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Nektar Therapeutics and Daiichi Sankyo Europe GmbH Sign European Licensing Agreement for ONZEALD™ (etirinotecan pegol), an Investigational Drug Candidate Being Developed to Treat Patients with Advanced Breast Cancer and Brain Metastases

SAN FRANCISCO, June 1, 2016 /PRNewswire/ -- Nektar Therapeutics (Nasdaq: NKTR) today announced that it has entered into an agreement with Daiichi Sankyo Europe for Nektar's investigational drug therapy, ONZEALD (etirinotecan pegol, NKTR-102), which has completed a Phase 3 clinical trial (the BEACON study) in patients with advanced breast cancer. The agreement grants Daiichi Sankyo Europe exclusive rights to market ONZEALD in Europe (EEA), Switzerland and Turkey. Nektar Therapeutics will retain rights to ONZEALD in the United States and the rest of the world.

Under the terms of the agreement, Nektar Therapeutics is entitled to an upfront payment of $20 million as well as an additional $60 million in milestone payments, based upon the achievement of European regulatory milestones and European sales of ONZEALD. Nektar is also entitled to significant double-digit royalties on net sales in Europe.

"This new collaboration with Daiichi Sankyo Europe allows Nektar to advance ONZEALD to a potential conditional approval and availability in Europe as early as next year, and also enables us to retain ownership of the drug in the U.S. and rest of world," said Howard W. Robin, President and Chief Executive Officer of Nektar Therapeutics. "We are pursuing conditional approval for ONZEALD based on highly promising data from our Phase 3 BEACON clinical trial in the pre-specified subgroup of patients with advanced breast cancer who have a history of brain metastases. A diagnosis of brain metastases in women with advanced breast cancer is devastating and there are no therapies approved to treat this specific patient population."

Nektar plans to submit an MAA filing in June 2016 seeking conditional approval from the European Medicines Agency (EMA) for the use of ONZEALD in the treatment of patients with advanced breast cancer and brain metastases. On May 26, 2016, the Committee for Medicinal Products for Human Use (CHMP) granted an accelerated assessment procedure for the planned ONZEALD filing, which provides for an accelerated MAA review timeline.

Nektar will be responsible for sponsoring and funding the confirmatory trial which will support the Marketing Authorization Application (MAA) filing for ONZEALD in Europe. The data from the confirmatory trial can be used by Nektar for a potential U.S. new drug application (NDA) filing for ONZEALD.

Breast cancer is the most frequently diagnosed cancer in women worldwide with nearly 1.7 million new cases diagnosed in 2012.[1] There are approximately 250,000 newly-diagnosed cases of breast cancer in the United States and 470,000 in Europe each year. [1] Approximately 10-30 percent of patients with advanced breast cancer are also diagnosed with brain metastases. [2]

Nektar's planned MAA filing is based upon data from a subgroup of patients from the completed BEACON study of single-agent ONZEALD in patients with advanced breast cancer. In this subgroup of 67 patients who also had a history of brain metastases, treatment with single-agent ONZEALD resulted in an improvement in median overall survival (OS) of 5.2 months compared to treatment with a single-agent chemotherapy of physician's choice (TPC) (10 months vs. 4.8 months, $P < 0.01$). TPC included a choice of ixabepilone, vinorelbine, gemcitabine, eribulin or a taxane. In the planned primary analysis for the overall patient population in the BEACON study, ONZEALD median OS was 2.2 months longer than TPC (12.4 months vs. 10.3 months, $P= 0.08$).[3] In the overall patient population in the BEACON study, fewer patients in the ONZEALD arm had grade 3 or worse adverse events (AEs) than those in the TPC arm (204 [48%] vs. 256 [63%]; $p < 0{\cdot}0001$).[3] The most common grade 3 and above AEs observed with ONZEALD were diarrhea (9.6%), neutropenia (9.6%), anemia (4.7%) and fatigue (4.5%). The most common grade 3 and above AEs observed with TPC were neutropenia (30.8%), anemia (4.7%), and dyspnea (4.4%).

In order to satisfy the EMA's requirement for additional controlled data with the MAA for conditional approval, Nektar will sponsor a global, randomized Phase 3 trial of ONZEALD in approximately 350 patients with advanced breast cancer and brain metastases. The trial will compare ONZEALD to TPC and the primary endpoint in the trial will be OS. The trial will include a pre-specified interim analysis for OS which is to be conducted after 130 events have been observed in the trial. The U.S. Food and Drug Administration has also reviewed the Phase 3 study design with the Statistical Analysis Plan, and indicated the trial could serve as a potential registrational study by Nektar for purposes of seeking approval of ONZEALD to

treat this patient population in the U.S.

