Flexion Therapeutics Announces That FDA Has Removed Clinical Hold on FX006

- Company Resumes Recruitment in Pivotal Phase 2b Trial; Initiation of Phase 3 Clinical Trial Planned for Early 2015
- Conference Call Scheduled for Tomorrow, December 2, 2014 at 9:00 a.m. ET

BURLINGTON, Mass., Dec. 1, 2014 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced that the U.S. Food and Drug Administration (FDA) has notified the company that it has lifted the clinical hold on Flexion's lead drug candidate FX006, based upon the company successfully completing the FDA's requested testing and investigation related to what was originally reported as a single case of septic arthritis of the knee. As a result, Flexion intends to immediately resume recruitment and dosing in its pivotal Phase 2b trial of FX006, and to initiate a planned Phase 3 trial in early 2015. FX006 is a first-in-class injectable, sustained-release, intra-articular steroid treatment in development for patients with moderate to severe osteoarthritis (OA) pain.

Michael Clayman, M.D., Flexion Therapeutics President and CEO, said, "We are pleased to have been able to rapidly provide data to the FDA that allowed the agency to remove the clinical hold. Now we can continue to advance FX006, which has the potential to make a real difference for the many individuals who suffer from OA pain."

On September 16, 2014, the FDA placed a clinical hold on FX006 due to a single occurrence of what was then described as an infection in the injected knee joint of a patient in the pivotal Phase 2b trial. The subsequent clinical hold letter from the FDA requested that the company:

- Determine whether the study drug was the source of infection by recovering both the specific study drug vials used in the treatment of the patient who experienced the infection, as well as unused study drug vials from the clinical site where the patient was injected and test them for contamination, and
- Explore other potential causes for infection, including a compromise of sterile procedures during injection.

In accordance with these FDA requests, the company performed industry standard contamination tests through a certified third-party sterility-testing firm, which demonstrated that no microbial growth could be detected in any of the used or unused vials. As a result, the company concluded that study drug was not contaminated. The company also explored other potential causes of possible infection including contamination during the preparation or administration of FX006. Following consultations with the principal investigator, the study coordinator that prepared the study drug, and the healthcare professional that administered the injection at the clinical site, the company could not find any indication that sterile procedures were compromised during the injection. There have been no other infections noted in the approximately 100 other patients dosed with FX006 in this trial.

On October 28, 2014, the company received notification that based on the highly atypical nature of this patient's presentation as it relates to septic arthritis and the subsequent clinical course, which was most consistent with rheumatoid arthritis, the principal investigator has changed the initial serious adverse event diagnosis from septic arthritis, possibly related to study drug treatment, to inflammatory arthritis, unrelated to study drug treatment. The original, and only, positive synovial fluid culture obtained from this patient is presumed to be a false positive, which occurs in about five percent of such cases. Thus there have been no confirmed diagnoses of septic arthritis among the more than 300 patients treated with FX006 in all clinical trials to date and no serious adverse events that have been attributed to study drug.

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.

Conference Call

Flexion's management team will host a conference call and webcast at 9:00 a.m. EST tomorrow, December 2, 2014, to discuss the removal of the clinical hold and to provide a clinical timing update. 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.

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, expectations of resuming the FX006 Phase 2b clinical trial, plans and timing for initiating a Phase 3 trial, anticipated clinical and other milestones (including the timing of such milestones) and potential benefits of FX006 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 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.

CONTACT: Media Contact

Jamie Lacey-Moreira
PressComm PR, LLC
T: 410-299-3310
jamielacey@presscommpr.com

Corporate Contact

Lisa Davidson, MBA
Vice President, Finance and Administration
Flexion Therapeutics, Inc.
T: 781-305-7765
ldavidson@flexiontherapeutics.com