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Flexion Therapeutics Initiates Clinical Trial to Evaluate the Safety of Repeat Administration of Zilretta™ (FX006) in Patients with Osteoarthritis of the Knee

BURLINGTON, Mass., Feb. 23, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today reported it has enrolled the first patient in a clinical trial to evaluate the safety of repeat administration of its investigational drug candidate Zilretta (also known as FX006) in patients with osteoarthritis (OA) of the knee. The open-label study is expected to enroll approximately 200 patients at up to 20 clinical sites in the United States. A list of participating trial centers is available on ClinicalTrials.gov.

"This trial is an important part of our ongoing clinical investigation of Zilretta in individuals who are confronting pain from OA of the knee," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "Previous clinical trials evaluating a single injection suggest Zilretta has an acceptable safety profile with side effects similar to placebo and active-control, and we look forward to reporting the results from the repeat administration study when the trial reads out in 2018."

The primary endpoint of the trial is overall safety and general tolerability of repeat administration of Zilretta in patients with symptomatic OA of the knee. Participants will receive an initial intra-articular injection of Zilretta on Day 1 and will be evaluated at Weeks 12, 16, 20 and 24 to determine patient eligibility for a second injection of Zilretta. Participants who are eligible for repeat administration of Zilretta will be followed for a total of 52 weeks after the initial injection, regardless of when the second injection is administered. At specified times throughout the trial, participants will undergo physical examinations, knee assessments and X-rays.

About Osteoarthritis of the Knee
While OA is being diagnosed at increasingly younger ages, prevalence rises after age 45. In 2015, more than 14 million Americans were diagnosed with OA of the knee. OA represents an enormous burden on the U.S. healthcare system, affecting approximately 31 million individuals and accounting for more than $185 billion in annual expenditures. About 13 percent of women and 10 percent of men aged 60 years and older have symptomatic OA of the knee, and rates are likely to increase due to an aging population and growing prevalence of overweight and obese individuals.

Each year, more than five million OA patients in the United States receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection for knee pain.

About Zilretta
Zilretta is being investigated as the first intra-articular, extended-release treatment for patients with OA related knee pain. Zilretta employs proprietary microsphere technology combining triamcinolone acetonide — a commonly administered, short-acting corticosteroid — with a poly lactic-co-glycolic acid (PLGA) matrix. To date, nearly 700 patients have been treated with Zilretta in clinical trials.

About Flexion Therapeutics
Flexion 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. The company's lead product candidate, Zilretta, is being investigated for its potential to provide improved analgesic therapy for the millions of U.S. patients who receive intra-articular injections for OA knee pain annually.

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; the potential therapeutic and other benefits of Zilretta, expected timing and design of clinical trials and availability of data, and expectations regarding the future prevalence and impact of OA, 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 discovering, developing, manufacturing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics; the fact that results of prior clinical trials may not predict results of future trials; our reliance on third parties to manufacture and conduct clinical trials of Zilretta, which could delay or limit its future

development or regulatory approval; our ability to meet anticipated clinical trial enrollment and completion timelines; the fact that we will require additional capital, including to fully commercialize Zilretta or any other product candidates, and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to us; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to Zilretta; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; the risk that the FDA and foreign regulatory authorities may not agree with our interpretation of the data from our clinical trials of Zilretta and may require us to conduct additional clinical trials; Zilretta may not receive regulatory approval or be successfully commercialized, including as a result of the FDA's or other regulatory authorities' decisions regarding labeling and other matters that could affect its availability or commercial potential; 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 most recent Annual Report on Form 10-K 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 Contacts:

Fred Driscoll
Chief Financial Officer
Flexion Therapeutics, Inc.
T: 781-305-7763
fdriscoll@flexiontherapeutics.com

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

Media Contact:

Danielle Lewis
Lazar Partners
T: 212-867-1768
flexionpr@lazarpartners.com

Investor Contact:

David Carey
Lazar Partners
T: 212-867-1768
dcarey@lazarpartners.com