The EMA may grant conditional marketing authorization when the potential treatment addresses a severely debilitating disease with an unmet medical need, has a positive benefit to risk profile, and the benefits to public health of its immediate availability outweigh the risks inherent in the fact that additional data are still required. Ongoing or new studies must be completed with the objective of confirming that the benefit to risk balance is positive. A conditional approval granted by the EMA is renewed on an annual basis until all obligations have been fulfilled, at which point a full approval may be granted by the EMA.

For additional terms and conditions of the licensing agreement between Nektar and Daiichi Sankyo Europe, please refer to the Current Report on Form 8-K filed today with the Securities and Exchange Commission.

About ONZEALD (etirinotecan pegol) (formerly NKTR-102)

ONZEALD is the first long-acting topoisomerase I inhibitor with an extended half-life and a unique structure that is designed to concentrate the drug in tumors. In patients, ONZEALD leads to greatly prolonged plasma SN38 exposure compared with irinotecan (elimination half-life of 37 days compared with 2 days) yet peak SN38 concentrations are at least 5- to 10-times less, which may also result in a favorable tolerability profile. ONZEALD was evaluated in a Phase 3, open-label, randomized, multicenter study (the BEACON study) that enrolled 852 women with locally recurrent or metastatic breast cancer, who have previously been treated with an anthracycline, taxane and capecitabine therapies.

About Nektar Therapeutics

Nektar Therapeutics has a robust R&D pipeline and portfolio of approved partnered medicines in oncology, pain, immunology and other therapeutic areas. In oncology, Nektar is also developing NKTR-214, an immuno-stimulatory CD122-biased agonist, which is in Phase 1/2 clinical development for patients with solid tumors. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for MOVANTIK™ (naloxegol), the first FDA-approved once-daily oral peripherally-acting mu-opioid receptor antagonist (PAMORA) medication for the treatment of opioid-induced constipation (OIC), in adult patients with chronic, non-cancer pain. The product is also approved in the European Union as MOVENTIG® (naloxegol) and is indicated for adult patients with OIC who have had an inadequate response to laxatives. NKTR-181, a wholly owned mu-opioid analgesic molecule for chronic pain conditions, is in Phase 3 development. In hemophilia, Nektar has a collaboration agreement with Baxalta for ADYNOVATE™ [Antihemophilic Factor (Recombinant)], a longer-acting PEGylated Factor VIII therapeutic approved in the U.S. and Japan for patients over 12 with hemophilia A. In anti-infectives, the company has two collaborations with Bayer Healthcare, Cipro Inhale in Phase 3 for non-cystic fibrosis bronchiectasis and Amikacin Inhale in Phase 3 for patients with Gram-negative pneumonia.

Nektar's technology has enabled nine approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including AstraZeneca's MOVANTIK™, Baxalta's ADYNOVATE™, 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.

MOVANTIK™ is a trademark and MOVENTIG® is a registered trademark of the AstraZeneca group of companies. ADYNOVATE™ is a trademark of Baxalta Inc.

ONZEALD™ is a trademark of Nektar Therapeutics.

Cautionary Note Regarding Forward-Looking Statements

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," "could," "potential," "believe," 'will" and similar reference to future periods. Examples of forward-looking statements include, among others, statements we make regarding the potential of ONZEALD, our regulatory plans for ONZEALD in Europe including the potential for conditional approval, and the value and potential of our technology and research and development 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 future of our business, future plans and strategies, anticipated events and trends, the economy and other future conditions. Important factors that could cause our actual results to differ materially from those indicated in the forward-looking statements include, among others: (i) the EMA has substantial discretion as to whether to grant marketing approval for ONZEALD and the EMA's final decisions are difficult to predict and the final decisions of the EMA for conditional or final approval of ONZEALD have significant financial consequences under the terms of our agreement with Daiichi Sankyo Europe, including payment and

milestone provisions; (ii) the risk of failure of any product candidate that is in clinical development and prior to regulatory approval is high and can occur at any stage due to efficacy, safety or other factors; (iii) the failure to achieve pre-specified regulatory outcomes with the EMA could result in a termination payment or reduced or no further milestone or royalty payments to Nektar from Daiichi, (iv) patents may not issue from Nektar's patent applications for ONZEALD and patents that have issued may not be enforceable; (v) potential future third-party intellectual property or licensing disputes and other litigation related to our drugs and drug candidates and those of our collaboration partners; and (vi) certain other important risks and uncertainties set forth in our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 4, 2016. Actual results could differ materially from these forward-looking statements. 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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1. *American Cancer Society, Global Cancer Facts and Figures 3rd Edition, 2012.*
2. *Witzel et al. Breast Cancer Research (2016) 18:8*
3. *Perez et. al., ASCO 2015.*