Flexion's Lead Osteoarthritis Drug Candidate Demonstrates Significant, Prolonged Improvement in Pain and Function in Phase 2 Trial

– – FX005, a Sustained Release p38 MAP Kinase Inhibitor, Demonstrated Significant Pain Relief at Four Weeks – –

– First-Ever Clinical Results Demonstrating Efficacy of a p38 MAP Kinase Inhibitor in Osteoarthritis –

WOBURN, Mass., May 30, 2012 – Flexion Therapeutics, Inc. today reported that its lead osteoarthritis drug candidate, FX005, demonstrated significant pain relief over placebo at four weeks* in a Phase 2 proof-of-concept trial. Top-line data showed FX005, delivered intra-articularly to the knee, was well-tolerated and resulted in prolonged improvement in joint pain and function throughout the 12-week duration of the study. These are the first-ever clinical results demonstrating the efficacy of a p38 MAP kinase inhibitor in osteoarthritis patients. Flexion plans to present the complete data set and analyses at an upcoming medical conference.

"There is considerable unmet need for treatments for the pain and damage caused by osteoarthritis," said Timothy McAlindon, chair of rheumatology and professor of medicine at Tufts Medical Center. "In particular, physicians and patients need targeted treatments for osteoarthritis that are more effective and longer lasting. These results represent a significant advance in that direction, so we will eagerly monitor development of this new treatment."

Michael Clayman, M.D., chief executive officer of Flexion, said, "We believe these data not only demonstrate the therapeutic potential of FX005 but also validate Flexion's approach to the treatment of osteoarthritis -- intra-articular delivery of sustained-release therapies providing prolonged activity at the site of disease while minimizing systemic exposure and the corresponding risk of systemic side effects. We are enthusiastic about advancing FX005 into the next phase of clinical development, which will be a Phase 2b dose-ranging study that we plan to initiate in the first half of 2013. The data from that study will then be used to identify an optimal dose for Phase 3."

The trial was a double-blind, placebo-controlled study in which 104 patients were randomized to receive FX005 or placebo via intra-articular injection. Each patient was evaluated using the WOMAC® Osteoarthritis Index to assess pain and function at two, four, eight and 12 weeks.

* as measured by WOMAC A (Western Ontario and McMaster Universities Osteoarthritis Index)

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 FX005

FX005 is Flexion's novel, sustained release, intra-articular inhibitor of p38 MAP kinase, a clinically validated target in pain and inflammation, and is positioned as second-line therapy following intra-articular steroids for the treatment of moderate osteoarthritis of the knee. FX005 is an anti-inflammatory drug-candidate that incorporates analgesic effects and has the potential to modify disease progression.

About Flexion Therapeutics

Flexion discovers and develops 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 this debilitating disorder.

For more information please visit www.flexiontherapeutics.com.

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