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Flexion Therapeutics Enrolls First Patient in Phase 2 Pharmacokinetics and Safety Study of ZILRETTA™ (triamcinolone acetonide extended-release injectable suspension) in Bilateral Osteoarthritis of the Knee

BURLINGTON, Mass., Dec. 07, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) announced today the enrollment of the first patient in a clinical trial to evaluate the pharmacokinetics (PK) and safety of concurrent injections of ZILRETTA (triamcinolone acetonide extended-release injectable suspension) in patients with bilateral osteoarthritis (OA) of the knee. The randomized, open-label, Phase 2 study is expected to enroll approximately 24 patients.

The safety and tolerability of a single injection of ZILRETTA has been established through multiple Phase 2 and Phase 3 clinical trials focused on administration in one knee. ZILRETTA received approval from the U.S. Food and Drug Administration on October 6, 2017 for the management of OA knee pain and the company initiated the full commercial launch on November 20, 2017.

"We know there are many patients who suffer from bilateral knee OA pain, yet physicians are often reluctant to administer an immediate-release steroid into both knees concurrently due to concerns about systemic exposure," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "The data from this study are expected to provide insight into ZILRETTA's potential to further demonstrate lower plasma concentrations from two injections compared with traditional immediate-release steroids."

The study will compare plasma PK profiles after concurrent injections of ZILRETTA versus immediate-release triamcinolone acetonide in crystalline suspension (TAcs). Patients will be randomized and treated with bilateral injections of either ZILRETTA (total dose of 64 mg) or TAcs (total dose of 80 mg). Each patient will be evaluated for six weeks following injection. Flexion expects to report top-line results of the study in the first half of 2018.

Indications and Select Important Safety Information for ZILRETTA™ (triamcinolone acetonide extended release injectable suspension)

Indication: ZILRETTA (triamcinolone acetonide extended-release injectable suspension) is indicated as an intra-articular injection for the management of osteoarthritis pain of the knee. It is not intended for repeat administration.

Contraindication: ZILRETTA is contraindicated in patients who are hypersensitive to triamcinolone acetonide, corticosteroids or any components of the product.

Warnings and Precautions:

- **Intra-articular Use Only:** ZILRETTA has not been evaluated and should not be administered by epidural, intrathecal, intravenous, intraocular, intramuscular, intradermal, or subcutaneous routes. ZILRETTA should not be considered safe for epidural or intrathecal administration.
- **Serious Neurologic Adverse Reactions with Epidural and Intrathecal Administration:** Serious neurologic events have been reported following epidural or intrathecal corticosteroid administration. Corticosteroids are not approved for this use.
- **Hypersensitivity reactions:** Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care if an anaphylactic reaction occurs.
- **Joint infection and damage:** A marked increase in joint pain, joint swelling, restricted motion, fever and malaise may suggest septic arthritis. If this occurs, conduct appropriate evaluation and if confirmed, institute appropriate antimicrobial treatment.

Adverse Reactions: The most commonly reported adverse reactions (incidence ≥1%) in clinical studies included sinusitis, cough and contusions.

Please see ZilrettaLabel.com for full Prescribing Information.

About ZILRETTA
ZILRETTA is the first and only FDA-approved extended-release, intra-articular therapy for patients confronting osteoarthritis-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 provide extended pain relief over 12 weeks.

About OA of the Knee
OA, also known as degenerative joint disease, affects more than 30 million Americans and accounts for more than $185 billion in annual expenditures. In 2016, more than 15 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. The prevalence of OA is expected to continue to increase as a result of aging, obesity and sports injuries. Each year, more than 15 million Americans are treated for OA-related knee pain, and approximately five million OA patients receive either an immediate-release corticosteroid or hyaluronic acid intra-articular injection to manage their knee pain.

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 and one of the *Top Places to Work* in Massachusetts by *The Boston Globe*.

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 expected size, scope and results of Flexion's trial to evaluate the PK and safety of concurrent injections of ZILRETTA in patients with bilateral OA of the knee; expected increases in the prevalence of OA; and the potential therapeutic and other benefits of ZILRETTA for patients with bilateral 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 designing and conducting clinical trials; 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; 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; 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 Quarterly Report on Form 10-Q 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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