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
August 3, 2017

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the efficacy of the proposed dose of tofacitinib for adult patients with active psoriatic arthritis. In your discussion, comment on the following:

    a. The overall efficacy of tofacitinib with respect to signs and symptoms and physical function for adult patients with psoriatic arthritis.

    b. The evaluation of the effect of tofacitinib on radiographic progression in psoriatic arthritis.

2. **DISCUSSION:** Discuss the safety of tofacitinib for the treatment of adult patients with active psoriatic arthritis.

3. **VOTE:** Overall, do the data provide substantial evidence of the efficacy of tofacitinib for the treatment of adult patients with active psoriatic arthritis?

    a. If not, what further data should be obtained?

4. **VOTE:** Is the safety profile of tofacitinib adequate to support approval of tofacitinib for the treatment of adult patients with active psoriatic arthritis?

    a. If not, what further data should be obtained?

5. **VOTE:** Do you recommend approval of the proposed dose of tofacitinib for the treatment of adult patients with active psoriatic arthritis?