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Takeda and Affymax Announce Supply Agreement for OMONTYS® (peginesatide) Injection with Fresenius Medical Care North America

DEERFIELD, Ill. & PALO ALTO, Calif.--(BUSINESS WIRE)-- Takeda Pharmaceuticals U.S.A. (TPUSA) and Affymax, Inc. (Nasdaq:AFFY) today announced that Takeda Pharmaceuticals America, Inc. (TPA) has entered into a supply agreement for sourcing and supply of OMONTYS® (peginesatide) Injection to Fresenius Medical Care North America and certain of its affiliates. OMONTYS is the only once-monthly erythropoiesis-stimulating agent (ESA) for anemia available to the dialysis patient population with chronic kidney disease (CKD) in the United States.

The agreement, which ends in April 2013, allows Fresenius Medical Care North America to purchase OMONTYS for use in U.S. centers within its organization and provides for discounts and rebates on the product, subject to certain requirements. Fresenius Medical Care North America has stated that its initial plans are to adopt the product into more than 100 dialysis centers in the U.S. over the next few weeks, and then, based on its experience, evaluate the potential to expand to additional centers. Financial terms were not disclosed.

"We are excited to partner with Fresenius Medical Care North America, one of the world's leading dialysis providers, to offer a new therapeutic option for the treatment of anemia in its chronic kidney disease patients on dialysis," said Nicole Mowad-Nassar, vice president, marketing at Takeda.

"As a biotechnology company dedicated to advancing new therapies for renal diseases, Affymax shares Fresenius Medical Care North America's commitment to innovation," stated John Orwin, chief executive officer of Affymax. "We are very pleased to support Fresenius Medical Care in these efforts to integrate OMONTYS into its organization and to collaborate with them moving forward."

OMONTYS was approved by the FDA on March 27, 2012, for the treatment of anemia due to CKD in adult patients on dialysis. OMONTYS is not indicated, and is not recommended, for use in patients with CKD not on dialysis, in patients receiving treatment for cancer and whose anemia is not due to CKD, or as a substitute for red blood cell (RBC) transfusions in patients who require immediate correction of anemia. OMONTYS has not been shown to improve symptoms, physical functioning, or health-related quality of life. Please see Important Safety Information including **Boxed WARNINGS** below.

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).

On March 27, 2012, the United States Food and Drug Administration approved OMONTYS for the treatment of anemia due to CKD in adult patients on dialysis. OMONTYS is the only once-monthly erythropoiesis-stimulating agent (ESA) for anemia available to this patient population in the United States.

About Anemia Due to CKD in Adult Patients on Dialysis

Anemia is a complication of CKD and is associated with cardiovascular illness and mortality. As of 2009, the United States Renal Data System noted there were nearly 400,000 people in the United States who were on dialysis.

About Fresenius Medical Care

Fresenius Medical Care is the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 2.1 million individuals worldwide. Through its network of 3,119 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatment to 253,041 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products.

For more information about Fresenius Medical Care, visit the company's website at www.fmc-ag.com.

IMPORTANT SAFETY INFORMATION

WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE.

Chronic Kidney Disease:

- In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL.
 - No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.
 - Use the lowest OMONTYS dose sufficient to reduce the need for red blood cell (RBC) transfusions.
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Contraindications

OMONTYS is contraindicated in patients with uncontrolled hypertension.

