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
October 10, 2018

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 761088 for CT-P10, a proposed biosimilar to Genentech, Inc.'s RITUXAN (rituximab), submitted by Celltrion, Inc. The proposed indications for CT-P10 are: treatment of adult patients with (1) relapsed or refractory, low-grade or follicular, CD20-positive, B-cell Non–Hodgkin's Lymphoma (NHL) as a single agent; (2) previously untreated follicular, CD20-positive, B-cell NHL in combination with first line chemotherapy and, in patients achieving a complete or partial response to a rituximab product in combination with chemotherapy, as single-agent maintenance therapy, and (3) non-progressing (including stable disease), low-grade, CD20-positive, B-cell NHL as a single agent after first-line cyclophosphamide, vincristine, and prednisone (CVP) chemotherapy.

8:00 a.m.	Call to Order and Introduction of Committee	**Brian I. Rini, MD, FACP** 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	**Vishal Bhatnagar, MD** Medical Officer Team Leader (Acting) 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**	**Celltrion, Inc.**
	Analytical Biosimilarity and Nonclinical Assessment	**Elizabeth Pollitt, PhD** CMC Expert, BPCRCS Ltd Former Vice President CELLTRION, Inc.
	Clinical Pharmacology, Efficacy and Safety Assessment	**Alexey Kudrin, MD, PhD, MBA** Clinical Expert, Biotech Consultancy Services Ltd Former Vice President CELLTRION, Inc.
	Clinical Perspective	**David Alan Rizzieri, MD** Professor of Medicine Chief, Section of Hematologic Malignancies Associate Director for Clinical Research Division of Hematologic Malignancies and Cellular Therapy Duke Cancer Institute, Duke University School of Medicine

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DRAFT AGENDA (cont.)

9:15 a.m.	**FDA PRESENTATIONS**	
	Product Quality	**Haoheng Yan, MD, PhD** Product Quality Reviewer Division of Biotechnology Review and Research IV Office of Biotechnology Products Office of Pharmaceutical Quality, CDER, FDA
		Yu-Ting Weng, PhD Product Quality Statistical Reviewer Division of Biometrics VI Office of Biostatistics (OB) Office of Translational Science (OTS) CDER, FDA
	Clinical Pharmacology and Immunogenicity Assessment	**Sang M. Chung, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology OTS, CDER, FDA
	Clinical Efficacy and Safety	**Rachel Ershler, MD** Clinical Reviewer DHP, OHOP, OND, CDER, FDA
		Cindy Gao, PhD Clinical Statistical Reviewer Division of Biometrics V OB, OTS, CDER, FDA
10:15 a.m.	Clarifying Questions to Presenters	
10:45 a.m.	**BREAK**	
11:00 a.m.	**OPEN PUBLIC HEARING**	
12:00 p.m.	Questions to the Committee/Committee Discussion	
1:00 p.m.	**ADJOURNMENT**	