



October 2, 2013

Flexion Therapeutics to Present Phase 2b Data for FX006 at 2013 American College of Rheumatology Annual Scientific Meeting

– Oral presentation at ACR will highlight results from first head-to-head dose-ranging study comparing FX006 with approved injectable dose of commonly prescribed, immediate release steroid for patients with osteoarthritis (OA) of the knee –

BURLINGTON, MASS., OCTOBER 2, 2013 - [Flexion Therapeutics, Inc.](#) announced today that new data from a Phase 2b dose-ranging trial of the company's lead compound, FX006, in osteoarthritis (OA) has been accepted for an oral presentation at the 2013 Annual Scientific Meeting of the American College of Rheumatology and the Association of Rheumatology Health Professionals (ACR/ARHP). Flexion's Chief Medical Officer [Neil Bodick, M.D., Ph.D.](#), will present the data during the meeting on October 29, 2013, in San Diego, California.

Information for the oral presentation session is highlighted below:

(Abstract #2668): Tuesday, October 29, 2013, 2:30 PM PST "A Randomized, Double-Blind, Dose Ranging Study Comparing FX006, an Intra-Articular (IA) Sustained-Release Formulation of Triamcinolone Acetonide (TCA), to an Approved Injectable Suspension of TCA in Patients with Osteoarthritis (OA) of the Knee," [Osteoarthritis I: Therapeutics in Osteoarthritis] [Hilton 306-A]

"We are excited to present these Phase 2b data since they show magnitude of pain relief with FX006 that is among the largest observed in clinical trials," said [Michael Clayman, M.D.](#), Flexion Therapeutics CEO. "FX006 was also well tolerated and overall the data indicate that FX006 has the potential to provide a more effective treatment option than current immediate release steroids."

The Phase 2b trial of FX006, a novel intra-articular (IA), sustained release steroid, 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. The primary outcome measure was the weekly mean of the average daily pain intensity score (on the 0 - 10 Numeric Rating Scale) at weeks 1 through 12. Secondary endpoints measured time to onset of analgesia, responder status, pain, stiffness and function measured using WOMAC, patient global impression of change, clinical global impression of change and rescue medical consumption. In the trial, FX006 demonstrated clinically meaningful, statistically significant and prolonged pain relief relative to the commonly prescribed, immediate release steroid, triamcinolone acetonide (TCA IR).

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 percent of people in the U.S. will experience the pain of osteoarthritis in their lifetime. Current oral therapies provide modest 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 a preclinical model of arthritis, 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 significantly reduced systemic exposures compared to the IR formulation. FX006 has been well tolerated in all clinical trials thus far.

About Flexion Therapeutics

Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, long-acting,

injectable pain therapies, beginning with OA, a type of degenerative arthritis. Our broad and diversified portfolio of product candidates addresses the OA pain treatment spectrum, from moderate to severe pain, and provides us with multiple unique opportunities to achieve our goal of commercializing novel, patient-focused pain therapies. Our pipeline consists of three proprietary product candidates: FX006, a sustained-release, intra-articular steroid; FX005, a sustained-release intra-articular p38 MAP kinase inhibitor; and FX007 a TrkA receptor antagonist for post-operative pain.

For more information, please visit <http://www.flexiontherapeutics.com>

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