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Flexion Therapeutics Announces Full Commercial Launch and Nationwide Availability of ZILRETTA™ (triamcinolone acetonide extended-release injectable suspension)

- Recently approved, non-opioid therapy now available for the management of osteoarthritis knee pain
- Launch of ZILRETTA commences with full complement of field sales personnel deployed across the U.S.

BURLINGTON, Mass., Nov. 20, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced the full commercial launch of ZILRETTA™ (triamcinolone acetonide extended-release injectable suspension), the company's new therapy for the management of pain associated with osteoarthritis (OA) of the knee. On October 6, 2017, ZILRETTA was approved by the U.S. Food and Drug Administration, and the product has been available on a limited basis since October 23. Flexion has hired and trained more than 100 field sales representatives, known as Musculoskeletal Business Managers, who are now deployed across the country.

"We have assembled a remarkable team of Musculoskeletal Business Managers, and last week they concluded their training at the ZILRETTA national launch meeting," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "We have already begun the process of informing and educating physicians about the important role ZILRETTA can play in the management of OA knee pain. With its extended-release microsphere formulation, we believe ZILRETTA holds the potential to disrupt the current treatment paradigm, and we are thrilled that it is now broadly available for the millions of Americans confronting this relentless disease."

OA is a progressive and incurable condition and the most common form of arthritis. Its effects may range from intermittent discomfort to the loss of function and severe chronic pain associated with irreversible structural damage. ZILRETTA is the first and only extended-release, intra-articular injection for OA knee pain. It is a non-opioid medicine that employs Flexion's proprietary microsphere technology to provide proven pain relief over 12 weeks.

For more information about ZILRETTA, visit www.ZILRETTA.com or call 1-844-FLEXION.

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 www.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 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 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 best places to work by both the Boston Globe and the Boston Business Journal.

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; our plans to commercialize Zilretta and its market potential; expected increases in the rate of individuals with OA of the knee; 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 the process of commercializing Zilretta, including the extent to which Zilretta is adopted by physicians and patients and is reimbursed by third party payors; the fact that results of past clinical trials may not be predictive of subsequent trials; our reliance on third parties to manufacture and distribute 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; regulatory developments and safety issues, including difficulties in maintaining regulatory approvals to market Zilretta; 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. 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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