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Flexion Therapeutics Enrolls First Patient in Study Evaluating the Pharmacokinetics and Safety of ZILRETTA™ (triamcinolone acetonide extended-release injectable suspension) in Osteoarthritis of the Shoulder and Hip

BURLINGTON, Mass., Dec. 18, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) announced today that it has enrolled the first patient in a clinical trial to evaluate the pharmacokinetics and safety of ZILRETTA™ (triamcinolone acetonide extended-release injectable suspension) in patients with osteoarthritis (OA) of the shoulder or hip. Known as the "SHIP" study, the randomized, open-label, Phase 2 trial is expected to recruit approximately 48 patients in total, including 24 patients with OA of the shoulder and 24 patients with OA of the hip.

"While ZILRETTA has been approved for use in the knee, this is the first trial to investigate ZILRETTA in other large joints," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "We are looking forward to the readout from this study, and the findings will inform our discussions with the U.S. Food and Drug Administration regarding a pathway for potential label expansion of ZILRETTA."

The SHIP study will compare ZILRETTA's pharmacokinetic profile to immediate-release triamcinolone acetonide in crystalline suspension (TAcs) and will also assess the safety and general tolerability of ZILRETTA in OA of the shoulder and OA of the hip. Patients will be randomized and treated with a single intra-articular injection of either ZILRETTA (32 mg) or TAcs (40 mg). Each patient will be evaluated for 12 weeks following injection. Flexion expects to report top-line results of the study in the second 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 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. ZILRETTA received approval from the U.S. Food and Drug Administration on October 6, 2017 and the company initiated the full commercial launch on November 20, 2017.

About Osteoarthritis (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 and scope of, and availability of data from, Flexion's SHIP study to evaluate the safety and pharmacokinetics of ZILRETTA in patients with OA of the shoulder or hip; potential future discussions with the FDA; opportunities to expand the ZILRETTA label; expected increases in the prevalence of OA; and the potential therapeutic and other benefits of ZILRETTA, 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, risks associated with developing and obtaining regulatory approval for ZILRETTA in additional indications; 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2017 filed with the SEC on November 6, 2017 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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