February 2013

IMPORTANT DRUG INFORMATION

Subject: Affymax and Takeda are instituting a voluntary product recall of OMONTYS following serious hypersensitivity reactions, including life threatening and fatal events, reported in patients receiving OMONTYS

Dear Healthcare Provider:

The purpose of this letter is to inform you to cease use of OMONTYS products in all patients at this time. All OMONTYS in your control should be quarantined until you receive further instructions on product returns. Any patients who have been given OMONTYS for home use should be immediately contacted and instructed to stop use of the product and to return the product to your facility.

This recall has been initiated due to postmarketing reports of serious hypersensitivity reactions in patients who received OMONTYS. Use of OMONTYS may result in serious hypersensitivity reactions including anaphylaxis, which may be life-threatening or fatal.

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.

No new or existing patients should receive OMONTYS. Patients returning to the clinic for future dosing should not receive OMONTYS and be converted to an alternative therapy as per your local clinical practice guidelines.

Should any patient that has already been dosed with OMONTYS present with hypersensitivity reactions, symptoms may respond to intravenous fluids, corticosteroids, epinephrine, and/or antihistamines.

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Reporting Adverse Events

To report all adverse events suspected with the use of OMONTYS contact:

- Affymax at 1-855-466-6689 [9:00 am to 5:00 pm Eastern Standard Time, Monday through Friday].

Adverse reactions or quality problems experienced with the use of this product may also 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 voluntary recall is being conducted with the knowledge of the Food and Drug Administration.

Further instructions on product returns will be provided in a further communication.

Sincerely,

Anne-Marie Duliege, M.D., M.S.
Chief Medical Officer
Affymax, Inc.