

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

May 30, 2008

8:00 a.m.	Call to Order Introduction of Committee	Maha Hussain, M.D. Chair, ODAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, ODAC
8:10 a.m.	ODAC Member Appreciation	Richard Pazdur, M.D. Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA

On May 30, 2008, the committee will discuss new drug application (NDA) 022-291, proposed trade name PROMACTA (eltrombopag olamine), GlaxoSmithKline, proposed indication for the short-term treatment of previously-treated patients with chronic idiopathic thrombocytopenic purpura (ITP) to increase platelet counts and reduce or prevent bleeding..

8:15 a.m.	<u>Sponsor Presentation</u> Introduction	<u>GlaxoSmithKline</u> Debasish Roychowdhury, M.D. GlaxoSmithKline Vice President, Global Clinical Development
	Idiopathic Thrombocytopenic Purpura	James Bussel, M.D. Platelet Disorders Center Departments of Pediatrics and Medicine Weill Cornell Medical College
	Clinical Overview	Michael Arning, M.D., Ph.D. GlaxoSmithKline Group Director, Global Clinical Development
	Concluding Remarks	Debasish Roychowdhury, M.D. GlaxoSmithKline Vice President, Global Clinical Development
9:00 a.m.	<u>FDA Presentation</u> FDA Review of Clinical Data	<u>NDA 022-291</u> Andrew Dmytrijuk, M.D. Medical Officer, Division of Medical Imaging and Hematology Products, OODP, OND, CDER, FDA
9:45 a.m.	Questions to the Presenters	
10:15 a.m.	<i>Break</i>	
10:30 a.m.	Open Public Hearing	
11:30 a.m.	Questions to the ODAC and ODAC Discussion	
12:30 p.m.	Adjourn	