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Affymax and Takeda Announce a Nationwide Voluntary Recall of All Lots of OMONTYS® (peginesatide) Injection

PALO ALTO, Calif., February 23, 2013 and OSAKA, Japan, February 24, 2013 – (BUSINESS WIRE) – Affymax, Inc. (Nasdaq: AFFY) and Takeda Pharmaceutical Company Limited (Takeda) today have decided to voluntarily recall all lots of OMONTYS® (peginesatide) Injection to the user level as a result of new postmarketing reports regarding serious hypersensitivity reactions, including anaphylaxis, which can be life-threatening or fatal. The companies have been working actively with the U.S. Food and Drug Administration (FDA) which has indicated its agreement with this decision. The companies have also issued a letter to health care professionals indicating that no new or existing patients should receive OMONTYS.

To date, fatal reactions have been reported in approximately 0.02% of patients following the first dose of intravenous administration. The reported serious hypersensitivity reactions have occurred within 30 minutes after such administration of OMONTYS. There have been no reports of such reactions following subsequent dosing, or in patients who have completed their dialysis session. Since launch, more than 25,000 patients have received OMONTYS in the postmarketing setting. The rate of overall hypersensitivity reactions reported is approximately 0.2% with approximately a third of these being serious in nature including anaphylaxis requiring prompt medical intervention and in some cases hospitalization. The companies are actively investigating these cases. In the meantime, dialysis organizations are instructed to discontinue use. Customers will be provided instructions on how to return the product to the manufacturer for a refund. For customers with questions, please call 1-855-466-6689 [9:00 a.m. to 5:00 p.m. Eastern Standard Time, Monday through Friday].

OMONTYS (peginesatide) Injection is indicated for the treatment of anemia due to chronic kidney disease in adult patients on dialysis and is packaged in 10 mg and 20 mg Multi-dose vials:

10mg Multi-dose Vials - NDC 64764-610-10

20mg Multi-dose vials - NDC 64764-620-20

All lots of OMONTYS are affected by this recall:

10 mg Multi-dose vials	20 mg Multi-dose vials
Lots C18685, C18881, C19258	Lots C18686, C18696

The product can be identified by its product labeling featuring the name OMONTYS. OMONTYS was distributed Nationwide, including Puerto Rico and Guam, to dialysis centers via specialty distributors.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**:www.fda.gov/medwatch/report.htm
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Affymax Teleconference and Webcast

Affymax will host a teleconference and webcast at 5:30 a.m. Pacific Time; 8:30 a.m. Eastern Time on Monday, February 25 to further discuss this news announcement. Interested parties can listen to the live teleconference by dialing (866) 393-1565 from the U.S. or +1(973) 409-9608 for international callers. Individuals may access the live audio webcast by visiting www.affymax.com and going to the Investors section. A replay of the webcast will be available on the company's website for 30 days following the live event.

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 RBC transfusions.**

Contraindications

OMONTYS is contraindicated in patients with uncontrolled hypertension and in patients who have had serious allergic reactions, which may include anaphylaxis, to OMONTYS.

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. 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 including myocardial infarction and stroke was observed.

- There is increased mortality and/or increased risk of tumor progression or recurrence in patients with cancer receiving ESAs.

- 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.

Hypertension (see Contraindications): Appropriately control hypertension prior to initiation of and during treatment with OMONTYS. Reduce or withhold OMONTYS if blood pressure becomes difficult to control.

Serious allergic reactions (see Contraindications): Serious allergic reactions, including anaphylactic reactions, hypotension, bronchospasm, angioedema and generalized pruritus, may occur in patients treated with OMONTYS. Immediately and permanently discontinue OMONTYS and administer appropriate therapy if a serious allergic reaction occurs.

Lack or loss of 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 adjustments to dialysis prescriptions and/or 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 100mcg/L or when serum transferrin saturation is less than 20%. Monitor hemoglobin every 2 weeks until stable and the need for RBC transfusions is minimized. Then, monitor monthly.

Adverse reactions
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, also available at www.omontys.com.

OMONTYS Indication and Limitations of Use

OMONTYS® (peginesatide) Injection is indicated for the treatment of anemia due to chronic kidney disease (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.

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. For additional information on Affymax, please visit www.affymax.com.

Affymax Forward-Looking Statement

This release contains forward-looking statements, including statements regarding the potential attributes and safety profile 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 recall and adverse events, ability to re-introduce OMONTYS to the market and future acceptance by dialysis organizations, patients and the medical community, and other factors affecting the commercial potential of OMONTYS, the continued safety and efficacy of OMONTYS, the industry and competitive environment, regulatory requirements or actions by the FDA or other regulatory authorities, including withdrawal, further changes to the label, post-marketing studies, trials and Risk Evaluation and Mitigation Strategy, the potential for disruptions to supply, potential litigation, 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 Pharmaceutical Company Limited
Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for patients worldwide through leading

innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

Takeda Forward-Looking Statement

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.

SOURCE: Affymax, Inc. and Takeda Pharmaceutical Company Limited

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