April 28, 2017

Flexion Therapeutics Highlights Two Clinical Data Presentations at the Osteoarthritis Research Society International 2017 World Congress

- *In an analysis of pooled Phase 2/3 data, Zilretta™ (FX006) demonstrated clinically meaningful pain relief and functional improvement in patients with osteoarthritis*
- *A separate Phase 2 study shows prolonged synovial localization and diminished systemic exposure of corticosteroid with Zilretta compared with traditional steroid injections*

BURLINGTON, Mass., April 28, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced results from two new analyses of the company's lead investigational drug candidate, Zilretta (also known as FX006), for the treatment of osteoarthritis (OA) related knee pain. The clinical findings will be presented at the Osteoarthritis Research Society International (OARSI) 2017 World Congress, taking place April 27-30 in Las Vegas.

Clinical Data Presentations:

Title: An Intra-articular, Extended Release Formulation of Triamcinolone (FX006) Affords Clinically Relevant Improvements in Pain and Function of Knee Osteoarthritis: Post-Hoc Pooled Analysis of 3 Randomized Controlled Trials
Poster: 715
Date and Time: Poster Session 1: 4/28, 12:00 PM — 12:30 PM; Poster Session 2: 4/28, 4:00 PM — 4:30 PM; Poster Session 3: 4/29, 3:30 PM — 4:15 PM
The authors examined improvements in pain and function using pooled data from three Phase 2 and 3 randomized trials, which individually demonstrated statistically significant reductions in weekly mean scores of Average Daily Pain (ADP). Utilizing data from 798 patients, the researchers sought to more fully characterize the clinical relevance of Zilretta using several established assessments including:

- Outcome Measures in Rheumatology (OMERACT)-OARSI strict responder definition (≥50% and absolute change of 20 in either WOMAC-A-Pain or WOMAC-C-Function[1]),
- Proportions of patients reporting ≥30% (moderate) and ≥50% (substantial) improvements in WOMAC-A-Pain,
- Standardized effect size calculations for ADP-intensity and WOMAC-A-Pain scores.

Zilretta was associated with clinically significant improvements in these WOMAC-based assessments of pain and function compared with saline-placebo (through Week 12) and triamcinolone acetonide crystalline suspension (TAcs) (through Weeks 8 and/or 12). The poster also highlights an analysis demonstrating that Zilretta may represent the first intra-articular treatment to achieve the WOMAC-based minimum clinically important improvement (MCII) criteria, established by the American Academy of Orthopaedic Surgeons (AAOS). The MCII criteria reflect the smallest clinical change that is important to patients, recognizing that there are some treatment-related statistically significant improvements that are too small to be relevant.[2]

Title: Synovial and Systemic Pharmacokinetics of Triamcinolone Acetonide Following Intra-Articular Injection of an Extended Release Formulation (FX006) or Standard Crystalline Suspension in Patients with Knee Osteoarthritis
Poster: 712
Date and Time: Poster Session 1: 4/28, 12:00 PM — 12:30 PM; Poster Session 2: 4/28, 4:00 PM — 4:30 PM; Poster Session 3: 4/29, 3:30 PM — 4:15 PM

This Phase 2, open-label study assessed the synovial fluid and systemic concentrations of triamcinolone acetonide (TA) following a single intra-articular (IA) injection of Zilretta. Eighty-one patients received a single IA injection of Zilretta or the standard crystalline suspension of TA (TAcs). A single IA injection of Zilretta resulted in a sustained presence in the joint and slow elimination into the systemic circulation in patients with knee OA. The authors concluded that microsphere-based delivery of TA via IA administration prolongs residency of TA and diminishes both peak plasma levels of and total systemic exposure to TA.

Commenting on the two presentations, Michael Clayman, M.D., President and Chief Executive Officer of Flexion said, "The data presented at OARSI confirm our belief in Zilretta's potential to provide extended, clinically relevant pain relief and functional improvement in patients with knee OA when evaluated across several important measures. Furthermore, the findings demonstrate Zilretta's ability to persist locally in the joint with reduced total systemic exposure. This may be particularly important for patients with Type 2 diabetes, who are susceptible to elevations in blood glucose levels following immediate-release steroid injections." Dr. Clayman added, "We believe that, if approved, Zilretta holds tremendous potential for patients suffering from OA, a progressive and debilitating condition."

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. To date, more than 800 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 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 interpretation of the data and results from our Zilretta clinical trials; the potential regulatory approval of Zilretta and potential benefits of Zilretta in treating patients, if approved; and predicted rates of incidence of knee 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; 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; 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.

[2] American Academy of Orthopaedic Surgeons. Treatment of Osteoarthritis of the Knee: Evidence-Based Guideline 2nd Edition. May 18, 2013. Available at http://www.aaos.org/research/guidelines/TreatmentofOsteoarthritisoftheKneeGuideline.pdf. Accessed April 24, 2017.

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