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
April 23, 2018

DRAFT QUESTIONS

---

1. **DISCUSSION:** Discuss the efficacy data for baricitinib for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX). Include a discussion of the 2 mg and 4 mg doses of baricitinib and whether available data support a benefit of one dose over the other.

2. **VOTE:** Do the data provide substantial evidence of the efficacy of baricitinib 2 mg for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX)?
   - If no, what data are needed?

3. **VOTE:** Do the data provide substantial evidence of the efficacy of baricitinib 4 mg for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX)?
   - If no, what data are needed?

4. **DISCUSSION:** Discuss the safety data for baricitinib for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX). Include a discussion of the following issues:
   a) Adequacy of safety database for the 2 mg dose of baricitinib
   b) Safety issues of interest and whether data suggest a dose response
      - Thromboembolic events
      - Malignancy
      - Serious infections, opportunistic infections, herpes zoster, tuberculosis
      - Abnormal laboratory parameters, specifically platelet count elevations
   c) Overall safety profile of the 2 mg dose and the 4 mg dose, and whether the data are more favorable for one dose versus the other

5. **VOTE:** Are the safety data adequate to support approval of baricitinib 2 mg for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX)?
   - If no, what data are needed?

6. **VOTE:** Are the safety data adequate to support approval of baricitinib 4 mg for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX)?
   - If no, what data are needed?

DRAFT QUESTIONS (cont.)

---

7. **VOTE:** Is the benefit-risk profile adequate to support approval of baricitinib 2 mg for the proposed indication of the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX)?
    - If no, what data are needed?

8. **VOTE:** Is the benefit-risk profile adequate to support approval of baricitinib 4 mg for the proposed indication of the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate (MTX)?
    - If no, what data are needed?