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 2, 2017

QUESTIONS

1. **DISCUSSION:** Discuss the efficacy of sirukumab for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to one or more disease-modifying anti-rheumatic drugs (DMARDs).

2. **VOTE:** Overall, do the data provide substantial evidence of the efficacy of sirukumab for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to one or more DMARDs?

    a. If not, what data are needed?

3. **DISCUSSION:** Discuss the design of the 52-week placebo-controlled radiographic study, ARA3002.

4. **DISCUSSION:** Discuss the safety findings in the phase 3 program, with particular consideration of the imbalance in all-cause death between sirukumab and placebo.

5. **DISCUSSION:** Discuss the dose selection for the phase 3 program.

6. **VOTE:** Is the safety profile of sirukumab adequate to support approval of sirukumab for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to one or more DMARDs?

    a. If not, what data are needed?

7. **VOTE:** Do you recommend approval of sirukumab at the proposed dose of 50 mg subcutaneously every 4 weeks 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 one or more DMARDs?

    a. If not, what data are needed?