# Nektar Reports Affymax Announced FDA Advisory Committee Voted in Favor of Benefit/Risk Profile for Peginesatide for Treatment of Anemia in Chronic Kidney Disease Patients on Dialysis

SAN FRANCISCO, Dec. 8, 2011 /PRNewswire/ -- Nektar Therapeutics (NASDAQ:NKTR) today reported that its partner Affymax, Inc. announced that the U.S. Food and Drug Administration (FDA) Oncologic Drugs Advisory Committee (ODAC) voted 15 to 1, with 1 abstention, that peginesatide demonstrated a favorable benefit/risk profile for use in the treatment of dialysis patients with anemia due to chronic kidney disease (CKD).

Nektar and Affymax have an exclusive agreement under which Nektar provides Affymax with its proprietary PEGylation technology for use in peginesatide. Under the terms of the agreement, Nektar receives manufacturing revenue, milestone and other payments, and is entitled to receive royalties on the global sales of peginesatide for all indications.

Nektar's technology has enabled seven approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including UCB's Cimzia® for Crohn's disease and rheumatoid arthritis, Pfizer's Somavert® for acromegaly, Roche's MIRCERA® for anemia, Roche's PEGASYS® for hepatitis C, and Amgen's Neulasta® for neutropenia.

While the FDA is not bound by the recommendations of its advisory committees, their guidance will be considered by the FDA in its review of the New Drug Application (NDA) that was submitted by Affymax, Inc. for peginesatide in May 2011. The scheduled Prescription Drug User Fee Act (PDUFA) date for peginesatide is March 27, 2012.

**About Peginesatide**

Peginesatide is a synthetic PEGylated peptidic compound that binds to and stimulates the erythropoietin receptor and thus acts as an ESA. The compound was discovered by Affymax and is being co-developed by Affymax and Takeda Pharmaceutical Company Limited. The peginesatide Phase 3 clinical program was the largest to support the new drug application of an ESA in the treatment of anemia in CKD and the first to prospectively evaluate the cardiovascular safety of an ESA via an analysis of independently adjudicated cardiovascular events. If approved, peginesatide may be the first once-monthly product for anemia in CKD for dialysis patients available in the United States.

**About Nektar Therapeutics**

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 areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for NKTR-118, an investigational drug candidate, being evaluated in Phase 3 clinical studies as a once-daily, oral tablet for the treatment of opioid-induced constipation. The agreement also includes NKTR-119, an earlier stage development program that is a co-formulation of NKTR-118 and an opioid. NKTR-181, a novel mu-opioid analgesic molecule, has completed Phase 1 single and multiple dose clinical studies, and is being prepared to start Phase 2. In oncology, NKTR-102, a novel topoisomerase I-inhibitor, is being evaluated in Phase 2 clinical studies for the treatment of breast, ovarian and colorectal cancers.

Nektar is headquartered in San Francisco, California, with additional R&D 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 press release contains forward-looking statements that reflect management's current views regarding peginesatide and certain drug candidates in Nektar's pipeline. These forward-looking statements involve numerous risks and uncertainties, including but not limited to: (i) ODAC's recommendation is not binding on the FDA and whether the FDA approves peginesatide for use in the treatment of dialysis patients with anemia due to CKD will depend on numerous factors that are difficult to predict such as the FDA's interpretation and review of the data in the NDA (including issues related to the subgroup analyses in non-

dialysis patients), clinical study design, the completeness of the NDA (including data quality and integrity of Affymax's non-inferiority designed trials), the continued safety and efficacy of peginesatide in clinical development, the risk/benefit profile of peginesatide for patients, and many other important factors that could negatively influence the FDA's decision; (ii) Nektar's product candidates and those of its collaboration partners are in various stages of clinical development and the risk of failure is high and can unexpectedly occur at any stage prior to regulatory approval for numerous reasons including safety and efficacy findings even after positive findings in preclinical and clinical studies; (iii) the timing of the commencement or end of clinical trials and the successful commercial launch of our drug candidates may be delayed or unsuccessful due to slower than anticipated patient enrollment, manufacturing challenges, changing standards of care, regulatory delay, evolving regulatory requirements, clinical trial design, clinical outcomes, competitive factors, or delay or failure in ultimately obtaining regulatory approval in one or more important markets; (iv) scientific discovery of new medical breakthroughs is an inherently uncertain process and the future success of the application of Nektar's technology platform to potential new drug candidates is therefore highly uncertain and unpredictable and one or more research and development programs could fail; (v) Nektar's patent applications for its proprietary or partner product candidates may not issue, patents that have issued may not be enforceable, or additional intellectual property licenses from third parties may be required in the future; (vi) the outcome of any future intellectual property or other litigation related to Nektar's proprietary product candidates or complex commercial agreements; and (vii) 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 November 4, 2011. Actual results could differ materially from the forward-looking statements contained in this press release. Nektar undertakes no obligation to update forward-looking statements, whether as a result of new information, future events or otherwise.


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