epilepsy. In addition, Neurocrine Biosciences gains an exclusive license to pre-clinical compounds for development, including selective Nav1.6 inhibitors and dual Nav1.2/1.6 inhibitors. The agreement also includes a multi-year research collaboration to discover, identify and develop additional novel Nav1.6 and Nav1.2/1.6 inhibitors.

"We are excited to enter into this agreement with Xenon and leverage their expertise in precision medicine drug discovery to benefit the lives of people with epilepsy and serious neurological disorders," said Kevin Gorman, Ph.D., Chief Executive Officer of Neurocrine Biosciences. "The agreement with Xenon strengthens Neurocrine Biosciences' diverse and growing pipeline and reinforces our long-term commitment of becoming a leading neuroscience-focused biopharmaceutical company."

"With its proven expertise in developing and commercializing treatments for neurological disorders, we believe Neurocrine Biosciences is an ideal partner to maximize the potential value of XEN901 for patients," said Dr. Simon Pimstone, Chief Executive Officer of Xenon. "Importantly, this collaboration represents a significant investment in XEN901 and Xenon's earlier-stage Nav1.6 and Nav1.2/1.6 inhibitor programs and allows for a broader development of these promising compounds than we could accomplish independently. Furthermore, the additional capital from this transaction will support our efforts to advance and expand our proprietary pipeline."

License and Collaboration Details / Financial Terms

Under the terms of the agreement, Neurocrine Biosciences will be responsible for development costs associated with the programs and the agreement will be subject to the following terms:

- Upfront License Payment: Xenon will receive \$50 million, including a \$30 million upfront payment in cash and a \$20 million equity investment by Neurocrine Biosciences at a Xenon per share price of \$14.196.
- XEN901 Investigational New Drug (IND) Milestone: Xenon will receive up to \$25 million upon the U.S. Food and Drug Administration (FDA) acceptance of an IND for XEN901, 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.
- Collaboration Milestones: Xenon may also be entitled to receive up to approximately \$1.7 billion in additional development, regulatory and commercial milestone payments related to XEN901 and other licensed Nav1.6 or Nav1.2/1.6 inhibitor products.
- XEN901 Royalties: Xenon will have the right to receive a tiered royalty ranging from the low double-digits to mid-teen percentage in the U.S. and a tiered royalty at slightly lower rates outside the U.S. based upon aggregate global net sales.
- Other Product Royalties: Xenon will have the right to receive a tiered royalty for other Nav1.6 and Nav1.2/1.6 inhibitor products ranging from the mid-single to low double-digits in the U.S. and a tiered royalty at slightly lower rates outside the U.S. based upon aggregate global net sales.
- Xenon Co-Fund Option: Xenon retains an option to co-fund 50% of the U.S. development costs of XEN901 or another product candidate in exchange for increased U.S. royalties, reaching 20% of U.S. net sales at the highest royalty tier for XEN901.
- Funded Collaboration: Neurocrine Biosciences will fund all clinical developments costs associated with the development of product candidates under the collaboration (subject to Xenon's Co-Fund Option) and will also fund a research collaboration up to 3 years with a minimum of 10 FTEs (full time equivalents) at Xenon. Xenon will be responsible for certain pre-clinical and a portion of certain near term manufacturing costs under the collaboration.

Neurocrine Biosciences anticipates filing an IND application with the FDA in the middle of 2020 in order to start a proposed clinical trial for XEN901 in SCN8A-DEE patients.

Conference Call Information

Neurocrine Biosciences will provide further commentary on the collaboration during its presentation at the Evercore ISI 2nd Annual HealthCONx Conference at 8:45 a.m. EST on Tuesday, December 3, 2019.

Today, Xenon will host a conference call at 8:30 a.m. EST to provide commentary on the collaboration. To access the call, please dial (855) 779-9075,

or (631) 485-4866 for international callers, and provide conference ID number 3665957.

Live audio webcasts of these presentations will be available under "Investors" on the companies' respective websites at: <u>www.neurocrine.com</u> and <u>www.xenon-pharma.com</u>. A replay of the webcast will be available for each presentation approximately one hour after the conclusion of each event and will be archived for approximately one month.

About XEN901 Program for Epilepsy

XEN901 is a potent, highly selective Nav1.6 sodium channel inhibitor being developed to treat pediatric patients with SCN8A developmental and epileptic encephalopathy (SCN8A-DEE) and other potential indications, including adult focal epilepsy. A Phase 1 clinical trial was completed using a powder-in-capsule formulation of XEN901 in healthy adult subjects. Xenon has developed a pediatric-specific, granule formulation of XEN901, and juvenile toxicology studies to support pediatric development activities have recently been completed.

About Neurocrine Biosciences

Neurocrine Biosciences (Nasdaq: NBIX) is a neuroscience-focused, biopharmaceutical company with more than 25 years of experience discovering and developing life-changing treatments for people with serious, challenging and under-addressed neurological, endocrine and psychiatric disorders. The company's diverse portfolio includes FDA-approved treatments for tardive dyskinesia and endometriosis* and clinical development programs in multiple therapeutic areas including Parkinson's disease, chorea in Huntington disease, congenital adrenal hyperplasia, uterine fibroids* and polycystic ovary syndrome*. Headquartered in San Diego, Neurocrine Biosciences specializes in targeting and interrupting disease-causing mechanisms involving the interconnected pathways of the nervous and endocrine systems. For more information, visit <u>neurocrine.com</u>, and follow the company on LinkedIn. (*in collaboration with AbbVie)

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, 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 <u>www.xenon-pharma.com</u>.

Neurocrine Biosciences Forward-Looking Statements

In addition to historical facts, this press release contains forward-looking statements that involve a number of risks and uncertainties. These statements include, but are not limited to, statements related to the benefits to be derived from transactions with Xenon Pharmaceuticals Inc. and the timing of completion of our clinical, regulatory, and other development activities. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are: the Company's future financial and operating performance; risks or uncertainties related to the development of the Company's product candidates; risks that the FDA or other regulatory authorities may make adverse decisions regarding our product candidates; risks that clinical development activities may not be completed on time or at all; risks that clinical development activities may be delayed for regulatory, manufacturing, or other reasons, may not be successful or replicate previous clinical trial results, may fail to demonstrate that our product candidates are safe and effective, or may not be predictive of real-world results or of results in subsequent clinical trials; risks and uncertainties relating to competitive products and technological changes that may limit demand for a product candidate; risks that the benefits of the agreements with Xenon Pharmaceuticals Inc. may never be realized; risks that our product candidates may be precluded from commercialization by the proprietary or regulatory rights of third parties, or have unintended side effects, adverse reactions or incidents of misuse; and other risks described in the Company's periodic reports filed with the Securities and Exchange Commission, including without limitation the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2019. Neurocrine disclaims any obligation to update the statements contained in this press release after the date hereof.

Xenon Pharmaceuticals Forward-Looking Statements

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 other development activities, including those related to XEN901 and the other pre-clinical compounds covered by our collaboration with Neurocrine Biosciences; the potential efficacy, safety profile, future development plans, addressable market, regulatory success and commercial potential of XEN901 and the other pre-clinical compounds covered by our collaboration with Neurocrine Biosciences; the anticipated timing of IND, or IND equivalent, submissions and the initiation of future clinical trials for XEN901 and the other pre-clinical compounds covered by our collaboration with Neurocrine Biosciences; our ability to achieve milestones in our collaboration with Neurocrine Biosciences and our other development programs; the progress and potential of our other ongoing development programs; and the potential receipt of milestone payments and royalties from our collaborators and partners. 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; 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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SOURCE Neurocrine Biosciences, Inc.

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