Flexion Therapeutics and Xenon Pharmaceuticals Announce Flexion's Acquisition of an Investigational NaV1.7 Inhibitor for the Treatment of Post-Operative Pain

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- *Flexion's new locally delivered product candidate, FX301, will combine Xenon's NaV1.7 inhibitor, XEN402, with a novel thermosensitive hydrogel*
- *FX301 is a potential first-in-class therapy with the aim of providing pain relief via peripheral nerve block for up to a week following surgery while preserving motor function*
- *Acquisition of XEN402 expands Flexion's portfolio focused on developing and commercializing non-opioid pain management therapies for musculoskeletal conditions*
- *FX301 is anticipated to enter clinical trials in 2021*

BURLINGTON, Mass. and BURNABY, British Columbia, Sept. 09, 2019 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) and Xenon Pharmaceuticals Inc. (Nasdaq:XENE) today announced that the companies have entered into a definitive agreement that provides Flexion with the global rights to develop and commercialize XEN402, a NaV1.7 inhibitor, for the management of post-operative pain.

Flexion's new preclinical program, known as FX301, will consist 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. Within minutes following injection, the thermosensitive formulation has been shown to transition from a liquid to a gel, an effect that provides local delivery of XEN402 near target nerves for up to a week. Unlike typical local anesthetics, the selective pharmacology of XEN402 has the potential to provide effective pain relief while preserving motor function. As such, FX301 is expected to enable ambulation, rapid discharge, and early rehabilitation following musculoskeletal surgery.

Under the terms of the agreement, Flexion acquired the global rights to the XEN402 program including a broad patent estate as well as the associated non-clinical, clinical and manufacturing components. As consideration for the acquisition, Flexion paid Xenon an upfront payment of $3 million. In addition, Xenon will also be eligible for various CMC, development and regulatory milestone payments of up to $9 million through initiation of a Phase 2 proof of concept (PoC) clinical trial. Following successful PoC, Xenon may be entitled to future clinical development and global regulatory approval milestone payments of up to $40.75 million, commercialization milestone payments of up to $75 million, as well as future sales royalties ranging from mid-single to low-double digit percentages. As part of the agreement, Flexion will assume Xenon's obligation to pay a low single-digit percentage of sales royalty to Teva Pharmaceuticals International GmbH. Flexion anticipates initiating FX301 clinical trials in 2021.

Commenting on the deal Michael Clayman, M.D., President and Chief Executive Officer of Flexion said, "FX301 is a natural fit for Flexion as it leverages our deep understanding of musculoskeletal pain and our demonstrated formulation expertise. Post-operative opioid use is considered a key cause of subsequent opioid use disorder, particularly following musculoskeletal surgery. We believe FX301 may directly address a substantial medical challenge by potentially providing durable and meaningful post-operative pain relief, while sparing motor function. Importantly, Xenon has amassed an extensive amount of pre-clinical data from in vivo pain models, and XEN402 has been previously tested in multiple human clinical trials, which we believe can accelerate our development efforts to move FX301 into the clinic."

Dr. Simon Pimstone, Xenon's Chief Executive Officer added, "We believe that FX301 holds great potential as a local therapy for post-operative pain based on in vivo data with XEN402 that demonstrated good efficacy when delivering this drug to the target site at high concentration. Thus, we believe that locally administered, long acting delivery of XEN402 may represent a promising new way to address post-operative pain. With their experience developing and commercializing novel and locally acting therapies, we are excited that Flexion is committed to advancing XEN402 in their proprietary formulation as FX301. We look forward to the progression of FX301 as it advances through clinical development."

About Flexion Therapeutics

Flexion Therapeutics (Nasdaq:FLXN) is a biopharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a type of degenerative arthritis. The Company's core values are focus, ingenuity, tenacity, transparency and fun. For the past three years, Flexion has been named one of the Best Places to Work by the Boston Business Journal, and Flexion was recognized as a Top Place to Work in Massachusetts by The Boston Globe in 2017 and 2018. For more information, visit www.flexiontherapeutics.com.

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. Xenon is 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.

Forward-Looking Statements

Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating to the future of Flexion or Xenon; Flexion's plans to develop and commercialize FX301, including the expected timing of clinical and regulatory events; future payments, if any, under the purchase agreement between Flexion and Xenon; and the potential therapeutic and other benefits of FX301, are forward-looking statements. These forward-looking statements are based on expectations and assumptions of Flexion's and Xenon's respective management as of the date of this press release and are subject to numerous risks and uncertainties, which could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, risks associated with developing and commercializing FX301, including potential delays in initiating clinical trials; the fact that the results of prior preclinical and clinical studies involving XEN402 may not predict results of subsequent preclinical or clinical studies; the risk that Flexion may incur unexpected expenses or cash requirements; reliance on third parties to manufacture FX301; the risk that Flexion may not be able to maintain and enforce its intellectual property rights, including its rights to acquired intellectual property related to FX301; the risk that Xenon may not receive additional payments pursuant to the agreement with Flexion; competition from alternative and/or standard of care therapies; regulatory developments and safety issues, including difficulties in obtaining and maintaining regulatory approvals to conduct clinical trials and market FX301; risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates; and other risks and uncertainties described in filings with the Securities and Exchange Commission (SEC). The forward-looking statements in this press release speak only as of the date of this press release, and Flexion and Xenon undertake no obligation to update or revise any of the statements. Flexion and Xenon caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

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