

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Oncologic Drugs Advisory Committee*

## AGENDA

March 12, 2008

8:00 a.m.	Call to Order Introduction of Committee	<b>S. Gail Eckhardt, M.D.</b> Acting Chair, ODAC
	Conflict of Interest Statement	<b>Nicole Vesely, Pharm.D.</b> Designated Federal Official, ODAC

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*The committee will discuss: biologic license application (BLA) 125268, proposed trade name Nplate (romiplostim), Amgen Inc., proposed indication for the treatment of thrombocytopenia in adults with chronic immune (idiopathic) thrombocytopenia purpura (ITP) who are nonsplenectomized and have had an inadequate response or are intolerant to corticosteroids and/or immunoglobulins; or patients who are splenectomized and have an inadequate response to splenectomy.*

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8:15 a.m.	<b><u>FDA Presentation</u></b> Introduction to Romiplostim	<b>David Frucht, M.D.</b> Product Quality Reviewer, Division of Monoclonal Antibodies, OBP, OPS, CDER, FDA
8:20 a.m.	<b><u>Guest Speaker</u></b> Overview of ITP	<b>Heather Mannuel, M.D., M.B.A</b> Assistant Professor of Medicine University of Maryland/Greenbaum Cancer Center
8:50 a.m.	<b><u>Sponsor Presentation</u></b> Background and Introduction	<b><u>Amgen Inc.</u></b> <b>Joseph Miletich, M.D., Ph.D.</b> Senior Vice President Research & Development, Amgen Inc.
	Thrombopoietin (TPO) and Management Of Immune Thrombocytopenic Purpura (ITP)	<b>David Kuter, M.D., Ph.D.</b> Professor, Dept of Medicine, Harvard Medical School Director, Clinical Hematology, Massachusetts General Hospital
	Romiplostim in ITP: Efficacy And Risk Assessment	<b>Dietmar Berger, M.D., Ph.D.</b> Executive Director Global Clinical Development, Amgen Inc.
	Risk Management Program & Closing Remarks	<b>Paul Eisenberg, M.D., MPH</b> Senior Vice President Global Regulatory Affairs & Safety, Amgen Inc.
9:50 a.m.	<i>Break</i>	

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(continued)

10:05 a.m.	<b><u>FDA Presentation</u></b> Romiplostim FDA Overview	<b><u>BLA 125268</u></b> <b>Faranak Jamali, M.D.</b> Medical Officer, Division of Medical Imaging and Hematology Products, OODP, OND, CDER, FDA
	Romiplostim Safety Review: MDS Progression	<b>Steven Lemery, M.D.</b> Medical Officer, Division of Biologic Oncology Products, OODP, OND, CDER, FDA
	Risk Management Considerations For Romiplostim	<b>Suzanne Berkman, Pharm.D.</b> Senior Drug Risk Management Analyst, Division of Risk Management, OSE, CDER, FDA
11:00 a.m.	Questions to the Presenters	
12:00 p.m.	<i>Lunch</i>	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the ODAC and ODAC Discussion	
2:45 p.m.	<i>Break</i>	
3:00 p.m.	Questions to the ODAC and ODAC Discussion	
4:00 p.m.	Adjourn	