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

Oncologic Drugs Advisory Committee (ODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
March 7, 2018

AGENDA

The committee will discuss supplemental biologic license application (sBLA) 125557/S-013, for BLINCYTO (blinatumomab) injection for intravenous use, application submitted by Amgen, Inc. The proposed indication (use) for this product is for the treatment of minimal residual disease-positive B-cell precursor acute lymphoblastic leukemia.

8:00 a.m.	Call to Order and Introduction of Committee	**Bruce J. Roth, MD** Chairperson, ODAC
8:05 a.m.	Conflict of Interest Statement	**Lauren D. Tesh, PharmD, BCPS** Designated Federal Officer, ODAC
8:10 a.m.	Opening Remarks	**Donna Przepiorka, MD, PhD** Cross-Discipline Team Leader Division of Hematology Products (DHP) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Amgen, Inc.**
	Introduction	**Kathy Kross, MSc** Executive Director, Global Regulatory Affairs Amgen, Inc.
	Overview of MRD+ ALL and Unmet Medical Need	**Jerald Radich, MD** External Consultant Fred Hutchinson Cancer Center
	Clinical Efficacy and Safety	**Janet Franklin, MD, MPH** Executive Medical Director, Global Development Lead for BLINCYTO Amgen, Inc.
	Benefit-Risk	**Gregory Friberg, MD** Vice President, Oncology Global Development Amgen, Inc.
	A Clinician's Perspective	**Aaron Logan, MD, PhD** External Consultant University of California, San Francisco

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AGENDA (cont.)

9:15 a.m.	**FDA PRESENTATIONS**	
	BLA 125557 S013 Blincyto (blinatumomab)	**Emily Jen, MD, PhD** Clinical Reviewer DHP, OHOP, OND, CDER, FDA
	Statistical Evaluation of Propensity Score Analyses	**Qing Xu, PhD** Statistical Reviewer Division of Biometrics V Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Safety Analysis	**Emily Jen, MD, PhD**
10:00 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**OPEN PUBLIC HEARING**	
11:30 a.m.	Questions to the Committee/Committee Discussion	
12:30 p.m.	**ADJOURNMENT**	