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
July 12, 2016

DRAFT QUESTIONS

FDA has requested additional data from Amgen regarding reverse signaling activity and this request is still pending. FDA will evaluate these additional data after they are submitted. To maximize the utility of the Committee's voting results, FDA requests that the Committee evaluate the discussion and voting questions based on the premise that the additional data provided by the sponsor would not preclude a demonstration that ABP 501 is biosimilar to US-licensed Humira.

1. **DISCUSSION:** Please discuss whether the evidence from analytical studies supports a demonstration that ABP 501 is highly similar to US-licensed Humira, notwithstanding minor differences in clinically inactive components.

2. **DISCUSSION:** Please discuss whether the evidence supports a demonstration that there are no clinically meaningful differences between ABP 501 and US-licensed Humira in the studied conditions of use (rheumatoid arthritis (RA) and plaque psoriasis (PsO)).

3. **DISCUSSION:** Please discuss whether the data provides adequate scientific justification to support a demonstration of no clinically meaningful differences between ABP 501 and US-licensed Humira for the following additional indications for which US-licensed Humira is licensed:
    - Juvenile Idiopathic Arthritis (JIA) in patients 4 years of age and older
    - Psoriatic Arthritis (PsA)
    - Ankylosing Spondylitis (AS)
    - Adult Crohn's Disease (CD)
    - Adult Ulcerative Colitis (UC)

    If not, please state the specific concerns and what additional information would be needed to support such a demonstration. Please discuss by indication if relevant.

4. **VOTE:** Does the totality of the evidence support licensure of ABP 501 as a biosimilar product to US-licensed Humira for the following indications for which US-licensed Humira is currently licensed and for which Amgen is seeking licensure (RA, JIA in patients 4 years of age and older, PsA, AS, adult CD, adult UC, and PsO)?

    Please explain the reason for your vote.