FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, Maryland
May 24, 2017

AGENDA

During the morning session, the committee will discuss new drug application (NDA) 208051, for neratinib maleate, an application submitted by Puma Biotechnology, Inc. The proposed indication (use) for this product is as a single agent for the extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab-based therapy. During the afternoon session, the committee will discuss NDA 208587 for L-glutamine powder (oral solution), submitted by Emmaus Medical, Inc. The proposed indication (use) for this product is for the treatment of sickle cell disease.

8:00 a.m.	Call to Order and Introduction of Committee	**Brian I. Rini, MD, FACP** Acting Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS** Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	**Laleh Amiri-Kordestani, MD** Medical Team Leader, Breast Cancer Group Division of Oncology Products 1 (DOP1) Office of Hematology and Oncology Products (OHOP), Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Puma Biotechnology, Inc.**
	Introduction	**Alan H. Auerbach, MS** Chief Executive Officer Puma Biotechnology, Inc.
	Unmet Clinical Need	**Jose Baselga, MD, PhD** Physician-in-Chief Memorial Sloan Kettering Cancer Center
	Efficacy	**Alvin Wong, PharmD** Vice President, Clinical Science and Clinical Pharmacology Puma Biotechnology, Inc.
	Safety	**Susan Moran, MD, MSCE** Vice President, Clinical Development Puma Biotechnology, Inc.
	Safety Perspective	**Hope Rugo, MD** Professor of Breast Oncology University of California, San Francisco Medical Center

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AGENDA (cont.)

	Clinical Perspective	**Joyce O'Shaughnessy, MD** Medical Director Texas Oncology-Baylor Charles A. Sammons Cancer Center
9:00 a.m.	**FDA PRESENTATIONS**	
	NDA 208051 – Neratinib	**Harpreet Singh, MD** Medical Officer DOP1, OHOP, OND, CDER, FDA
	FDA Statistical Analysis	**Joyce Cheng, PhD** Statistical Reviewer Division of Biometrics V (DBV) Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Safety Results	**Amanda Walker, MD** Medical Officer DOP1, OHOP, OND, CDER, FDA
9:45 a.m.	Clarifying Questions to the Presenters	
10:15 a.m.	**BREAK**	
10:30 a.m.	Open Public Hearing	
11:00 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Call to Order and Introduction of Committee	**Brian I. Rini, MD, FACP** Acting Chairperson, ODAC
1:05 p.m.	Conflict of Interest Statement	**Lauren Tesh, PharmD, BCPS** Designated Federal Officer, ODAC
1:10 p.m.	Opening Remarks	**Kathy Robie-Suh, MD, PhD** Medical Team Leader Division of Hematology Products (DHP) OHOP, OND, CDER, FDA
1:15 p.m.	**APPLICANT PRESENTATIONS**	**Emmaus Medical, Inc.**
	Introduction	**Lan T. Tran, MPH** Emmaus Medical, Inc.

AGENDA (cont.)

	The Medical Need to Reduce Sickle Cell Crises	**Victor R. Gordeuk, MD** Professor of Medicine Division of Hematology and Oncology Director, Comprehensive Sickle Cell Center University of Illinois at Chicago
	Efficacy and Safety	**Yutaka Niihara, MD, MPH** Emmaus Medical, Inc.
	Clinical Perspective/Benefit Risk	**Wally R. Smith, MD** Florence Neal Cooper Smith Professor of Sickle Cell Disease Vice Chair for Research, Division of General Internal Medicine Virginia Commonwealth University
2:00 p.m.	**FDA PRESENTATIONS**	
	NDA 208587: L-glutamine	**Rosanna Setse, MD, MPH, PhD** Medical Officer DHP, OHOP, OND, CDER, FDA
	Statistical Review Considerations	**Che Smith, PhD** Statistical Reviewer DBV, OB, OTS, CDER, FDA
	Saftey	**Rosanna Setse, MD, MPH, PhD**
2:45 p.m.	Clarifying Questions to the Presenters	
3:15 p.m.	**BREAK**	
3:30 p.m.	Open Public Hearing	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	