Nektar Therapeutics Presents Clinical Data from Phase 3 SUMMIT-07 Study of NKTR-181, a First-in-Class Investigational Opioid to Treat Chronic Pain, at 2017 PAINWeek®

September 6, 2017

SAN FRANCISCO, Sept. 6, 2017 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today presented clinical data from the SUMMIT-07 Phase 3 study of NKTR-181, a first-in-class opioid analgesic to treat chronic pain, at the 2017 PAINWeek® Conference in Las Vegas taking place September 5-9. NKTR-181 is a new chemical entity (NCE) and mu-opioid agonist molecule designed to provide potent pain relief without the high levels of euphoria that can lead to abuse and addiction with standard opioids.[1]

NKTR-181 is the first analgesic opioid molecule to exhibit reduction in specific CNS-mediated side effects, like euphoria, through the strategic alteration of brain-entry kinetics. The U.S. Food and Drug Administration (FDA) has granted the investigational medicine NKTR-181 Fast Track designation for the treatment of moderate to severe chronic pain.

"The data presented at PAINWeek for SUMMIT-07 show that NKTR-181 represents a major step forward for the treatment of chronic pain and could be a fundamental building block in the fight against prescription opioid abuse," said Ivan Gergel, MD, Senior Vice President and Chief Medical Officer of Nektar Therapeutics. "Conventional opioid analgesics can produce withdrawal symptoms after cessation of chronic administration, which can lead to drug craving and opioid misuse. The withdrawal measurements taken throughout the efficacy trial of NKTR-181 show that 98 percent or more of patients in the study experienced no opioid withdrawal either during or after treatment with NKTR-181. The totality of our efficacy and safety data show that NKTR-181 provides strong analgesia in patients suffering from chronic pain without fear of serious safety concerns or the potential for abuse and addiction of conventional opioids. We are highly committed to bringing this critical new medicine to patients and physicians as quickly as possible."

Pain is one of the most common reasons people seek medical treatment.[2] Low back pain is the second most common cause of disability for adults in the U.S. [3] Approximately 149 million work days are lost every year because of low back pain, with total costs estimated to be $100 to 200 billion a year (of which two-thirds is due to lost wages and lower productivity).[4] A study published in the American Pain Society's The Journal of Pain in October 2014 estimated that 19 percent of the U.S. population, or 39 million people, suffer from some type of persistent pain.[5]

The poster session presented at PAINWeek began Wednesday, September 6th at 3:00 p.m. Pacific Daylight Time. Authors will be available at the Scientific Session reception on Thursday, September 7th from 6:30 - 8:30 p.m. PDT.

Links to the poster presentations at PAINWeek® are below:

Poster Number: 41
Title: Efficacy, safety, and tolerability of NKTR-181 in patients with moderate to severe chronic low-back pain: A Phase 3 study, Markman J, et al.

Poster Number: 38
Title: Measuring withdrawal in a phase 3 study of a new analgesic, NKTR-181, in subjects with moderate to severe chronic low-back pain, Henningfield, J., et al.

Opioid analgesics are commonly used in the treatment of chronic pain; however, their use is limited by poor tolerability and a high prevalence of abuse and drug-related mortality.[6-8]. NKTR-181 was designed to have a reduced rate of entry into the central nervous system (CNS) compared with standard opioids, thereby reducing a key pharmacokinetic risk factor related to potential for euphoria and abuse.[9]

About Nektar
Nektar Therapeutics is a research-based development stage biopharmaceutical company whose mission is to discover and develop innovative medicines to address the unmet medical needs of patients. Our R&D pipeline of new investigational medicines includes treatments for cancer, auto-immune disease and chronic pain. We leverage Nektar's proprietary and proven chemistry platform in the discovery and design of our new therapeutic candidates. 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.

About NKTR-181
NKTR-181 is the first long-acting, selective mu-opioid agonist designed to provide potent pain relief without the inherent high levels of euphoria which lead to abuse and addiction with standard opioids. The novel molecular structure of NKTR-181 is

designed to have low permeability across the blood-brain barrier in order to slow its rate of entry into the brain and attenuate the dopamine release that underlies euphoria. In addition, NKTR-181 is designed with an inherent 12-hour elimination half-life to enable twice-daily dosing with continuous pain control.

