FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 19, 2016

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss the safety data for brodalumab.

    a. **DISCUSSION:** Do the safety data for brodalumab suggest a signal for:
        i. Suicide Ideation and Behavior (SIB)?
        ii. Major Adverse Cardiovascular Events (MACE)?

    b. **DISCUSSION:** If you believe there is a safety signal for SIB and/or MACE, comment on possible approaches to further evaluate these signals.

2. **VOTE:** Is the overall benefit/risk profile of brodalumab acceptable to support approval for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

    a. Yes, with labeling alone to manage the risks
    b. Yes, but only if certain risk management options for SIB beyond labeling are implemented
    c. No

    Please provide a rationale for your vote. If you voted for A, please describe the labeling you would recommend to manage the risks. If you voted for B, describe the interventions or tools you believe would help mitigate the risk of SIB, in addition to labeling.

3. **DISCUSSION:** If you voted for approval in question #2, please comment on post-marketing studies/trials that are needed to further define the safety of brodalumab, including, but not limited to, the need for long-term studies to evaluate suicidality and cardiovascular events.