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

Arthritis Advisory Committee (AAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 9, 2016

DRAFT AGENDA

The committee will discuss biologics license application (BLA) 125544, for CT-P13, a proposed biosimilar to Janssen Biotech Inc.'s REMICADE (infliximab), submitted by Celltrion, Inc. The proposed indications (uses) for this product are: (1) Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; (2) reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease; (3) reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy; (4) reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy; (5) reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy;[*] (6) in combination with methotrexate, reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis; (7) reducing signs and symptoms in patients with active ankylosing spondylitis; (8) reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in patients with psoriatic arthritis; and (9) treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate.

[*] *This indication is protected by orphan drug exclusivity expiring on September 23, 2018.*

7:30 a.m.	Call to Order and Introduction of Committee	**Liron Caplan, MD, PhD** Acting Chairperson, AAC
7:35 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AAC
7:40 a.m.	**FDA OPENING REMARKS**	**Janet Woodcock, MD** Director CDER, FDA
7:50 a.m.	351(k) Regulatory Pathway	**Leah Christl, PhD** Associate Director, Therapeutic Biologics and Biosimilars Staff (TBBS) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

8:25 a.m.	Introductory Remarks	**Nikolay P. Nikolov, MD** Clinical Team Leader Division of Pulmonary, Allergy & Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE-II) OND, CDER, FDA
8:30 a.m.	**APPLICANT PRESENTATIONS**	**CELLTRION, Inc.**
	Introduction	**Elizabeth Pollitt, PhD** Vice President Head of CMC for Regulatory Affairs CELLTRION, Inc.
	Physicochemical and Functional Studies	**Elizabeth Pollitt, PhD**
	Nonclinical Studies	**Elizabeth Pollitt, PhD**
	Clinical Review: Pharmacology, Immunology, Efficacy and Safety	**Alex Kudrin, MD, PhD, MBA** Vice President, Head of Clinical Development CELLTRION, Inc.
	Totality of Evidence	**Alex Kudrin, MD, PhD, MBA**
	CT-P13 Use in Patients with IBD: Post-Marketing Clinical Studies and Real-World Experience	**Peter Laszlo Lakatos, MD, DsC** Associate Professor Head of Gastroenterology/Hepatology Unit and Endoscopy Semmelweis University Budapest, Hungary
	Totality of Evidence of CT-P13: Clinical Perspective	**Vibeke Strand, MD, MACR, FACP** Adjunct Clinical Professor Division of Immunology/Rheumatology Stanford University
10:00 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

10:30 a.m.	**FDA PRESENTATIONS**	
	CT-P13 Product Quality Review	**Kurt Brorson, PhD** Lab Chief (Acting) Division of Biotechnology Research and Review 2 Office of Biotechnology Products (OBP) Office of Pharmaceutical Quality (OPQ), CDER, FDA
	CT-P13 Statistical Equivalence Testing for Bioactivity	**Meiyu Shen, PhD** CMC Statistical Reviewer Division of Biometrics VI, Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Clinical Pharmacology Review	**Lei He, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology (OCP) OTS, CDER, FDA
	Clinical Efficacy Review	**Gregory Levin, PhD** Mathematical Statistician Division of Biometrics II, OB, OTS, CDER, FDA
	Clinical Safety and Immunogenicity Review	**Juwaria Waheed, MD** Medical Officer DPARP, ODE-II, OND, CDER, FDA
	Considerations for Extrapolation and Summary of FDA Presentation	**Nikolay P. Nikolov, MD**
12:00 p.m.	Clarifying Questions for FDA	
12:15 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:45 p.m.	**BREAK**	
3:00 p.m.	**CHARGE TO THE COMMITTEE**	**Nikolay P. Nikolov, MD**
3:15 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	