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 25, 2017

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 125545 for a proposed biosimilar to Amgen Inc.'s Epogen/Procrit (epoetin alfa), submitted by Hospira Inc., a Pfizer company. The proposed indications (uses) for this product are (1) for the treatment of anemia due to chronic kidney disease (CKD), including patients on dialysis and not on dialysis to decrease the need for red blood cell (RBC) transfusion, (2) for the treatment of anemia due to zidovudine administered at ≤ 4,200 mg/week in HIV-infected patients with endogenous serum erythropoietin levels of ≤ 500 mUnits/mL, (3) for the treatment of anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppresive chemotherapy, and upon initiation, there is a minimum of two additional months of planned chemotherapy, and (4) to reduce the need for allogeneic RBC transfusions among patients with perioperative hemoglobin > 10 to < 13 g/dL who are at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery.

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.	351(k) Regulatory Pathway	**Leah Christl, PhD** Associate Director for Therapeutic Biologics Office of New Drugs (OND)Therapeutic Biologics and Biosimilars Staff (TBBS), CDER, FDA
8:40 a.m.	Clarifying Questions to the Presenter	
8:55 a.m.	Opening Remarks	**R. Angelo de Claro, MD** Medical Officer Team Leader Division of Hematology Products (DHP) Office of Hematology and Oncology Products (OHOP) Office of New Drugs (OND), CDER, FDA
9:00 a.m.	**APPLICANT PRESENTATIONS**	**Hospira Inc., a Pfizer company**
	Introduction to Epoetin Hospira – Biosimilar to Epogen®/Procrit®	**Sumant Ramachandra, MD, PhD** Senior VP, Research & Development Head Pfizer Essential Health
	Analytical Biosimilarity Assessment	**Thomas Vanden Boom, PhD** VP, Biosimilars Pharmaceutical Sciences Pfizer World Wide Research & Development
	Nonclinical, Clinical Pharmacology and Clinical Biosimilarity Assessment	**Nancy Martin, MD, PharmD, FCP** Consultant, previously VP Clinical Development, Biosimilars Hospira, A Pfizer Company

DRAFT AGENDA (cont.)

	Conclusion Supporting Biosimilarity and Extrapolation Across Indications	**Sumant Ramachandra, MD, PhD**
9:45 a.m.	**FDA PRESENTATIONS**	
	"Epoetin Hospira", a proposed biosimilar to US-licensed Epogen/Procrit - BLA 125545	**Frances Namuswe, PhD** CMC Reviewer Office of Biotechnology Products (OBP) Office of Pharmaceutical Quality (OPQ), CDER, FDA
	Chemistry, Manufacturing, and Controls (CMC)	**Chao Wang, PhD** CMC Statistical Reviewer Division of Biometrics VI (DBVI) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Pharmacology/Toxicology	**Natalie Simpson, PhD** Pharmacology/Toxicology Reviewer Division of Hematology Oncology Toxicology OHOP, OND, CDER, FDA
	Clinical Immunogenicity	**Steven Bowen, PhD** Immunogenicity Reviewer OBP, OPQ, CDER, FDA
	Clinical Pharmacology	**Vicky Hsu, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology V Office of Clinical Pharmacology, OTS, CDER, FDA
	Clinical Efficacy	**Lola Luo, PhD** Clinical Statistical Reviewer Division of Biometrics V (DBV) OB, OTS, CDER, FDA
	Clinical Safety	**Lori Ehrlich, MD, PhD** Medical Officer DHP, OHOP, OND, CDER, FDA
10:30 a.m.	**BREAK**	
10:45 a.m.	Clarifying Questions to the Presenters	
11:15 a.m.	Open Public Hearing	

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
May 25, 2017

DRAFT AGENDA (cont.)

12:15 p.m. Questions to the Committee/Committee Discussion

1:30 p.m. **ADJOURNMENT**