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Flexion Therapeutics to Present Data on ZILRETTA® (triamcinolone acetonide extended-release injectable suspension) at the Academy of Managed Care Pharmacy Annual Meeting 2018

- | Post-hoc analysis indicated ZILRETTA provided significant improvements in pain and function in patients with unilateral knee osteoarthritis
- | Abstract receives silver ribbon designation

BURLINGTON, Mass., April 24, 2018 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) will present positive clinical data from a post-hoc analysis of patients with unilateral knee osteoarthritis (OA) pain from its Phase 3 trial. The results indicated that patients with unilateral knee OA pain treated with ZILRETTA (triamcinolone acetonide extended-release injectable suspension) experienced significant and sustained improvements in pain, function, and knee-related quality of life metrics compared with immediate-release triamcinolone acetonide crystalline suspension (TAcS). The data will be presented in a poster session, entitled "Efficacy of triamcinolone acetonide extended-release injectable suspension in patients with unilateral knee osteoarthritis," at the Academy of Managed Care Pharmacy (AMCP) Annual Meeting 2018, taking place April 23 — 26 in Boston.

"We are encouraged by these data as they further bolster our confidence in ZILRETTA's ability to deliver meaningful relief to those suffering from knee OA pain," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "This analysis enhances our understanding of ZILRETTA's clinical profile within a specific subpopulation and provides deeper insight into the benefit it provides."

The post-hoc analysis evaluated the efficacy of ZILRETTA in a subgroup of patients with unilateral OA pain of the knee. Of the 484 patients enrolled in the Phase 3 trial, the results of which were recently published, ([Journal of Bone and Joint Surgery](#), Vol 100 (8) pp 666 — 677), 170 (35.1%) had unilateral OA and received either a single IA injection of ZILRETTA (n=51), TAcS 40mg (n=59) or saline-placebo (n=60). ADP-intensity data were collected daily for up to 24 weeks post-injection. Western Ontario and McMaster Universities OA Index (WOMAC)-A (pain), -B (stiffness), and -C (function) scores, collected at baseline and every four weeks up to 24 weeks post-injection, and Knee Injury and OA Outcome Score Quality of Life (KOOS-QOL) subscale scores, collected at baseline and Weeks 4/8/12/24, were also assessed.

Results indicated that ZILRETTA provided significant improvement in ADP-intensity at Week 12 compared with placebo (P<0.0001) and TAcS (P<0.01). ZILRETTA treated patients also appeared to have sustained response over placebo and TAcS with respect to improvements in the WOMAC pain, stiffness, and physical function, and KOOS-QOL subscale scores at Weeks 4, 8, and 12 (P<0.05 for all instruments).

Additionally, independent AMCP reviewers awarded the abstract a silver ribbon based on assessment across five categories: relevance, originality, quality, bias and clarity. Only 20 percent of abstracts submitted for the 2018 meeting were awarded ribbons this year.

Indication 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.

- 1 **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.
- 1 **Hypersensitivity reactions:** Serious reactions have been reported with triamcinolone acetonide injection. Institute appropriate care if an anaphylactic reaction occurs.
- 1 **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 $\geq 1\%$) 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 biopharmaceutical 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

This release contains forward-looking statements that are based on the current expectations and beliefs of Flexion. Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating to the future of Flexion; ZILRETTA's 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 commercializing new pharmaceutical products; 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 Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 8, 2018 and subsequent filings with the SEC. The forward-looking statements in this press release speak only as of the date of this 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.

References

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.

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