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Nektar Announces that FDA Grants Fast Track Designation to NKTR-181, a New Oral Opioid Analgesic Molecule, for the Treatment of Moderate to Severe Chronic Pain

SAN FRANCISCO, June 7, 2012 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) announced today that the U.S. Food and Drug Administration (FDA) has designated NKTR-181 as a Fast Track development program for the treatment of moderate to severe chronic pain. NKTR-181 is a novel mu-opioid agonist molecule, which is designed to have a slow rate of entry into the brain to reduce the attractiveness of the molecule as a target of abuse and to reduce its CNS-mediated side effects. NKTR-181 was created using Nektar's proprietary polymer conjugate technology and its potential differentiating properties are inherent to the design of the new molecule. NKTR-181 is an NCE and as a new molecular structure does not rely on a formulation approach to prevent its conversion into an abusable form of an opioid.

"We are very pleased that the NKTR-181 development program has been granted Fast Track designation and we look forward to working closely with the FDA on this program," said Robert Medve, MD, Chief Medical Officer of Nektar Therapeutics. "NKTR-181 could have significant advantages over currently-available opioids, including reduced attractiveness for abuse and reduced CNS-mediated side effects, such as sedation and respiratory depression. As a new chemical entity with these properties, we believe NKTR-181 has the potential to transform the treatment of chronic pain. We are excited about advancing NKTR-181 into Phase 2 development in July of this year."

Nektar requested Fast Track designation from the FDA for NKTR-181 based upon what is known about its safety and efficacy profile to-date from both preclinical and Phase 1 clinical studies, as well as NKTR-181's potential to treat chronic pain conditions with an improved safety profile over existing therapies. Given the properties and potential of NKTR-181 in the treatment of chronic pain, Nektar believes that this promising therapy could provide a unique solution to pain management with its intrinsic abuse deterrent design.

NKTR-181 has completed a Phase 1 clinical development program, which evaluated its pharmacokinetics, pharmacodynamics and safety in more than 180 healthy subjects. The Phase 2 development program for NKTR-181 will use a standard, randomized, placebo-controlled withdrawal design to evaluate the efficacy and safety of this new opioid molecule in up to 200 patients with chronic pain from osteoarthritis of the knee. A human abuse liability study is also planned as part of NKTR-181's Phase 2 development.

Under the FDA Modernization Act of 1997, the Fast Track program facilitates interactions with the FDA before and during the submission of a New Drug Application (NDA) for therapeutics being investigated as a treatment for serious or life-threatening conditions, which demonstrate the potential to address an unmet medical need for such a condition. The Fast Track program enables a company to file sections of an NDA on a rolling basis as data becomes available. This permits the FDA to review portions of the NDA as they are received, rather than waiting for the entire NDA filing prior to commencing the review process. With a Fast Track designation, there is an opportunity for more frequent interactions with the FDA and the possibility of a priority review, which could decrease the typical development time and review period.

About Opioids and Pain Management

Pain is the most common symptom for which patients seek medical attention.(1) According to the American Pain Society, the prevalence of chronic pain in the United States is estimated to be 35.5% or 105 million people. Chronic pain conditions, such as osteoarthritis, back pain and cancer pain, affect at least 126 million adults in the U.S. annually and contribute to over $100 billion a year in direct health-care expenditures and lost work time.(1) Opioids are considered to be the most effective therapeutic option for pain and have over $10 billion a year in sales in the U.S. alone.(2,3) However, opioids cause significant problems for physicians and patients because of their serious side effects such as respiratory depression and sedation, as well as the risks they pose for addiction, abuse, misuse, and diversion. The U.S. Food and Drug Administration has cited prescription opioid analgesics as being at the center of a major public health crisis of addiction, misuse, abuse, overdose and death.(4) A 2010 recent report from the Centers for Disease Control and Prevention (CDC) notes that emergency room visits tied to the abuse of prescription painkillers is at an all-time high, having increased 111 percent over a five-year period.(5)

