April 30, 2014

Flexion Therapeutics Initiates a Phase 2b Confirmatory Dose-Ranging Trial With Lead Compound FX006

Multi-Center Trial Will Enroll Approximately 300 Patients in the U.S. for the Treatment of Pain Associated With Osteoarthritis (OA) of the Knee

BURLINGTON, Mass., April 30, 2014 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) announced today that the first patient has been dosed in a confirmatory Phase 2b clinical trial designed to further evaluate the safety, tolerability and efficacy of certain doses of FX006 as a treatment for relieving pain associated with OA of the knee. FX006 is Flexion's novel, non-opioid, sustained-release, intra-articular (IA) formulation of triamcinolone acetonide (TCA). It is designed to provide prolonged pain relief for the treatment of mild to moderate OA of the knee, while avoiding untoward systemic effects associated with immediate release steroids.

Michael Clayman, M.D., Flexion Therapeutics President and CEO, said, "We believe that the superior performance of FX006 in a completed Phase 2b trial against active comparator -reported at the 2013 American College of Rheumatology Annual Scientific Meeting - illustrates the potential of this product candidate to make a meaningful difference for the many patients who suffer the often debilitating pain of osteoarthritis of the knee."

Dr. Clayman continued, "Our newly initiated Phase 2b confirmatory trial is powered to provide pivotal data for FX006 compared to placebo. We anticipate receiving topline data from this trial in the first half of 2015 and, if positive, these data would set the stage for Phase 3 development next year."

In the newly initiated Phase 2b confirmatory study, approximately 300 patients will be randomized and treated with a single injection of either 20 mg or 40 mg of FX006 or placebo and will be evaluated for 20 weeks. The primary outcome measure is the weekly mean of the average daily pain intensity scores as assessed using an 11-point numerical rating scale. Secondary endpoints include Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC®), patient global impression of change, clinical global impression of change and responder status.

Flexion Therapeutics is concurrently conducting a study of FX006 synovial fluid pharmacokinetics in patients with OA to better characterize local exposure and assist in setting the interval for repeat dosing. Topline data from that trial are expected in the second quarter of 2014.

About Flexion Therapeutics

Flexion is a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel pain therapies. The company is currently advancing a portfolio of injectable drug candidates that have the potential to provide better and more persistent analgesia compared with existing therapy. The company's lead program, FX006, is an intra-articular sustained release steroid in development for patients with moderate to severe OA pain. The company also has two additional product candidates, FX007, a locally administered TrkA receptor antagonist for post-operative pain, and FX005, an intra-articular, sustained-release p38 MAP kinase inhibitor for end-stage OA patients.

Forward-Looking Statements

Statements in this press release regarding matters that are not historical facts, including statements relating to the future of Flexion, its ongoing development of its product candidates, expected size and design of clinical trials, and anticipated clinical and other milestones (including the timing of such milestones), 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 and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics, the fact that Flexion relies on third parties to manufacture and conduct the clinical trials of its product candidates, which could delay or limit their future development or regulatory approval, the fact that Flexion will require additional capital, including prior to completing Phase 3 development of, filing for regulatory approval for, or commercializing, FX006 or any of its other product candidates and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to it, and other risks and

uncertainties described in Flexion's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in Flexion's Annual Report on Form 10-K for the year ended December 31, 2013. You are encouraged to read Flexion's filings with the SEC, available at www.sec.gov, for a discussion of these and other risks and uncertainties. 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.

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