



## **Flexion's FX006 Achieves Prolonged Therapeutic Concentrations in Joints of Osteoarthritis Patients**

— *FX006 Exhibits Reduced Systemic Steroid Exposure Compared to Immediate Release Steroid* —

WOBURN, Mass., Dec. 17, 2012 – [Flexion Therapeutics, Inc.](#) today reported that FX006, its novel intra-articular, sustained release steroid, maintained therapeutic concentrations in the knee joint significantly longer than the most commonly prescribed immediate release (IR) steroid, triamcinolone acetonide (TCA) in a Phase 2 pharmacokinetic study. At six weeks, FX006, a sustained release formulation of TCA, remained in the joint at clinically active concentrations while the IR steroid was no longer detectible. Patients treated with FX006 also showed a significantly reduced systemic exposure to the parent steroid compared to the IR formulation. FX006 was well tolerated at all doses throughout the study.

“FX006’s sustained release formulation allowed the concentration of steroid at the site of osteoarthritic disease to remain at therapeutic levels for the duration of the six-week study,” said Neil Bodick, M.D., Ph.D., co-founder and chief medical officer of Flexion. “The sustained steroid levels have the potential to result in persistent suppression of synovitis which may prove beneficial to patients by extending symptomatic relief and slowing disease progression.”

Michael Clayman, M.D., co-founder and chief executive officer of Flexion added, “These data, together with the reduced systemic steroid exposure seen with FX006 compared to the IR steroid, validate our sustained release, intra-articular approach for giving our drugs the best chance to work locally while minimizing the risk of systemic side effects.”

### **About The Study**

This trial was a double-blind, parallel group, active comparator pharmacokinetics study in which 24 patients with osteoarthritis were randomized to receive sustained release FX006 (10, 40 or 60mg) or IR TCA (40 mg) via intra-articular injection. Eighteen patients received FX006 while six received the commonly prescribed IR TCA.

### **About Osteoarthritis**

Osteoarthritis is a leading cause of disability that affects more than 27 million adults in the U.S. and more than 100 million people worldwide. Almost 50% of people in the U.S. will experience the pain of osteoarthritis in their lifetime. Current treatment is inadequate. Oral therapies have limited pain relief and serious cardiovascular, liver and gastrointestinal side effects as well as black box warnings. Available intra-articular therapies are generally well-tolerated but provide limited therapeutic efficacy or provide good pain relief with an inadequate duration of effect. Despite these inadequacies, there are over 50 million intra-articular injections per year worldwide with sales in excess of \$1.5 billion a year.

## **About FX006**

FX006 is Flexion's novel, proprietary, sustained-release, intra-articular formulation of triamcinolone acetonide for the treatment of mild to moderate OA of the knee. It is designed to provide prolonged pain relief while avoiding untoward systemic effects associated with steroids as front-line therapy. In preclinical models of OA, FX006 demonstrates both superior efficacy to immediate release steroids and beneficial effects on structural progression. A Phase 2b dose-ranging study evaluating safety and efficacy is currently underway in Canada and Australia and will include sites in the U.S. beginning in January; data are expected in the middle of 2013.

## **About Flexion Therapeutics**

Flexion is a clinical-stage specialty pharmaceutical company developing innovative therapeutics for musculoskeletal disorders. In our efforts to provide products with superior efficacy and safety, we are merging novel pharmacology with local, sustained delivery of drug to the site of disease – an approach that aims to ensure lasting therapeutic effect and systemic safety. We are currently advancing a portfolio of best-in-class drug candidates that have the potential to treat mild, moderate and severe forms of osteoarthritis. Top-line data for FX005, an intra-articular sustained release p38 MAP kinase inhibitor and our lead compound, showed prolonged improvement in joint pain and function throughout the 12-week duration of the Phase 2 study. FX006, an intra-articular sustained release steroid, is currently being evaluated in a Phase 2b dose-ranging study with data expected in the middle of 2013. FX007, an intra-articular sustained release TrkA inhibitor, is being developed to safely address the intractable pain associated with end-stage osteoarthritis.

For more information please visit [www.flexiontherapeutics.com](http://www.flexiontherapeutics.com).

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