Nektar Reports that Partner Affymax Has Announced FDA Approval of OMONTYS® (Peginesatide) Injection for the Treatment of Anemia Due to Chronic Kidney Disease in Adult Patients on Dialysis

SAN FRANCISCO, March 28, 2012 /PRNewswire/ -- Nektar Therapeutics (NASDAQ: NKTR) today reported that its partner Affymax, Inc. announced that the U.S. Food and Drug Administration (FDA) has approved OMONTYS® (peginesatide) Injection for the treatment of anemia due to chronic kidney disease (CKD) in adult patients on dialysis.

Nektar and Affymax have an exclusive agreement under which Nektar provides Affymax with its proprietary PEGylation technology for use in OMONTYS®. Under the terms of the agreement, Nektar is entitled to milestones, manufacturing revenues, and royalties on the global sales of OMONTYS®.

Nektar's technology has now enabled eight approved products in the U.S. or Europe through partnerships with leading biopharmaceutical companies, including Affymax's OMONTYS®, 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.

About OMONTYS®

OMONTYS® (peginesatide) Injection is a synthetic, pegylated, peptide-based ESA. It is the only ESA that is peptide-based and its building blocks (amino acids) are arranged in a different order than erythropoietin (i.e., it has no sequence homology to endogenous erythropoietin). OMONTYS was discovered by Affymax and will be co-commercialized in the United States by Affymax and Takeda. In February 2012, Takeda and its wholly-owned subsidiary, Takeda Global Research & Development Centre (Europe) Ltd., announced the acceptance of a Marketing Authorization Application for peginesatide by the European Medicines Agency. The application is currently under review by that agency.

The objective of the OMONTYS Phase 3 dialysis studies (EMERALD 1 and 2) was to evaluate the safety and efficacy of OMONTYS, dosed once monthly, compared to epoetin alfa or beta, dosed one-to-three times per week (according to the product labels), in maintaining Hb levels. The primary efficacy endpoint of these two studies was a mean change in Hb between baseline and evaluation period (between weeks 29 through 36) following entry into the study.

In the EMERALD studies, CKD patients on dialysis who were stable on epoetin were randomized to receive OMONTYS either once monthly or to continue treatment with epoetin.

For more information about OMONTYS, visit www.omontys.com.

About Nektar

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 therapeutic areas. In the area of pain, Nektar has an exclusive worldwide license agreement with AstraZeneca for NKTR-118, an investigational drug candidate, which is 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, has completed Phase 1 development and is being prepared for a Phase 2 study. NKTR-102 is being evaluated in a Phase 3 clinical study for the treatment of metastatic breast cancer and Phase 2 studies for the treatment of ovarian and colorectal cancers.

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.

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