About Nektar

Nektar Therapeutics is a biopharmaceutical company developing novel therapeutics based on its PEGylation and advanced polymer conjugation technology platforms. Nektar has a robust R&D pipeline of potentially high-value therapeutics in oncology,

pain and other areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for NKTR-118, an investigational drug candidate, being evaluated in Phase 3 clinical studies as a once-daily, oral tablet for the treatment of opioid-induced constipation. The agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of NKTR-118 and an opioid. NKTR-181, a novel long-acting mu-opioid analgesic molecule being investigated for chronic pain, has completed Phase 1 clinical studies. NKTR-192, a novel, short-acting mu-opioid analgesic molecule being investigated for acute pain, is in Phase 1 development. In oncology, NKTR-102, a novel topoisomerase I-inhibitor, is being evaluated in a Phase 3 clinical study for the treatment breast cancer (BEACON trial) and in Phase 2 clinical studies for ovarian and colorectal cancers.

Nektar's technology has enabled seven approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia.

Nektar is headquartered in San Francisco, California, with additional 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" within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "expect," "believe," "should," "could," "potential," "may" and similar references to future periods. Examples of forward-looking statements include our current views as to the potential of NKTR-181 as a new approach to opioid analgesia and pain therapy; the potential of NKTR-181 to be less attractive as a target of user abuse than standard opioid therapies; the potential of NKTR-181 to exhibit reduced CNS-related side effects associated with standard opioid therapies; our plans to initiate a Phase 2 clinical study for NKTR-181 in July 2012; the value of our polymer conjugate technology platform; and the potential of certain of our other drug candidates and those of our collaboration partners. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, observations and assumptions regarding the potential of our drug candidates and our technology. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) the statements regarding the therapeutic potential of NKTR-181 are based on preclinical data and data from the completed Phase 1 clinical studies and future clinical studies may not confirm these potential therapeutic benefits; (ii) although we have conducted various experiments using laboratory and home-based chemistry techniques that have so far been unable to convert NKTR-181 into a rapid-acting, more abusable opioid, there is a risk that an alternative chemistry technique or process may be discovered in the future that would enable the conversion of NKTR-181 into a more abusable opioid; (iii) NKTR-181 is in early stage clinical development and could fail at any time due to numerous unpredictable and significant risks related to safety, efficacy and other important findings that can negatively impact clinical development; (iv) the U.S. Food and Drug Administration and other health authorities could impose significant risk mitigation requirements that hamper the commercial potential of NKTR-181, even if this drug candidate receives regulatory approval; (v) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of Nektar's technology platform to potential new drug candidates such as NKTR-181 is therefore very uncertain and unpredictable and could unexpectedly fail at any time; (vi) patents may not issue from our patent applications for NKTR-181, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vii) the outcome of any existing or future intellectual property or other litigation related to our proprietary drug candidates. Other important risks and uncertainties are detailed in our reports and other filings with the Securities and Exchange Commission ("SEC"), including without limitation, those risks and uncertainties set forth in our Form 10-Q for the quarter ended March 31, 2012, filed with the SEC on May 4, 2012 and our Form 8-K filed with the SEC on June 5, 2012. We undertake no obligation to update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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(1) 2011 National Academy of Sciences. Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research, 2010 Decision Resources, and Harstall, C. How prevalent is chronic pain? *Pain Clinical Updates* X, 1—4 (2003).

(2) IMS, NSP, NPA and Defined Health 2010 Estimates.

(3) Melnikova, I, Pain Market, *Nature Reviews Drug Discovery*, Volume 9, 589-90 (August 2010).

(4) Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee, "*Risk Evaluation and Mitigation Strategies (REMS) for Extended-Release and Long-Acting Opioid Analgesics*", July 23-4, 2010.

(5) *Morbidity and Mortality Weekly Report (MMWR),* Emergency Department Visits Involving Nonmedical Use of Selected Prescription Drugs --- United States, 2004—2008, 59(23);705-709 (June 2010).

SOURCE Nektar Therapeutics