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# Flexion Therapeutics to Start FX006 Phase 3 Pivotal Trial in 2014; Following FDA Meeting, Development Plan Advanced by One Year

*- Company to Host Conference Call Tomorrow, September 4, 2014 at 8:30 a.m. EST, During Which Management Will Discuss Updated Timing and Plans*

BURLINGTON, Mass., Sept. 3, 2014 (GLOBE NEWSWIRE) -- Based on a recent meeting with the U.S. Food and Drug Administration (FDA) to review the clinical development program for Flexion's lead drug candidate FX006, Flexion Therapeutics, Inc. (Nasdaq:FLXN), a clinical-stage specialty pharmaceutical company focused on the development and commercialization of novel pain therapies, today announced plans to initiate a pivotal Phase 3 clinical trial for FX006 in late 2014. FX006 is a steroid, triamcinolone acetonide (TCA), formulated for sustained-release, which is delivered by intra-articular ("IA" or "in the joint") injection in patients with osteoarthritis (OA) pain of the knee. The company believes the new timing will allow Phase 3 development to be completed by the end of 2015, a year earlier than previously planned.

In a recent meeting with the FDA, the agency communicated that it will consider the company's ongoing placebo-controlled Phase 2b confirmatory trial of FX006 as one of two key efficacy trials required for registration of a single-dose administration for FX006. In addition, the FDA provided guidance that a second placebo-controlled pivotal trial would be sufficient to support the filing of a new drug application (NDA). The FDA also communicated that the approval of FX006 for single-dose administration will not require data from a repeat-dose safety trial, which enabled the most significant change from the company's prior clinical development plan. As a result, the company has decided to advance the initiation of the Phase 3 trial of FX006 to late 2014, to remove the repeat-dose safety trial from its pre-approval plans, and to develop and file the repeat-dose safety data in a supplemental new drug application (sNDA) after approval and launch of FX006 for single-dose administration.

"We view the recent guidance from the FDA and our new clinical development plan for FX006 as transformative for our company. This plan reduces both technical and regulatory risk and allows us to accelerate our commercial launch by a year," said Michael D. Clayman, M.D., President and CEO of Flexion. "In addition, our plan to evaluate FX006 compared to immediate-release TCA is intended to complement the clinically meaningful and statistically significant data demonstrating superior pain relief of FX006 observed in our initial Phase 2b dose-ranging trial and to support a commercial advantage in the launch of the drug."

The Phase 3 trial will be an international, multi-center, randomized, blinded, single-dose study in 462 patients with OA of the knee. It will have three arms that include a 40 mg dose of FX006, placebo and a 40 mg dose of immediate-release TCA. The primary objective of the trial will be to provide the second pivotal efficacy dataset against placebo at 12 weeks for an NDA submission. In addition, the trial will provide a key comparative dataset against the current standard of care, immediate-release TCA.

**Conference Call**

Flexion's management team will host a conference call and webcast at 8:30 a.m. EST tomorrow, September 4, 2014, to provide an update on the new clinical development plan for FX006. The dial-in number for the conference call is toll-free (855) 770-0022 for domestic participants and (908) 982-4677 for international participants. A live webcast of the conference call can also be accessed through the "Investors" tab on the Flexion Therapeutics website at www.flexiontherapeutics.com. A webcast replay will be available online after the call.

**About FX006**

FX006 is a first-in-class injectable, sustained-release, IA steroid in development for patients with moderate to severe OA pain. FX006 was specifically designed to address the limitations of current IA therapies by providing long-lasting, local analgesia while avoiding systemic side effects. To date, over 300 patients have been exposed to FX006. In a completed Phase 2b dose-ranging clinical trial, FX006 demonstrated clinically meaningful and significantly better pain relief compared to the current injectable standard of care, TCA. In two Phase 2a synovial fluid PK studies, a single IA injection of FX006 demonstrated therapeutic concentrations of drug in joint fluid for at least 12 weeks. FX006 is currently being studied in a pivotal Phase 2b confirmatory clinical trial to further identify a safe and well-tolerated dose of FX006 that demonstrates superior pain relief to placebo.

**About Osteoarthritis of the Knee**

OA, also referred to as degenerative joint disease, is the most common joint disease in the United States, affecting 27 million Americans, with numbers expected to grow as a result of aging, obesity and sports injuries. With the U.S. population between the ages of 45 and 64 having grown 31.5 percent from 2000 through 2010 and accounting for 26.4 percent of the total population, changing demographics - as well as increasing obesity among this population - will likely contribute to a growing number of OA patients. In addition, knee injury is common, particularly amongst young athletes, and increases the risk of developing OA by more than fivefold. One in two Americans is expected to develop symptomatic knee OA, the most common form of OA, during their lifetime, according to the U.S. Centers for Disease Control and Prevention (CDC). Recent research estimates that the average age of physician-diagnosed knee OA has fallen by 16 years, from age 72 in the 1990s to age 56 in the 2010s. According to the same research, Americans between the ages of 35 and 84 in the early 2010s will account for approximately 6.5 million new cases of knee OA over the next decade.

**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, the initiation of a Phase 3 trial for FX006, the potential timing for completing Phase 3 development for FX006, the anticipated requirements for filing an NDA and obtaining regulatory approval for FX006, initiation of a repeat-dose safety trial 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, whether the company's patents will be held valid and enforceable, 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 possibility that future trial results may not be consistent with past results, 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, the fact that the FDA may change its guidance at any time or impose additional requirements, 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 and subsequent filings with the SEC. 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 Flexion undertakes no obligation to update or revise any of the statements.

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