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Flexion Therapeutics to Present Data on Zilretta™ (FX006) at the American Diabetes Association's 77th Scientific Sessions

Full findings from Phase 2 study in patients with knee osteoarthritis and Type 2 diabetes show Zilretta avoids the significant rise in blood glucose seen with an immediate-release corticosteroid

BURLINGTON, Mass., June 10, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) will present the full results from a Phase 2 study which found its lead investigational product candidate Zilretta (also known as FX006) was associated with reduced blood glucose (BG) elevation compared with immediate release triamcinolone acetonide in crystalline suspension (TAcs) in patients with Type 2 diabetes and knee osteoarthritis (OA). Flexion reported the top-line results from this study in November 2016, and the full analysis will be presented in a poster session (abstract #1091-P) on June 11 at 12:00 p.m. PDT during the American Diabetes Association's 77th Scientific Sessions.

Approximately 20 percent of patients with osteoarthritis of the knee also have Type 2 diabetes.[1] While intra-articular (IA) injections of corticosteroids are commonly used to manage pain and inflammation associated with knee OA, the rapid systemic absorption of these medications results in elevated BG levels. Changes in BG concentrations can pose important clinical challenges in diabetic patients.[2]

The objective of the double-blind, randomized, parallel-group study was to examine BG concentrations following a single injection of 40 mg Zilretta or 40 mg TAcs. Thirty-three patients with Type 2 diabetes and knee OA who were actively being treated with one or two oral diabetes medications were enrolled in the study and randomized 1:1. Blood glucose levels were monitored continuously for one week prior and for two weeks following injection. The primary endpoint was change in average BG concentration from the 3 day pre-treatment baseline period to the 3 day post-treatment period for Zilretta versus TAcs.

The primary endpoint of the study was met, with patients experiencing a significantly lower change in average BG concentration following administration of Zilretta (14.7 mg/dL) compared with TAcs (33.9 mg/dL). In addition:

- Mean average BG levels increased significantly from the pre-treatment baseline period to the post-treatment period in patients receiving TAcs but did not change significantly in patients receiving Zilretta,
- The percent of time that average BG levels were within the American Diabetes Association's target range was greater for Zilretta compared with TAcs, a clinically important indication of improved glycemic control,
- During the post-treatment period, significantly less glycemic variability was observed following IA injection of Zilretta compared with TAcs.

The poster authors attribute these results to the low systemic exposure to triamcinolone acetonide from the extended-release formulation of Zilretta compared with immediate release TAcs.

Incidences of adverse events (AEs) in the study were low and similar between the Zilretta and TAcs treatment arms. All AEs were Grade 1 (Zilretta: 0/18, 0%; TAcs: 2/15, 13.3%) or Grade 2 (Zilretta: 2/18, 11.1%; TAcs: 0/15, 0%). No patients treated with Zilretta experienced an index-knee or injection-related AE.

"Treating OA-related knee pain in patients with Type 2 diabetes can be complicated by the hyperglycemia which commonly occurs following the use of immediate-release corticosteroids. The findings from this study suggest that Zilretta may significantly reduce those blood glucose spikes by delivering a slower and extended release of corticosteroid in the knee joint and minimizing systemic exposure," said Michael Clayman, MD, President and CEO of Flexion. "We believe that Zilretta, if approved, has the potential to provide extended pain relief while supporting these patients in their efforts to maintain consistent blood glucose levels."

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 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. In February 2017, the U.S. Food and Drug Administration (FDA) accepted Flexion's New Drug Application (NDA) for Zilretta in OA of the knee. Under the Prescription Drug User Fee Act (PDUFA), the agency has established a user fee goal date of October 6, 2017.

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 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 benefits of Zilretta; and expected increases in the incidence of OA of the knee, 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; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; the risk that 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] IMS PharMetrics Plus Database. 2014 — 2015.

[2] Habib GS. Clin Rheumatol 2009;28:749—56.

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