October 15, 2012

Nektar Presents Positive Preclinical Data for NKTR-171, A Novel Sodium Channel Blocker to Treat Neuropathic Pain, at 41st Annual Meeting of the Society for Neuroscience

NKTR-171 Demonstrates Dose-Dependent Analgesia with Significantly Reduced CNS-Related Side Effects in Preclinical Studies

SAN FRANCISCO, Oct. 15, 2012 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that preclinical data for NKTR-171, a new investigational drug candidate to treat neuropathic pain, was presented at the 41st Annual Meeting of the Society for Neuroscience: Neuroscience 2012. NKTR-171 is a novel sodium channel blocker designed to act in the periphery in order to treat neuropathic pain while avoiding the serious central nervous system (CNS) side effects associated with current therapies, including anti-epileptic and anti-convulsant medications, such as gabapentinoids.

Neuropathic pain, also known as nerve pain, is a type of chronic pain that occurs when nerves become injured or damaged by systemic disease, infections, autoimmune disease, or physical trauma due to toxins or injuries. It is estimated to effect more than 20 million people in the U.S. alone.[1]

"Sodium channels have long been known to play a significant role in the changes in neuronal excitability that lead to neuropathic pain," said Stephen Doberstein, Ph.D., Senior Vice President and Chief Scientific Officer of Nektar Therapeutics. "We are extremely pleased that NKTR-171 exhibits effective analgesia in multiple neuropathic pain models without generating the CNS side effects observed with current therapies used to treat neuropathic pain. We look forward to continuing to prepare NKTR-171 for our first human studies, which are planned for 2013."

In a series of *in vitro* and *in vivo* preclinical studies examining the pharmacokinetics and efficacy of NKTR-171, NKTR-171 effectively blocks the inactivated state of sodium channel cells and, at the same time, demonstrates a significantly reduced brain to plasma ratio when compared to currently-approved sodium channel blockers. In well-validated animal models of persistent neuropathic pain, NKTR-171 shows superior or comparable efficacy to gabapentin. In addition, at analgesic doses, NKTR-171 did not significantly impair motor coordination in an established preclinical model of sedative potential in animals, suggesting that the therapeutic index (the ability to provide analgesia at doses that do not cause significant side effects) could potentially be greater for NKTR-171 than for currently available therapies.

These data presented in Abstract #81.06/JJ11 at the Society for Neuroscience Annual Meeting can be found on Nektar's website at:

http://www.nektar.com/pdf/pipeline/SFN_2012_NKTR_171_poster.pdf

About NKTR-171

NKTR-171 is a new sodium channel blocker that was designed to block sodium channels in the peripheral nervous system and was created using Nektar's advanced polymer conjugation technology. By selectively restricting the molecule to the periphery, NKTR-171 is intended to provide analgesia for neuropathic pain conditions without the severe sedation and other CNS side effects associated with current therapies used in the treatment of neuropathic pain. In preclinical testing, NKTR-171 demonstrates dose-dependent and effective pain relief without exhibiting sedative effects at analgesic doses.

About Neuropathic Pain

Neuropathic pain, also known as nerve pain or peripheral neuropathy, is the result of nerve damage and can be caused by such diverse conditions as diabetes, shingles, cancer, HIV, multiple sclerosis and fibromyalgia, as well as injury or trauma to the nerves. According to the Neuropathy Association, an estimated 1 in 15 Americans suffer from peripheral neuropathy[1]. Its prevalence is particularly high among diabetes patients and incidence increases with age[1]. Though neuropathic pain is a very common condition, the symptoms of it can be highly variable, including numbness, tingling, and pricking sensations, sensitivity to touch, or burning sensations, making diagnosis difficult. If left untreated, peripheral neuropathy can lead to permanent nerve damage[2].

Today, medicines that act by blocking sodium or calcium channels such as the gabapentinoids and anti-epileptic medications, are used in the treatment of neuropathic pain but are known to cause serious CNS-related side effects, such as sedation and dizziness. Sodium channel blockers, such as Lidocaine, are known to be effective in addressing peripheral nerve pain, however the lack of an oral form limits its utility[2]. In spite of the shortcomings of medications currently prescribed for neuropathic pain, total U.S. sales in 2011 were $2.5 billion[3].

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 therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for naloxegol (NKTR-118), an investigational drug candidate, which is being evaluated in Phase 3 clinical studies as a once-daily, oral tablet for the treatment of opioid-induced constipation. This agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of naloxegol and an opioid. NKTR-181, a novel mu-opioid analgesic candidate for chronic pain conditions, is in Phase 2 development in osteoarthritis patients with chronic knee pain. NKTR-192, a novel mu-opioid analgesic in development to treat acute pain is in Phase 1 clinical development. In oncology, etirinotecan pegol (NKTR-102) is being evaluated in a Phase 3 clinical study (the BEACON study) for the treatment of metastatic breast cancer and is also in Phase 2 studies for the treatment of ovarian and colorectal cancers.

Nektar's technology has enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including Affymax's OMONTYS® for anemia, UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Roche's PEGASYS® for hepatitis C and Amgen's Neulasta® for neutropenia. Additional development-stage products that leverage Nektar's proprietary technology platform include Baxter's BAX 855, a long-acting PEGylated rFVIII program, which is in Phase 1 clinical development.

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.

Cautionary Note Regarding Forward-Looking Statements (NEEDS UPDATING)

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," "may" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the therapeutic potential of NKTR-171 based on preclinical data including the potential for NKTR-171 to exhibit reduced CNS side-effects associated with current therapies; our future plan to initiate a Phase 1 study for NKTR-171 some time in 2013; and the value and potential of certain other drug candidates in our R&D pipeline. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the potential of our drug candidates, the future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. 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, the following: (i) our statements regarding the therapeutic potential of NKTR-171 are based on preclinical data we have generated to date and further preclinical studies may not confirm the results of this early data; (ii) prior to commencing human clinical studies for NKTR-171, we must complete toxicology studies and, as with any preclinical drug candidate, the timing and outcomes of toxicology studies could significantly and negatively impact continued development of NKTR-171 or Nektar's current estimate of the time period during which the Phase 1 clinical study would begin; (iii) NKTR-171 is in preclinical 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 drug development particularly at this very early stage; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of our technology platform to potential new drug candidates such as NKTR-171, is therefore very uncertain and unpredictable and could unexpectedly fail at any time; (v) patents may not issue from our patent applications for NKTR-171, patents (if issued) may not be enforceable, or additional intellectual property licenses from third parties may be required; and (vi) the outcome of any existing or future intellectual property or other litigation related to Nektar's proprietary drug candidates including without limitation NKTR-171; and (vii) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 9, 2012 which filing can be accessed at www.sec.gov. Any forward-looking statement made by us in this press release is based only on information currently available to us and speaks only as of the date on which it is made. 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.

Nektar Investor Inquiries:
Jennifer Ruddock/Nektar Therapeutics (415) 482-5585

Susan Noonan/SA Noonan Communications, LLC (212) 966-3650

Nektar Media Inquiries:

Mary Cunney (917) 208-2162
Mike Huckman (646) 500-7631

1) Neuropathy Association; Facts (http://www.neuropathy.org/site/PageServer?pagename=About_Facts)
2) NINDS Peripheral Neuropathy Fact Sheet
(http://www.ninds.nih.gov/disorders/peripheralneuropathy/detail_peripheralneuropathy.htm)
3) IMS Health 2011

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