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

Bone, Reproductive and Urologic Drugs Advisory Committee (BRUDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 30, 2019

DRAFT QUESTIONS

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1. **DISCUSSION**: Discuss the effectiveness of AG200-15, including:
    a. Interpretation of efficacy results from Study 23 as they relate to study design and enrolled patient population
    b. Interpretation of subgroup analyses by body mass index, weight, and race/ethnicity

2. **DISCUSSION**: Discuss the safety profile of AG200-15, including:
    a. Interpretation of the venous thromboembolism (VTE) safety signal as it relates to weight and body mass index (BMI)
    b. Interpretation of the product tolerability (e.g., cycle control)

3. **VOTE**: Do the benefits of AG200-15 outweigh its risks to support the drug's approval for the prevention of pregnancy?

    If you vote YES, explain the rationale for your vote and address the following:
    - Whether this product should be approved for use in the general population or a more narrowly defined patient population
    - How this product should be used within the context of available contraceptive therapies

    If you vote NO, explain the rationale for your vote and provide any recommendations.