Current and past strategies of abuse deterrence to address the addictive qualities of standard opioids rely on formulations alone. However, all abuse-deterrent formulations are pre-cursors to highly euphorigenic rapid-acting opioids, which can be liberated through tampering. The National Survey on Drug Use and Health (NSDUH) indicated that 16.0 million people in the U.S. reported using oxycodone products non-medically in their lifetime in 2012.

Preclinical and clinical data show that the inherent properties of NKTR-181 reduce its rate of entry into the brain compared to standard mu opioids, regardless of route of administration.[10]

The U.S. Food and Drug Administration (FDA) has granted the investigational medicine NKTR-181 Fast Track designation for the treatment of moderate to severe chronic pain. NKTR-181 is an investigational medicine and has not been approved by the FDA or any other regulatory agencies.

PAINWeek® is a registered trademark of painweek.org.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements which can be identified by words such as: "plan," "expect," "may," "will," "believe," "can," "should," "could" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding the potential therapeutic benefit of NKTR-181 for treating patients with pain, the potential importance of NKTR-181 in addressing opioid abuse, the risks of opioid abuse resulting from use of NKTR-181, and certain other statements regarding the prospects and potential of NKTR-181 specifically, and Nektar's business and technology platform generally. 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 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: (i) challenges and uncertainties inherent in pharmaceutical research and development, including the uncertainty of future clinical and regulatory success, where the risk of failure remains high and failure can unexpectedly occur at any stage prior to regulatory approval due to lack of sufficient efficacy, safety considerations or other factors; (ii) the regulatory pathway to review and approve NKTR-181 for use in patients, even with a Fast Track designation by the FDA, is subject to substantial uncertainty; (iii) regulations concerning and controlling the access to opioid-based pharmaceuticals are strict and there is no guarantee which scheduling category will apply to NKTR-181 if regulatory approval is achieved; (iv) drug manufacturing challenges which can delay or render unavailable sufficient supplies of NKTR-181; (v) changing standards of care and new regulations (including, but not limited to, standards and regulations related to health care cost containment) can affect the use NKTR-181 and commercial success following a regulatory approval; (vi) Nektar's patent applications for NKTR-181 may not issue in one or more jurisdictions, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required in the future; (vii) the outcome of any existing or future intellectual property or other litigation related to Nektar's proprietary product candidates, including, without limitation, NKTR-181, is unpredictable and could have a material adverse effect on our business; and (viii) certain other important risks and uncertainties set forth in Nektar's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017 filed with the Securities and Exchange Commission on August 9, 2017. 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.

Contact:

For Investors:
Jennifer Ruddock of Nektar Therapeutics
415-482-5585

Jodi Sievers of Nektar Therapeutics
415-482-5593

For Media:
Jennifer Paganelli
347-658-8290
jpaganelli@purecommunications.com

1. Melnikova, I, Pain Market, Nature Reviews Drug Discovery, Volume 9, 589-90 (August 2010).
2. 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).
3. Arch Intern Med 2009 February 9; 169(3): 251-258.

4. World Health Organization: Priority Medicines for Europe and the World Update Report, 2013; Background Paper 6.24, Low Back Pain.
5. http://americanpainsociety.org/about-us/press-room/persistent-pain-incidence-news-release.
6. Ballantyne JC. Assessing the prevalence of opioid misuse, abuse, and addiction in chronic pain. *Pain.* 2015;156(4):567-568.
7. Centers for Disease Control and Prevention (CDC). Increases in drug and opioid overdose deaths—United States, 2000-2014. *MMWR.* 2016;64(50):1378-1382.
8. Chou R, Turner JA, Devine EB, Hansen RN, Sullivan SD, Blazina I, et al. The effectiveness and risks of long-term opioid therapy for chronic pain: a systematic review for a National Institutes of Health Pathways to Prevention Workshop. *Ann Intern Med.* 2015;162(4):276-286.
9. Miyazaki T, et al., *J Pharmacol Exp Ther.* 2017. doi:10.1124/jpet.117.243030.
10. 2010 Society of Neuroscience Annual Meeting (Nov 13-17, #HHH11).

View original content:http://www.prnewswire.com/news-releases/nektar-therapeutics-presents-clinical-data-from-phase-3-summit-07-study-of-nktr-181-a-first-in-class-investigational-opioid-to-treat-chronic-pain-at-2017-painweek-300515073.html

SOURCE Nektar Therapeutics

News Provided by Acquire Media