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Flexion Therapeutics Announces Positive Topline Results From Phase 2a Pharmacokinetic Trial With Lead Compound FX006

- Following intra-articular injection, sustained release of triamcinolone acetonide (TCA) from FX006 maintained therapeutic concentration levels in knee joints of patients through 12 weeks -

- Pharmacokinetic (PK) data support previously completed Phase 2b dose-ranging efficacy trial that demonstrated superior magnitude and duration of pain relief over 12 weeks compared to current standard of care -

BURLINGTON, Mass., June 17, 2014 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced positive topline clinical trial results from a Phase 2a synovial fluid PK study of FX006, which demonstrated, for the first time, that a single intra-articular (IA) injection of FX006 can provide therapeutic concentrations of drug in joint fluid for at least 12 weeks. FX006 is Flexion's novel, non-opioid, sustained-release, IA formulation of TCA. It is designed to provide prolonged pain relief for the treatment of osteoarthritis (OA) of the knee, while potentially avoiding untoward systemic effects associated with immediate-release steroids.

These FX006 data represent a six-fold increase in the duration of joint residency compared with immediate-release TCA, which is the current standard of care injectable therapy. It is also noteworthy that a prior PK study of FX006 demonstrated that the peak plasma concentration in the hours following injection was decreased 40-fold relative to immediate-release TCA, a decrease that may meaningfully reduce adverse systemic side effects.

Neil Bodick, M.D., Ph.D., Flexion Therapeutics Chief Medical Officer, said, "The pharmacokinetic data from this Phase 2a clinical trial underpin the differentiation of FX006 from the current standard of care. They are consistent with the efficacy observed in our initial Phase 2b dose-ranging clinical trial, where a single dose of FX006 produced a meaningful prolongation and amplification of pain relief compared to immediate-release TCA. Importantly, the results from this trial will inform the design of our planned repeat-dose clinical study of safety and tolerability in patients with OA."

In this multi-center, open-label study of 50 patients with OA of the knee, researchers assigned patients sequentially to one of five groups that received a single IA injection of either 10 or 40 mg of FX006 or 40 mg of immediate-release TCA. Synovial fluid concentrations of drug were measured at 12 weeks in all dose groups and also at 16 and 20 weeks in the FX006 40 mg dose group. At 12 weeks both the FX006 10 mg and 40 mg dose groups had therapeutic concentrations of drug in synovial fluid. In contrast, the 40 mg immediate-release TCA dose group had concentrations of drug that were below the lower limit of quantitation. The FX006 40 mg dose group also demonstrated readily measurable concentrations of drug at 16 weeks, which fell to below the lower limit of quantitation at 20 weeks.

Michael Clayman, M.D., President and CEO, said, "We believe these data validate our sustained-release technology and bolster our confidence that FX006 can provide patients with persistent and prolonged pain relief. We anticipate sharing more details from the Phase 2a trial at an upcoming scientific meeting and to receiving topline data from the Phase 2b confirmatory trial in the first half of 2015. We would anticipate initiation of Phase 3 development next year pending the data readout of the Phase 2b confirmatory trial."

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 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 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, 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 we undertake no obligation to update or revise any of the statements.

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