



November 3, 2016

## **Flexion Therapeutics Announces that Analysis from Phase 3 Clinical Trial of Zilretta™ for Osteoarthritis of the Knee to be presented at AAHKS**

BURLINGTON, Mass., Nov. 03, 2016 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) today announced that further analysis of Phase 3 data evaluating its investigational product, Zilretta™ (also known as FX006), in patients with osteoarthritis (OA) of the knee will be presented during the 26<sup>th</sup> American Association of Hip and Knee Surgeons Annual Meeting, taking place in Dallas from November 10-13, 2016.

Results will be presented during a podium presentation by Andrew Spitzer, M.D., Co-Director of the Joint Replacement Program at Cedars-Sinai Orthopaedic Center, on Friday, November 11 at 3:52 p.m. CST. The primary objective of the Phase 3 trial was to assess the magnitude of pain relief of Zilretta at 12 weeks against placebo as measured by weekly mean average daily pain (ADP) scores.

### **About Osteoarthritis of the Knee**

While OA is currently being diagnosed at increasingly younger ages, prevalence rises after age 45. In 2015, more than 14 million Americans were diagnosed with OA of the knee. OA represents an enormous burden on the U.S. healthcare system, affecting more than 27 million individuals and accounting for more than \$185 billion in annual expenditures. These costs are expected to rise with a predicted increase in OA prevalence, which is expected to affect 67 million Americans by 2030.

Each year, more than five million OA patients in the U.S. receive immediate-release corticosteroid and hyaluronic acid IA injections for knee pain, but these injections generally provide limited relief, and no alternative injectable therapy has been approved in more than a decade.

### **About Zilretta**

Zilretta is being investigated as the first intra-articular extended-release, non-opioid treatment for patients with moderate to severe knee OA pain. Zilretta employs proprietary microsphere technology combining TCA — a commonly administered, short-acting corticosteroid — with a polymer (PLGA) intended to provide persistent concentrations of drug locally to both amplify the magnitude and prolong the duration of pain relief.

To date, more than 600 patients have been treated with Zilretta in clinical trials. No drug-related serious adverse events have been observed in these trials and adverse events have typically been localized, mild and comparable to those observed with immediate-release TCA and placebo. The data from these trials are consistent with Zilretta providing meaningful and durable pain relief.

Zilretta is an investigational agent and, as such, has not been approved by the U.S. Food and Drug Administration (FDA) or any other regulatory agencies.

### **About Flexion Therapeutics**

Flexion is a specialty pharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with OA. The company's lead product candidate, Zilretta, is being investigated for its potential to provide improved analgesic therapy for the millions of U.S. patients who receive IA injections for knee OA annually.

### **Forward-Looking Statements**

Statements in this press release regarding matters that are not historical facts, including, but not limited to, statements relating to expected increases in costs and prevalence of OA, 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, manufacturing and obtaining regulatory approval for drugs that are safe and effective for use as human therapeutics; competition from alternative therapies; risks related to economic conditions, health care reform, prices and reimbursement rates; and other risks and uncertainties described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our most recent Annual Report on Form 10-K and

subsequent filings with the SEC. The forward-looking statements in this press release speak only as of the date of this press release, and we undertake no obligation to update or revise any of the statements. We caution investors not to place considerable reliance on the forward-looking statements contained in this press release.

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