Nektar Therapeutics Announces New Drug Application for NKTR-181 Accepted for Review by FDA

Treatment for Pain

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SAN FRANCISCO, July 30, 2018 /PRNewswire/ — Nektar Therapeutics (Nasdaq: NKTR) today announced that the U.S. Food and Drug Administration (FDA) has filed and accepted for review the company's New Drug Application (NDA) for NKTR-181 for the treatment of chronic low back pain in adult patients new to opioid therapy. NKTR-181 is a new molecular entity (NME) and the first analgesic opioid molecule to exhibit a low incidence of specific CNS-mediated side effects, such as euphoria, through the targeted alteration of brain-entry kinetics. The NDA is expected to be assigned a PDUFA (Prescription Drug User Fee Act) target action date of May 28, 2019 by the FDA.

Nektar's NDA submission is supported by an extensive clinical and nonclinical data package. The clinical data submitted in the NDA comprised 15 studies in 2,234 subjects and includes a 600-patient efficacy study in patients with chronic low back pain who are new to opioid therapy; a 630-patient long-term 52-week safety study in patients with noncancer pain, who are new to opioid therapy, as well as those who are experienced with opioid therapy; pharmacokinetic/ pharmacodynamic studies in over 450 subjects; and two human abuse potential studies evaluating both therapeutic and supratherapeutic doses of NKTR-181 versus an oxycodone control in recreational drug users.

NKTR-181 is an investigational medicine and has not been approved by the FDA or any other regulatory agencies. While the NDA submission for NKTR-181 has been accepted for review by the FDA, such acceptance does not mean that NKTR-181 will be approved by the FDA.

About Chronic Low Back Pain

Low back pain is the second most common cause of disability for adults in the U.S.1 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).2

About NKTR-181

NKTR-181 is the first long-acting, selective full mu-opioid receptor agonist designed to provide potent pain relief, without the inherent high levels of euphoria, which contribute to abuse and addiction with 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 has a 14-hour elimination half-life to enable twice-daily dosing for pain control.

Current and past strategies of abuse deterrence to address the abuse potential properties 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.

NKTR-181 is not a prodrug, a reformulation, or a drug product formulated for sustained release of an existing opioid. Nonclinical 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.3

About Nektar Therapeutics

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.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements which can be identified by words such as: "design," "leads to," "address," "can," "will," 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 low back 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. 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 the regulatory review of new drugs, where the risk of failure remains high due to negative determinations by the FDA or other regulatory agencies regarding efficacy, safety or other requirements, which determinations which are outside the control of Nektar; (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 both in the United States and in equivalent foreign regulatory agencies; (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 filed with the Securities and Exchange Commission on May 10, 2018. 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.

1. Arch Intern Med 2009 February 9; 169(3): 251-258.

2. World Health Organization: Priority Medicines for Europe and the World Update Report, 2013; Background Paper 6.24, Low Back Pain.

3. 2010 Society of Neuroscience Annual Meeting (Nov 13-17, #HHH11)

SOURCE Nektar Therapeutics

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NKTR-181 (loxicodegol) FDA Approval History