

**BL 125268 Nplate<sup>®</sup> (romiplostim)**  
**Amgen Inc.**  
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**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOAL**

To inform healthcare providers about the risks of progression of myelodysplastic syndromes (MDS) to acute myelogenous leukemia (AML), thrombotic/thromboembolic complications, bone marrow reticulin formation, bone marrow fibrosis, worsened thrombocytopenia after cessation of Nplate<sup>®</sup>, and Nplate medication errors associated with serious outcomes.

**II. REMS ELEMENTS**

**A. Communication Plan**

Amgen will implement a communication plan to healthcare providers to support implementation of this REMS.

The communication plan will provide for the dissemination of information about the elimination of the elements to assure safe use, inform prescribers and institutions how to obtain Nplate, and remind healthcare providers about the serious risks associated with Nplate and appropriate patient selection in accordance with the approved labeling.

The communication plan consists of:

1. A *Dear Healthcare Provider Letter* will be distributed via direct mail, electronic delivery or via a hand carry program to the following within 15 working days of the most recent REMS approval 12/2011:

- Hematologists
- Oncologists
- Hospitals and Institutions

In addition, Amgen will send the *Dear Healthcare Provider Letter* to MedWatch at the same time it is disseminated to the target audience.

The *Dear Healthcare Provider Letter* is part of the Nplate REMS and is appended.

2. A *Dear Professional Society Letter* will be distributed to the leadership of the following societies via direct mail or electronic delivery within 15 working days of the most recent REMS approval 12/2011:
  - American Society of Clinical Oncology
  - American Society of Hematology

- National Comprehensive Cancer Network
- American Society of Pediatric Hematology/Oncology
- Oncology Nursing Society
- Hematology Oncology Pharmacy Association
- American Society of Health-System Pharmacists

The *Dear Professional Society Letter* is part of the Nplate REMS and is appended.

Both letters will be posted prominently on [www.nplate.com](http://www.nplate.com) and [www.nplatenexus.com](http://www.nplatenexus.com) within 5 working days of the most recent REMS approval 12/2011. This information will remain on [www.nplate.com](http://www.nplate.com) for 6 months and [www.nplatenexus.com](http://www.nplatenexus.com) for 4 weeks.

### **III. TIMETABLE FOR SUBMISSION OF ASSESSMENTS**

Amgen will submit REMS Assessments to the Food and Drug Administration (FDA) on 30 June 2012, 30 June 2015, and 30 June 2019 for the Nplate<sup>®</sup> (romiplostim) 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. Amgen will submit each assessment so that it will be received by FDA on or before the due date.