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Flexion Therapeutics to Present Data on Zilretta™ (FX006) at PAINWeek 2017

Analysis shows statistically significant reduction in the use of rescue medications following treatment with Zilretta

BURLINGTON, Mass., Sept. 07, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today will present results from an analysis that found patients treated in clinical trials of Zilretta™ (FX006), its lead candidate for the treatment of osteoarthritis (OA) knee pain, had a statistically significantly lower use of analgesic rescue medications following treatment compared to placebo. The data will be presented in a poster session (abstract #92) at PAINWeek 2017, the largest U.S. pain conference for frontline clinicians.

A post hoc, pooled analysis of three Phase 2/3 double-blind, randomized, placebo-controlled clinical trials was conducted with 586 patients suffering from OA of the knee. Patients received a single, intra-articular (IA) injection of Zilretta (32 mgs) or saline-placebo, and average daily pain (ADP) intensity was assessed for a period of at least 12 weeks. Trial participants received a rescue medication (acetaminophen/paracetamol 500 mg tablets) at the beginning of the study. The patients' consumption of the rescue medication was monitored through a daily diary reporting system, and pill counts were confirmed at the clinical sites.

Rescue medications are commonly provided to patients in clinical trials investigating analgesic therapies. Patients can use rescue medicines to manage pain on an as-needed basis during the trial, and their utilization can provide investigators with important information about the overall analgesic effect of the therapy being studied.

The analysis showed that the use of rescue medication was statistically significantly lower ($p<0.05$) with Zilretta compared to saline-placebo at each of Weeks 1—12. At Week 12, the mean number of daily rescue medication tablets taken was 0.86 for Zilretta compared with 1.23 for saline-placebo, resulting in a least-square-mean (LSM) difference of -0.37. These results support the analgesic efficacy of Zilretta through 12 weeks post-IA injection. The incidence of adverse and serious adverse events were similar across the Zilretta and saline-placebo groups (51.9% vs 49.2%, and 3.1% vs 1.1%, respectively). No drug-related serious adverse events were observed in these trials and adverse events have typically been localized, mild and comparable to those observed with saline-placebo.

"In clinical trials, Zilretta has demonstrated clinically meaningful pain relief for patients with OA of the knee for at least 12 weeks, and the reduced utilization of rescue medicines observed in this analysis serves as another important indicator of the robustness of Zilretta's analgesic profile," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "We believe that, pending regulatory approval, Zilretta has the potential to bring meaningful pain relief to millions of Americans who make up this large and growing patient population."

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 2015, more than 14 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. OA prevalence is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, more than five million OA patients in the U.S. 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 matrix. In February 2017, the FDA accepted the company's New Drug Application for Zilretta in OA of the knee. Under the Prescription Drug User Fee Act, the agency has established a user fee goal date of October 6, 2017.

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.

Forward-Looking Statements
Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating the potential therapeutic and other benefits of Zilretta, potential regulatory approval of Zilretta, and expectations regarding the prevalence 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 past clinical trials may not be predictive of subsequent 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; 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; Zilretta may not 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; 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.

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