

**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

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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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**