June 26, 2013

Flexion's FX006 Demonstrates Superior Pain Relief Compared to Standard-of-Care in Phase 2b Osteoarthritis Trial

– FX006 Provides Pain Relief Signal That is Among the Largest Seen in Osteoarthritis Clinical Trials –
– Optimal Dose for Phase 3 Trial Identified –

BURLINGTON, Mass., June 26, 2013 - Flexion Therapeutics, Inc., today reported that its lead compound FX006, a novel intra-articular (IA), sustained release steroid, demonstrated pain relief that is of both greater magnitude and longer duration than the most commonly prescribed immediate release steroid, triamcinolone acetonide (TCA IR), in a Phase 2b dose-ranging trial in osteoarthritis (OA). Top-line results for FX006 include:

- The optimal dose of FX006 showed a statistically significant and clinically meaningful improvement in the magnitude and duration of pain relief relative to TCA IR
- FX006 was very well-tolerated and the systemic exposure produced by FX006 was substantially less than that of TCA IR
- All secondary measures including functional assessment, responder status, patient global impression of change, clinical global impression of change and rescue medicine consumption demonstrated significant improvement compared to TCA IR
- Onset of pain relief occurred within hours to days--as rapid as TCA IR

"It's not often we see a pain relief signal in osteoarthritis clinical trials as dramatic as the one seen with FX006," said Matt Provencher, M.D., Chief, Sports Medicine Service, Massachusetts General Hospital, Harvard Medical School. "Immediate release steroids are currently front-line intra-articular therapy for patients with degenerative conditions of the knee. With the magnitude and durability of both pain relief and improvement in function seen in this trial, FX006 has the potential to become the new front-line standard-of-care for patients with knee osteoarthritis."

Michael Clayman, M.D., co-founder and chief executive officer of Flexion, added, "Flexion's drug candidates are designed to provide safe and long lasting benefit using sustained release therapies delivered locally to the site of disease. These data, together with earlier Phase 2a data for FX006 and for FX005, validate our intra-articular, sustained release strategy, and provide a high level of confidence as FX006 progresses toward pivotal Phase 3 trials. We expect to initiate these trials early in 2014."
The Phase 2b trial was a double-blind, comparator-controlled study in which 228 patients were randomized to receive 10 mg, 40 mg or 60 mg of FX006 or 40 mg TCA IR via intra-articular knee injection. Efficacy was evaluated using the weekly mean of the average daily pain intensity score (on the 0 - 10 Numeric Rating Scale) at weeks 1 through 12.

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 oral therapies provide largely inadequate pain relief and are associated with serious side effects, while intra-articular therapies are generally safe but have limited duration and or magnitude of effect. Despite these limitations, there are over 50 million intra-articular injections per year worldwide with sales in excess of $1.5 billion annually.

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 immediate release steroids. In preclinical models of OA, FX006 demonstrated both superior efficacy to immediate release steroids and beneficial effects on structural progression. In a Phase 2 trial of pharmacokinetics and pharmacodynamics, FX006 maintained therapeutic concentrations in the knee joint significantly longer than TCA IR and showed a significantly reduced systemic exposure to the parent steroid compared to the IR formulation. FX006 has been well-tolerated in all clinical trials thus far.

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 drug candidates that together have the potential to treat mild, moderate and severe forms of osteoarthritis. FX006, an intra-articular sustained release steroid, demonstrated positive Phase 2b data and is expected to begin pivotal registration trials in early 2014. FX005, an intra-articular sustained release p38 MAP kinase inhibitor, showed prolonged improvement in joint pain and function throughout the 12-week duration of its Phase 2 trial. FX007, an intra-articular sustained release TrkA antagonist, is being developed to safely address the intractable pain associated with end-stage osteoarthritis.

For more information please visit www.flexiontherapeutics.com.

###

Media Contacts
Tony Russo, Ph.D.
Matt Middleman, M.D.
Russo Partners
T: 212-845-4251
T: 212-845-4272
tony.russo@russopartnersllc.com
matt.middleman@russopartnersllc.com

Corporate Contact
Lisa Davidson, MBA
Vice President, Finance and Administration
T: 781-897-9965
ldavidson@flexiontherapeutics.com