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.  Overview of the Regulatory Pathway and FDA’s Guidance for the Development and Approval of Biosimilar Products in the US  Leah Christl, PhD  Associate Director, Therapeutic Biologics  Therapeutic Biologics and Biosimilars Staff  Office of New Drugs (OND)  CDER, FDA

8:20 a.m.  Clarifying Questions
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
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting
February 9, 2016

AGENDA (cont.)

10:30 a.m.  FDA PRESENTATIONS

CT-P13 Product Quality Review  Kurt Brorson, PhD
Product Quality Team Leader
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 of Biosimilarity  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