Nektar Issues Statement Regarding FDA Advisory Committee Vote for Oxycodegol

January 14, 2020

SAN FRANCISCO, Jan. 14, 2020 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) issued a statement today following a meeting of the Food and Drug Administration's (FDA's) Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and Drug Safety and Risk Management Advisory Committee (DSaRM) to discuss the New Drug Application (NDA) for oxycodegol (formerly NKTR-181) where the Committees did not recommend approval of oxycodegol.

The Company is disappointed in the Committees' vote regarding oxycodegol and believes it is also disappointing for patients suffering from chronic pain and the physicians that treat those patients who are currently relying on existing opioid therapies. The Company created oxycodegol specifically to both help these patients and physicians and address the opioid abuse epidemic. For the development of oxycodegol, the Company used well-established efficacy, safety and human abuse potential study designs that have led to many prior FDA approvals of opioid medications. The development program for oxycodegol included over 2,000 patients and volunteers.

As a result of today's vote at the meeting, the Company has decided to withdraw the NDA for oxycodegol and to make no further investment into the program.

The Company estimates that this will afford Nektar cost savings of between $75 million to $125 million in 2020 based upon its projections of the estimated costs related to commercialization plans and post-approval studies previously discussed with the FDA.

About Nektar Therapeutics

Nektar Therapeutics is a biopharmaceutical company with a robust, wholly-owned R&D pipeline of investigational medicines in oncology and immunology as well as a portfolio of approved partnered medicines. 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.

Forward-Looking Statements

This statement contains forward-looking statements which can be identified by words such as: "will," "estimate," and similar references to future periods. Examples of forward-looking statements include, among others, the estimated savings associated with withdrawing the NDA for oxycodegol. 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, 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) the accuracy of estimates regarding cost savings is based on a number of assumptions, which are necessarily uncertain and subject to change, including management estimates of cost savings; and (ii) certain other important risks and uncertainties set forth in the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 7, 2019. 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.

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