



Nektar Presents Data Demonstrating Favorable Oral Bioavailability and Drug-Drug Interaction Profile for NKTR-118

Oral Tablet Clinical Pharmacokinetic Data Presented at 38th Annual American College of Clinical Pharmacology (ACCP) Meeting in San Antonio

SAN ANTONIO and SAN CARLOS, Calif., Sept 13, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Nektar Therapeutics (Nasdaq: NKTR) presented clinical study data today demonstrating that the oral tablet formulation of NKTR-118 has favorable systemic bioavailability and a low risk for mediating significant drug-drug interactions. NKTR-118, an oral peripherally-acting opioid antagonist, is in clinical development for the treatment of opioid-induced constipation. These findings were presented today at the 38th Annual American College of Clinical Pharmacology (ACCP) Meeting in San Antonio, Texas.

Oral NKTR-118 combines Nektar's advanced small molecule polymer conjugate technology platform with naloxol, a derivative of the opioid-antagonist drug, naloxone. Nektar's proprietary advanced polymer conjugate technology increases the bioavailability and half-life of naloxol, enabling NKTR-118 to act selectively in the periphery while preserving centrally-mediated opioid analgesic clinical benefits.

"The data reported today, in combination with our strong Phase 2 clinical results, support advancing the oral tablet formulation of NKTR-118 into pivotal Phase 3 studies. NKTR-118 is an excellent example of how our novel advanced polymer conjugate platform improves oral bioavailability and enables preferential distribution of a drug within the body," said Lorianne Masuoka, M.D., Chief Medical Officer of Nektar. "By significantly improving the pharmacological activity of small molecule drugs, we are building an impressive portfolio of innovative treatments for diseases with high unmet needs."

A human pharmacokinetic study conducted in 20 healthy subjects demonstrated the comparative bioavailability of NKTR-118 in tablets and solution, confirming the drug's rapid absorption profile in both formulations and demonstrating the bioequivalence of the oral tablet formulation to solution. In vitro studies demonstrated the high metabolic stability of NKTR-118 compared to naloxone. Results of in vitro testing indicate that NKTR-118 has a low potential for clinically important drug-drug interactions, thereby facilitating the combination of NKTR-118 with a wide range of drugs in clinical development.

NKTR-118 Phase 2 Clinical Trial Data to be presented in Oral Plenary Session at ACG 2009

Nektar also announced today that results from a separate Phase 2 clinical trial of NKTR-118 have been accepted for presentation at an oral plenary session of the American College of Gastroenterology (ACG) 2009 Annual Scientific Meeting to be held in San Diego on October 27, 2009. The data will be presented by Dr. Lynn Webster, medical director of Lifetree Clinical Research and lead clinical investigator of the Phase 2 trial.

Topline data from this Phase 2 study showed that NKTR-118 met the primary endpoint of increase in spontaneous bowel movements over the baseline period in a double-blind, randomized, placebo-controlled study in 208 patients with opioid-induced constipation, while preserving the analgesic effect of opioid by reducing the blood-brain barrier penetration.

Download Today's Data Presentations for NKTR-118

The poster presentations presented today at the ACCP 38th Annual Meeting (Poster Session 1, 6:00 - 8:00 PM Central time) can be found on Nektar's website at http://www.nektar.com/product_pipeline/cns_pain_oral_nktr-118and119.html

ACCP Poster #140: "NKTR-118, an oral peripheral opioid antagonist, has low potential for drug-drug interactions"

ACCP Poster #141: "Comparative bioavailability of NKTR-118 tablets and solution: a case of bioequivalence between dosage forms for a rapidly absorbed drug"

The corresponding abstracts for these presentations are published in the September 2009 issue of The Journal of Clinical Pharmacology (J. Clin. Pharmacol., Sept 2009; 49:1123).

About Opioid-Induced Constipation

The oral peripheral antagonist NKTR-118 targets mu-opioid receptors within the enteric nervous system, which mediate opioid-induced bowel dysfunction, a symptom complex resulting from opioid use that encompasses symptoms such as constipation, bloating, abdominal cramping, and gastroesophageal reflux. Constipation is the hallmark of this syndrome and is generally its most prominent component. In patients who take opiates chronically for pain management, anywhere from 45-90% of patients will develop debilitating constipation associated with other symptoms of opioid-induced bowel dysfunction as a result of the drug binding to the mu-opioid receptor in the gut(1).

According to IMS Health, about 230 million prescriptions were written for opioids in 2007 in the United States alone. Currently, there are no oral drugs approved that are indicated to treat opioid-induced constipation (OIC). Opioid bowel dysfunction and OIC can significantly impact quality of life and increase healthcare utilization.

Nektar is also developing NKTR-119, an investigational drug candidate that is a co-formulation of oral NKTR-118 and an opioid analgesic. The product is designed to provide good analgesic properties in the chronic treatment of moderate to severe pain patients while avoiding the debilitating side effects that are common with opioid use, such as constipation and other symptoms of bowel dysfunction.

About Nektar

Nektar Therapeutics is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar's technology and drug development expertise have enabled nine approved products in the U.S. or Europe for partners, which include leading biopharmaceutical companies, including UCB's Cimzia(R), Roche's PEGASYS(R) for hepatitis C and Amgen's Neulasta(R) for neutropenia. Nektar has created a robust pipeline of potentially high-value therapeutics to address unmet medical needs by leveraging and expanding its technology platforms to improve and enable molecules. Nektar is currently conducting clinical and preclinical programs in oncology, pain and other therapeutic areas. NKTR-102, PEGylated irinotecan, is currently in Phase 2 clinical studies in ovarian, breast and colorectal cancer. NKTR-105, PEGylated docetaxel, is currently in a Phase 1 clinical study in patients with refractory solid tumors.

Nektar is headquartered in San Carlos, California, with additional R&D operations in Huntsville, Alabama and Hyderabad, India. Further information about the company and its drug development programs and capabilities may be found online at <http://www.nektar.com>.

This press release contains forward-looking statements that reflect the company's current views regarding the potential of the company's technology platforms, the tablet formulation of NKTR-118, and the scientific and commercial potential of NKTR-118 and the results of the Phase 2 study for that drug candidate. These forward-looking statements involve risks and uncertainties, including but not limited to: (i) NKTR-118 is in mid-stage clinical development and the risk of failure remains high and failure can unexpectedly occur at any stage prior to regulatory approval due to efficacy, safety or other factors; (ii) the timing or success of the commencement or end of clinical trials and commercial launch of new drugs may be delayed or unsuccessful due to regulatory delays, clinical trial design, slower than anticipated patient enrollment, drug manufacturing challenges, changing standards of care, clinical outcomes, or delay or failure in obtaining regulatory approval in one or more important markets; (iii) the company's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may not be enforceable, or intellectual property licenses from third parties may be required in the future; (iv) the outcome of any existing or future intellectual property or other litigation related to the company's proprietary product candidates; and (v) the timing and success of the company's efforts to establish and maintain future collaboration partnerships on attractive commercial terms or at all. Other important risks and uncertainties are detailed in the company's reports and other filings with the Securities and Exchange Commission, including its most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K.

Actual results could differ materially from the forward-looking statements contained in this press release. The company undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise. For more information on Nektar Therapeutics, please visit <http://www.nektar.com>.

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1. Panchal SJ, Muller-Schwefe P, Wurzelmann JI. Opioid-induced bowel dysfunction: prevalence, pathophysiology and burden. *Int J Clin Pract.* 2007;61(7):1181-1187.

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