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Flexion Therapeutics Announces Issuance of Two New Patents Further Strengthening Intellectual Property Protection (IP) for Zilretta™ (FX006)

New Patents Cover Method of Use and Method of Manufacturing

BURLINGTON, Mass., April 04, 2017 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced the U.S. Patent and Trademark Office has issued two new patents covering the company's lead investigational product candidate Zilretta™ (FX006). The new patents further strengthen the existing patent estate surrounding Zilretta. The patents cover the injectable formulation comprised of controlled or sustained-release microparticles that contain triamcinolone acetonide in a poly lactic-co-glycolic acid co-polymer (PLGA) matrix.

The first new patent, U.S. Patent No. 9,555,048, is entitled "Corticosteroids for the Treatment of Joint Pain" and includes claims directed to treatment of pain or inflammation in patients. The claims also include treatment of a variety of indications associated with pain and inflammation. The second new patent, U.S. patent, U.S. Patent No. 9,555,047, is entitled "Corticosteroids for the Treatment of Joint Pain" and includes claims directed to methods of manufacturing injectable extended-release microparticles that combine triamcinolone acetonide and PLGA.

"The issuance of these patents bolsters our strong intellectual property position," said Michael Clayman, M.D., President and Chief Executive Officer of Flexion. "We have great confidence in the strength of our IP, and these new patents provide additional protection for our lead product candidate."

Zilretta's composition of matter, method of use and method of manufacturing patents provide protection into 2031.

About Zilretta™
Zilretta is being investigated as the first intra-articular, extended-release treatment for patients with osteoarthritis (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, Flexion announced that the U.S. Food and Drug Administration (FDA) accepted the New Drug Application 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, nearly 700 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 and the strength of Flexion's patents related to 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 risk that we may not be able to maintain and enforce our intellectual property, including the two newly-issued patents related to Zilretta; 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.

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