



February 7, 2017

Flexion Therapeutics Announces New Drug Application for Zilretta™ (FX006) Accepted by U.S. Food and Drug Administration

FDA Reviewing Zilretta as Potential New Treatment for Osteoarthritis of the Knee

Assigns PDUFA date of October 6, 2017

BURLINGTON, Mass., Feb. 07, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing the Company's New Drug Application (NDA) for its lead investigational product candidate Zilretta (also known as FX006). Zilretta is being evaluated as a new treatment option for patients with osteoarthritis (OA) of the knee. In accordance with the FDA's standard 10-month review designation, the agency has established a user fee goal date under the Prescription Drug User Fee Act (PDUFA) of October 6, 2017.

"The FDA's acceptance of the NDA for Zilretta is a seminal milestone for Flexion and encouraging news for the many millions of people who are confronting OA of the knee," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "The pain associated with OA of the knee can be debilitating, and we believe that, if approved, Zilretta could serve as an important new treatment option for patients suffering from this progressive condition."

The Zilretta NDA for OA of the knee is supported by previously reported results from a pivotal Phase 3 clinical trial. The randomized, double blind, placebo and active-comparator (immediate-release triamcinolone acetonide (TA)) controlled trial enrolled 484 patients at 37 centers worldwide. Data from the trial showed that Zilretta demonstrated a highly significant ($p < 0.0001$) reduction in average daily pain versus placebo at week 12 (primary endpoint), with durable and clinically meaningful pain relief in patients with moderate to severe OA knee pain. In addition, analyses of a number of OA-specific secondary endpoints such as WOMAC A^[1] (pain), WOMAC B (stiffness) and WOMAC C (function), showed encouraging results favoring Zilretta compared to both placebo and immediate-release TA. The frequency of treatment-related side effects was comparable across all treatment arms in the trial. The most common adverse events for Zilretta with an incidence greater than 2% were arthralgia, headache, joint swelling and back pain. No drug-related serious adverse events were observed and no patients treated with Zilretta were discontinued from the study due to a treatment-related side effect.

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, with rates likely to increase due to the aging of the population and the rate of obesity or overweight individuals in the general population.

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

About Zilretta

Zilretta is being investigated as the first intra-articular, extended-release treatment for patients with knee OA pain. Zilretta employs proprietary microsphere technology combining TA — 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 of the knee. The company's lead product candidate, Zilretta, is being investigated for its potential to provide improved analgesia for the millions of U.S. patients who receive intra-articular injections for OA related 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, potential regulatory approval of

Zilretta 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; 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 regulatory approval and commercial launch dates for Zilretta; 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.

[1] WOMAC (Western Ontario and McMaster Universities Arthritis Index) is a validated, widely used, proprietary set of standardized questionnaires used by health professionals to evaluate the condition of patients with osteoarthritis of the knee and hip, including pain, stiffness and physical functioning of the joints.

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