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Flexion Therapeutics Announces Acquisition of Novel, Non-Opioid Asset for Osteoarthritis of the Knee

- *Acquisition complements existing portfolio with an innovative, locally administered therapeutic intended to provide persistent effective concentrations of IL-1Ra in the knee for at least a year*
- *New preclinical program holds potential to be a next-generation therapeutic that could provide long-lasting pain relief and disease modification*
- *Program aligns with Flexion's life-cycle management strategy and established commercial infrastructure*
- *Pending positive preclinical studies, FX201 anticipated to enter clinical trials in 2019*

BURLINGTON, Mass., Dec. 13, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced it has entered into a definitive agreement with GeneQuine Biotherapeutics GmbH to acquire the global rights to GQ-203. As part of the agreement, Flexion obtained an exclusive license to the underlying intellectual property rights for human use of GQ-203 from Baylor College of Medicine. GQ-203, now known as FX201, is a preclinical, non-opioid, intra-articular therapeutic being developed for symptomatic pain relief and disease modification in patients with osteoarthritis (OA) of the knee.

As part of the deal, Flexion will make an upfront payment of $2 million to GeneQuine and may incur milestone payments of up to $8.7 million through Phase 2 proof of concept (PoC). Following successful PoC, Flexion may incur up to $54 million in future development and global regulatory approval milestone payments, with Baylor also receiving a low single-digit royalty on net sales of FX201. After taking into account Flexion's payment obligations in connection with the acquisition and the anticipated preclinical and clinical development costs for FX201, the company still expects current cash to bring Flexion to profitability.

FX201 is a locally administered gene therapy designed to stimulate the production of an anti-inflammatory protein, interleukin-1 receptor antagonist (IL-1Ra), whenever inflammation is present within the joint. Inflammation is a known cause of pain, and chronic inflammation is thought to play a major role in the progression of OA. By persistently suppressing inflammation, FX201 may both reduce pain and modify the disease.

"We believe FX201 could represent a next-generation therapeutic approach for OA, and it supports our long-term objective of having a pipeline of high-quality drug candidates that are positioned to enter the market as ZILRETTA™ matures," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "With its potential to deliver an unprecedented duration of pain relief and possibly arrest the progression of disease, FX201 could transform the treatment of OA, while fitting nicely within our commercial infrastructure."

Based on strong preclinical data, a single injection of FX201 could potentially enable expression of IL-1Ra in an osteoarthritic joint for a least a year. Initially, FX201 will be targeted towards a subpopulation of patients who confront aggressive OA of the knee and would be expected to differentially benefit from this therapy. Flexion expects to hold a pre-Investigational New Drug meeting with the U.S. Food and Drug Administration in the first half of 2018, and pending successful results from preclinical studies, the company aims to initiate a Phase 1 clinical trial in 2019.

About Osteoarthritis (OA) of the Knee
OA is the most common joint disease, affecting more than 30 million Americans and accounting for more than $185 billion in annual expenditures. In 2016, more than 15 million Americans were diagnosed with OA of the knee and the average age of physician-diagnosed knee OA has fallen by 16 years, from 72 in the 1990s to 56 in the 2010s. The prevalence of OA is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, more than 15 million Americans are treated for OA-related knee pain, and approximately five million OA patients receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection to manage their knee pain.

About Flexion Therapeutics
Flexion Therapeutics (Nasdaq:FLXN) is a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with OA, a type of degenerative arthritis. The company's core values are focus, ingenuity, tenacity, transparency and fun. Flexion

was named one of the *Boston Business Journal's* 2017 Best Places to Work and one of the Top Places to Work in Massachusetts by *The Boston Globe*.

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; our plans to develop and commercialize FX201, including the expected timing of clinical and regulatory events; expected financial results and Flexion's ability to reach profitability; the market potential of FX201; expected increases in the rate of individuals with OA of the knee; and the potential therapeutic and other benefits of FX201, are forward-looking statements. These forward-looking statements are based on management's expectations and assumptions 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 the acquisition of and the process of developing FX201; the fact that the results of prior preclinical studies may not predict results of subsequent preclinical or clinical studies; risks associated with the process of commercializing ZILRETTA, including the extent to which ZILRETTA is adopted by physicians and patients and is reimbursed by third party payors; the risk that we may incur unexpected expenses or cash requirements; our reliance on third parties to manufacture FX201 and ZILRETTA; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property acquired and licensed in related to FX201; the risk the license agreement with Baylor could be terminated early if we do not comply with our obligations; competition from alternative therapies; regulatory developments and safety issues, including difficulties in obtaining and maintaining regulatory approvals to market FX201 and our other products; risks related to key employees, markets, economic conditions, health care reform, prices and reimbursement rates; and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed with the SEC on November 6, 2017. The forward-looking statements in this press release speak only as of the date of this press release, and we undertake no obligation to update or revise any of the statements. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

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