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Flexion to Present New Cost-Effectiveness Data on Zilretta™ (FX006) at the International Society for Pharmacoeconomics and Outcomes Research 22nd International Meeting

Findings suggest Zilretta could potentially provide a cost-effective treatment option for patients with osteoarthritis of the knee

BURLINGTON, Mass., May 22, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced the findings from a new health economics analysis of Zilretta (also known as FX006), the company's lead investigational candidate for the treatment of knee osteoarthritis (OA) pain. The study, which utilized established health economic metrics, demonstrated that Zilretta has the potential to be a cost-effective therapy in this indication. The findings will be presented at the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 22nd International Meeting, taking place May 20-24 in Boston.

The study was designed to estimate the impact of Zilretta on overall quality of life in patients with knee OA and to evaluate its cost-effectiveness compared with other therapeutic interventions including conventional care (over-the-counter non-steroidal anti-inflammatory drugs (NSAIDs), acetaminophen, physical therapy and assistive devices)[1], diclofenac (a prescription NSAID)[2,3,4] and hyaluronic acid (HA)[1] injections. With respect to Zilretta, the study utilized previously collected WOMAC[5] scores from 324 patients enrolled in three separate Phase 2 and Phase 3 randomized clinical trials of Zilretta in patients with knee OA pain.

Using an established algorithm, the authors were able to convert the WOMAC assessments to Health Utilities Index Mark 3 (HUI-3) scores. The cost-effectiveness analyses were based on a Quality Adjusted Life Year (QALY) gain, which was calculated from the improvement in HUI-3 scores over six months.[6]

For the analysis, Zilretta was assigned a hypothetical cost of $500 per treatment and the comparator treatments were assigned their respective 2016 wholesale acquisition costs. Key study findings include:

- Zilretta produced an average QALY gain from baseline of 0.189 per six months, which suggests a greater improvement in quality of life compared with the average values for conventional care (0.030), diclofenac (0.078) and HA injections (0.109).
- Zilretta yielded a cost per QALY estimate of $3,201, compared with cost per QALY estimates for conventional care ($10,717), diclofenac ($2,708) and an average HA treatment course ($13,389).

"OA is a chronic, debilitating condition accounting for more than $185 billion[7] in healthcare expenditures annually. We conducted this study to determine whether Zilretta, if approved for commercialization, may have the potential to help ease the significant burden that OA places on the healthcare system," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "While the potential clinical benefit of an extended-release treatment for knee OA pain is supported by our clinical trial results, these are the first data to show the potential pharmacoeconomic value of Zilretta as a cost-effective treatment option for these patients."

The poster (PMS28) is scheduled to be displayed at ISPOR on Monday, May 22 from 3:45 — 7:45 p.m. ET. The abstract and the poster can be found on the ISPOR website: https://www.ispor.org/ScientificPresentationsDatabase/Presentation/72176?pdfid=49648.

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 potential benefits of Zilretta and cost-effectiveness compared to other treatments, if approved; our interpretation of the data and results from the health economics analysis; 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 discovering, developing, manufacturing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics; the fact that the assumptions used in the health economics analysis may be different than actual circumstances if and when Zilretta is commercialized; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; the risk that 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.

References

[1] Rosen J, Sancheti P, Fierlinger A, Niazi F, Johal H, Bedi A. Cost-Effectiveness of Different Forms of Intra-Articular Injections for the Treatment of Osteoarthritis of the Knee. Adv Ther. 2016;33(6):998-1011.

[2] Latimer N, Lord J, Grant RL, et al. Cost effectiveness of COX 2 selective inhibitors and traditional NSAIDs alone or in combination with a proton pump inhibitor for people with osteoarthritis. BMJ. 2009;339:b2538.

[3] Brereton N, Winn B, Akehurst R. The cost-effectiveness of celecoxib vs diclofenac in the treatment of osteoarthritis in the UK; an update to the NICE model using data from the CONDOR trial. J Med Econ. 2012;15(3):465-72.

[4] National Collaborating Centre for Chronic Conditions. Osteoarthritis: national clinical guideline for care and management in adults. London: Royal College of Physicians, 2008.

[5] 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

[6] Glossary. National Institute for Health and Care Excellence. https://www.nice.org.uk/glossary?letter=q. Accessed April 6, 2017

[7] Kotlarz, H., Gunnarsson, C.L., Fang, H., & Rizzo, J.A. (2009). Insurer and out-of-pocket costs of osteoarthritis in the US: Evidence from national survey data. Arthritis & Rheumatology. 60(12), 3546 — 3553.

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