



April 29, 2018

## **Flexion Therapeutics Announces Presentation of Positive FX201 Data at the Osteoarthritis Research Society International World Congress**

*Results from preclinical osteoarthritis (OA) models demonstrate relief of pain, functional improvement and suggest disease-modifying efficacy following a single intra-articular injection*

BURLINGTON, Mass., April 29, 2018 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced the presentation of positive preclinical data supporting the FX201 program at the Osteoarthritis Research Society International 2018 World Congress, April 26-29, Liverpool, United Kingdom. In December 2017, Flexion acquired the global rights to GQ-203 for human applications, now known as FX201, from GeneQuine Biotherapeutics GmbH and obtained an exclusive license to the underlying intellectual property rights to the program from Baylor College of Medicine in Houston, Texas.

FX201 is an intra-articular (IA) gene therapy candidate designed to induce the production of human interleukin-1 receptor antagonist (IL-1Ra) whenever inflammation is present within the joint. Based on strong preclinical data, a single injection of FX201 could potentially enable expression of IL-1Ra in an osteoarthritic joint for a least one year. By controlling chronic inflammation for extended periods of time, Flexion believes FX201 holds the potential to both reduce OA pain and modify disease.

The oral presentation, "Interleukin-1 Receptor Antagonist Gene Therapy Prevents and Delays Surgically-Induced Osteoarthritis in Small and Large Animal Models" (Abstract #85), was given by Matthew Grol, Ph.D., postdoctoral associate in Dr. Brendan Lee's laboratory at Baylor College of Medicine. The presentation described the results of animal models of OA using the murine and equine equivalents of the FX201 gene therapy construct.

"These data strongly support the continued evaluation of FX201 as a novel, non-opioid approach that may provide long-term pain relief and modify disease in patients confronting progressive OA," said Michael Clayman, M.D., President and Chief Executive Officer. "This presentation bolsters our excitement about advancing the development of FX201, and we look forward to achieving our goal of initiating first in human clinical trials in 2019."

Key findings from the studies include:

- 1 Mice receiving the murine equivalent of FX201 were observed to have a reduced sensitivity to pain compared to the placebo group;
- 1 Advanced imaging (microCT) of the joints showed that treatment with the murine equivalent of FX201 resulted in increased cartilage volume compared to controls;
- 1 The administration of the equine equivalent of FX201 in an equine OA model resulted in successful pain relief and improvement of function compared to placebo;
- 1 Macroscopic and histological cartilage analyses in the equine study favored FX201 over control, a finding that may be indicative of an effect on disease modification in human OA; and
- 1 Single administration of the FX201 murine and equine equivalents was well-tolerated in each respective preclinical model and no significant biodistribution outside the target joint tissues was observed.

### **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 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**

This release contains forward-looking statements that are based on the current expectations and beliefs of Flexion. Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating to the future of Flexion; the potential therapeutic and other benefits of FX201; our plans to develop and

commercialize FX201, including the expected timing of human clinical trials; and the market potential 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 process of developing FX201; the fact that the results of preclinical studies may not predict results of subsequent preclinical or clinical studies; the risk that we may incur unexpected expenses or cash requirements; our reliance on third parties to manufacture FX201; 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 allowances to conduct human clinical trials; and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 8, 2018 and subsequent filings with the SEC. 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.

**Corporate Contact:**

Scott Young  
Vice President, Corporate Communications & Investor Relations  
Flexion Therapeutics, Inc.  
T: 781-305-7194  
syoung@flexiontherapeutics.com

Julie Downs  
Manager, Corporate Communications  
Flexion Therapeutics, Inc.  
T: 781-305-7137  
jdowns@flexiontherapeutics.com