Warnings and Precautions

Increased mortality, myocardial infarction, stroke, and thromboembolism:

- Using ESAs to target a hemoglobin level of greater than 11 g/dL increases the risk of serious adverse cardiovascular reactions and has not been shown to provide additional benefit. Use caution in patients with coexistent cardiovascular disease and stroke. Patients with CKD and an insufficient hemoglobin response to ESA therapy may be at even greater risk for cardiovascular reactions and mortality than other patients. A rate of hemoglobin rise of > 1 g/dL over 2 weeks may contribute to these risks
- In controlled clinical trials of ESAs in patients with cancer, increased risk for death and serious adverse cardiovascular reactions was observed. These adverse reactions included myocardial infarction and stroke
- In controlled clinical trials of ESAs, ESAs increased the risk of death in patients undergoing coronary artery bypass graft surgery (CABG) and deep venous thrombosis (DVT) in patients undergoing orthopedic procedures
- In 2 trials of OMONTYS, patients with CKD not on dialysis experienced increased specific cardiovascular events

Increased mortality and/or increased risk of tumor progression or recurrence in patients with cancer: The safety and efficacy of OMONTYS have not been established for use in patients with anemia due to cancer chemotherapy. OMONTYS is not indicated in patients with cancer receiving chemotherapy.

Hypertension: OMONTYS is contraindicated in patients with uncontrolled hypertension. Appropriately control hypertension prior to initiation of and during treatment with OMONTYS. Reduce or withhold OMONTYS if blood pressure becomes difficult to control. Advise patients of the importance of compliance with antihypertensive therapy and dietary restrictions.

Lack or loss of response to OMONTYS: For lack or loss of hemoglobin response to OMONTYS, initiate a search for causative factors. If typical causes of lack or loss of hemoglobin response are excluded, evaluate for antibodies to peginesatide.

Dialysis management: Patients receiving OMONTYS may require increased anticoagulation with heparin to prevent clotting of the extracorporeal circuit during hemodialysis.

Laboratory monitoring: Evaluate transferrin saturation and serum ferritin prior to and during OMONTYS treatment. Administer supplemental iron therapy when serum ferritin is less than 100 mcg/L or when serum transferrin saturation is less than 20%.

Adverse reactions

The most common adverse reactions in clinical studies in patients with CKD on dialysis treated with OMONTYS were dyspnea, diarrhea, nausea, cough, and arteriovenous fistula site complication.

Please click [here](#) for Full Prescribing Information, including Boxed WARNINGS, or visit www.omontys.com.

About Affymax, Inc.

Affymax, Inc. is a biopharmaceutical company based in Palo Alto, California. Affymax's mission is to discover, develop and deliver innovative therapies that improve the lives of patients with kidney disease and other serious and often life-threatening

illnesses. The company's first marketed product, OMONTYS, was approved by the U.S. Food and Drug Administration (FDA) in March 2012. For additional information on Affymax, please visit www.affymax.com.

This release contains forward-looking statements, including statements regarding the timing, terms and potential of an agreement with Fresenius Medical Care North America, the potential advantages of OMONTYS, the continuation and success of Affymax's collaboration with Takeda and the commercialization of OMONTYS. Affymax's actual results may differ materially from those indicated in these forward-looking statements due to risks and uncertainties, including risks relating to the continued safety and efficacy of OMONTYS, industry and competitive environment, regulatory requirements by the FDA or other regulatory authorities, including post-marketing studies, trials and Risk Evaluation and Mitigation Strategy, the timing of patient accrual in ongoing and planned clinical studies, financing requirements and our ability to access capital and other matters that are described in Affymax's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Affymax undertakes no obligation to update any forward-looking statement in this press release.

About Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc.

Based in Deerfield, Ill., Takeda Pharmaceuticals U.S.A., Inc. and Takeda Development Center Americas, Inc. are subsidiaries of Takeda Pharmaceutical Company Limited, the largest pharmaceutical company in Japan. The respective companies currently market oral diabetes, insomnia, rheumatology, gastroenterology and cardiovascular disease treatments and seek to bring innovative products to patients through a pipeline that includes compounds in development for diabetes, gastroenterology, neurology and other conditions. To learn more about these Takeda companies, visit www.tpna.com.

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume," "continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.

The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.

Photos/Multimedia Gallery Available: <http://www.businesswire.com/cgi-bin/mmg.cgi?eid=50338610&lang=en>

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Source: Takeda Pharmaceuticals U.S.A. and Affymax, Inc.

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