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 QUESTIONS

1. **DISCUSSION:** Does the Committee agree that CT-P13 is highly similar to the reference product, US-licensed Remicade, notwithstanding minor differences in clinically inactive components?

2. **DISCUSSION:** Does the Committee agree that there are no clinically meaningful differences between CT-P13 and US-licensed Remicade in the studied conditions of use (rheumatoid arthritis (RA) and ankylosing spondylitis (AS))?

3. **DISCUSSION:** Does the Committee agree that there is sufficient scientific justification to extrapolate data from the comparative clinical studies of CT-P13 in RA and AS to support a determination of biosimilarity of CT-P13 for the following additional indications for which US-licensed Remicade is licensed (psoriatic arthritis (PsA), plaque psoriasis (PsO), adult and pediatric Crohn's disease (CD), and adult and pediatric ulcerative colitis (UC)[1])? If not, please state the specific concerns and what additional information would be needed to support extrapolation. Please discuss by indication if relevant.

4. **VOTE:** Does the Committee agree that based on the totality of the evidence, CT-P13 should receive licensure as a biosimilar product to US-licensed Remicade for each of the indications for which US-licensed Remicade is currently licensed and CT-P13 is eligible for licensure (RA, AS, PsA, PsO, adult CD, pediatric CD, adult UC)?

    a. **DISCUSSION:** Please explain the reason for your vote. If you voted no, explain whether this was applicable to all or some of the indications and why.

[1] Remicade's indication for pediatric ulcerative colitis is protected by orphan drug exclusivity expiring on September 23, 2018. Although FDA is interested in the Committee's views regarding the scientific justification for extrapolating clinical data to support a determination of biosimilarity for CT-P13 for this indication, FDA is not asking the Committee to vote on licensure of CT-P13 for pediatric ulcerative colitis because FDA will not be able to license a proposed biosimilar product for this indication until the orphan exclusivity expires.