

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

June 2, 2006

10:00 a.m.	Call to Order Introduction of Committee	Silvana Martino, D.O. Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.Sc., RN Executive Secretary, ODAC
10:15 a.m.	Opening Remarks & ODAC Member Appreciation	Richard Pazdur, M.D., Director Office of Oncology Drug Products, OODP, FDA

The committee will discuss the following new drug application (NDA) 21-986, proposed trade name Sprycel™ (dasatinib) tablets, Bristol-Myers Squibb Company, with proposed indications for (1) the treatment of adults with chronic, accelerated, or blast phase chronic myeloid leukemia with resistance or intolerance to prior therapy including imatinib, and (2) the treatment of adults with Philadelphia chromosome-positive acute lymphoblastic leukemia and lymphoid blast chronic myeloid leukemia with resistance or intolerance to prior therapy.

10:25 a.m.	<u>Sponsor Presentation</u> Introduction	<u>Bristol-Myers Squibb Company</u> Donna Morgan Murray, Ph.D. Vice President, Global Regulatory Sciences
	Problem Statement	Neil Shah, M.D., Ph.D. UCLA Medical Center
	Clinical Program	Claude Nicaise, M.D. Vice President, Global Development
	Clinical Perspective & Benefit and Risk Assessment	Hagop Kantarjian, M.D. MD Anderson Center Center
	Conclusion	Donna Morgan Murray, Ph.D.
11:10 a.m.	<u>FDA Presentation</u> Efficacy	<u>NDA 21-986</u> Edvardas Kaminskas, M.D., Medical Officer Division of Drug Oncology Products, OODP, FDA &
	Safety	Vicki Goodman, M.D., Medical Officer Division of Drug Oncology Products, OODP, FDA
11:45 a.m.	<i>Questions from the Committee</i>	
12:15 p.m.	Break	
12:30 p.m.	Open Public Hearing	
1:30 a.m.	<i>Questions to the ODAC and ODAC Discussion</i>	
2:00 p.m.	<i>Adjourn</i>	