July 6, 2016

Flexion Therapeutics Adds Three New Executives in Key Roles to Support the Planned Commercial Launch of Zilretta™

BURLINGTON, Mass., July 06, 2016 (GLOBE NEWSWIRE) -- Flexion Therapeutics, Inc. (Nasdaq:FLXN) announced today that three new executives have joined the company in key marketing, medical affairs and market access roles. Mark Fraga, Scott Kelley, MD, and Dan Thornton take on vice president positions at Flexion as the company prepares to submit a new drug application (NDA) in the fourth quarter of 2016 to the U.S. Food and Drug Administration (FDA) for its drug candidate Zilretta, a potential treatment for patients with moderate to severe knee osteoarthritis (OA) pain.

Michael Clayman, MD, President and Chief Executive Officer of Flexion, stated, "We are delighted to be hiring Mark, Scott and Dan, each of whom comes to Flexion with deep expertise in their respective functions, a track record of strong accomplishment, and a professional style that we believe will contribute importantly to Flexion's culture. Their leadership will critically enable the launch of Zilretta, which we anticipate in 2017."

The three recently appointed executives are:

Mark Fraga, Vice President, Marketing: Mr. Fraga is a proven global marketing and commercialization leader in the pharmaceutical and medical device markets. Before joining Flexion, Mr. Fraga served as head of global marketing at Sanofi, where he led two franchises in OA and surgical devices, including Synvisc®, an injectable product for OA of the knee. Prior to Sanofi, he was director of marketing for Codman Neuro, a neurosurgery device subsidiary of Johnson & Johnson, where he had several leadership roles in commercial, global, and strategic marketing. He earned his BA and MBA degrees from the University of Pennsylvania, and his MPhil from the University of Oxford.

Scott Kelley, MD, Vice President, Medical Affairs: Dr. Kelley has over 25 years of clinical, academic and industry medical affairs experience. Most recently, he served as Vice President, Global Medical Affairs at Sanofi where he oversaw global data generation, data dissemination and key opinion leader engagement for the Biosurgery portfolio including Synvisc®. Prior to Sanofi, Dr. Kelley led medical affairs functions at Covidien Respiratory & Monitoring Solutions and at Aspect Medical Systems. He earned his BS and MS from Stanford University and his MD from University of California, San Francisco. He completed his residency and fellowship in Anesthesiology at UCSF and obtained board certifications in Anesthesiology and Pain Management. Dr. Kelley maintains a clinical practice at Brigham & Women's Hospital.

Dan Thornton, Vice President, Market Access: Mr. Thornton has had leadership roles for nearly 20 years in patient and market access, pricing and distribution, and market development for a number of biotechnology and pharmaceutical firms. Most recently, he was VP of market access and patient services at Chiasma, where he built a comprehensive patient services and market access organization for the launch of an oral product for the treatment of acromegaly. He has also built and executed market access strategies at a number of companies including Shire Pharmaceuticals, Santhera Pharmaceuticals and Targanta Therapeutics. Mr. Thornton earned his BA from Duke University and his MBA from the University of Pennsylvania.

About Zilretta

Zilretta is being investigated as the first intra-articular sustained-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.

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 the future of Flexion; our interpretation of the data and results from our Zilretta clinical trials; our plans for, and the expected timing of, our Zilretta NDA submission with the FDA; our plans to commercialize Zilretta, including the expected timing for commercial launch and our having strong commercial and medical affairs operations at launch; and the potential therapeutic and other benefits of Zilretta, 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; the fact that results of past clinical trials may not be predictive of subsequent trials; our reliance on third parties to manufacture and conduct clinical trials of Zilretta, which could delay or limit its future development or regulatory approval; our ability to meet anticipated clinical trial commencement, enrollment and completion dates and regulatory filing and commercial launch dates for Zilretta; the fact that we will require additional capital, including prior to commercializing Zilretta or any other product candidates, and may be unable to obtain such additional capital in sufficient amounts or on terms acceptable to us; the risk that we may not be able to maintain and enforce our intellectual property, including intellectual property related to Zilretta; competition from alternative therapies; regulatory developments and safety issues, including difficulties or delays in obtaining regulatory approvals to market Zilretta; the risk that the FDA and foreign regulatory authorities may not agree with our interpretation of the data from our clinical trials of Zilretta and may require us to conduct additional clinical trials; Zilretta may not receive regulatory approval or be successfully commercialized, including as a result of the FDA's or other regulatory authorities' decisions regarding labeling and other matters that could affect its availability or commercial potential; risks related to key employees, markets, 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.

Investor Contact
David Carey
Lazar Partners LTD
T: 212-867-1768
dcarey@lazarpartners.com

Media Contact
Mariann Caprino
TogoRun
T: 917.242.1087
M.Caprino@togorun.com

Corporate Contact
Fred Driscoll
Chief Financial Officer
Flexion Therapeutics, Inc.
T: 781-305-7763
fdriscoll@flexiontherapeutics.com