

**Initial REMS approval 03/2012**

**NDA 202799**

**OMONTYS<sup>®</sup> (peginesatide) Injection**  
**An erythropoiesis-stimulating agent (ESA)**

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**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOALS**

- To inform healthcare professionals that OMONTYS Injection is indicated only for use in the treatment of patients with anemia due to chronic kidney disease on dialysis.
- To inform healthcare professionals of the serious risks associated with the use of OMONTYS Injection including potentially fatal cardiovascular and/or thromboembolic adverse events, and the increased risk of these events in non-dialysis patients.

**II. REMS ELEMENTS**

**A. Communication Plan**

Affymax, Inc. will implement the following elements of a communication plan:

**1. A Dear Healthcare Professional (DHCP) letter** will be sent within 60 days of product approval or at the time of product launch, whichever is sooner, and again after 12 months. The letter will be available via a REMS-specific link from the OMONTYS website and through Affymax's medical information department for 2 years following approval of the REMS. The intended audience for this letter is the nephrology community of Healthcare Professionals (HCPs) who are likely to prescribe OMONTYS.

The letter will be sent to all nephrologists, to related professional societies, and to dialysis facilities. Dialysis facilities and professional societies receiving the DHCP letter will be requested to distribute the DHCP letter to their staff, including other HCPs, or membership.

In addition, for 18 months following approval of the REMS, new nephrologists and new dialysis facilities ordering OMONTYS will receive the letter if they have not previously received it. The list of HCPs to receive the letter will be derived from a comprehensive commercially available database.

Within 60 days of product approval or at the time of product launch, whichever is sooner, and again after 12 months, Affymax, Inc. will send the DHCP letter to the following professional organizations, and will request that the letter be provided to the members of the professional organizations:

National Renal Administrators Association (NRAA)  
American Society of Nephrology (ASN)  
Renal Physicians Association (RPA)  
American Nephrology Nurses Association (ANNA)  
National Kidney Foundation (NKF)

The letter will be available at the OMONTYS booth at the following scientific meetings for the two years following approval of OMONTYS:

American Nephrology Nurses Association (ANNA)  
National Kidney Foundation (NKF)  
National Renal Administrators Association (NRAA)  
American Society of Nephrology (ASN)  
Renal Physicians Association (RPA)

The letter will be provided to MedWatch at the same time it is provided to the professional organizations.

The Dear Healthcare Professional letter is part of the REMS and is appended.

The communication plan will be updated to reflect any changes in labeling for the risks outlined above.

Affymax, Inc. will make the REMS, the DHCP letter, and professional labeling available via a REMS-specific link from the OMONTYS website as well as through the medical information department for 2 years after the initial date of approval.

The OMONTYS REMS web page is part of the REMS; the landing page screen shot is appended.

## **B. Timetable for Submission of Assessments**

Affymax, Inc. will submit REMS Assessments to FDA at 12 months, 24 months, 36 months and 7 years from the date of initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by

each assessment should conclude no earlier than 60 days before the submission date for that assessment. Affymax, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.