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

Bone, Reproductive, and Urologic Drugs Advisory Committee (BRUDAC) Meeting
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd. East, Hyattsville, Maryland
January 9, 2018

DRAFT QUESTIONS

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1. **DISCUSSION:** Discuss whether the safety of Jatenzo has been adequately characterized. If additional safety data are needed, discuss the type(s) of data that are needed and whether these data should be obtained pre-approval or whether these data can be obtained post-approval. Specifically cover:

    a. The effects of Jatenzo on cardiovascular risk factors, including blood pressure and lipids, together with effects on hematocrit, and the potential for Jatenzo to increase the risk of adverse cardiovascular outcomes in the population that will likely use the drug, if it is approved.

    b. Supraphysiologic dihydrotestosterone (DHT) concentrations in some subjects.

    c. Subjects with maximal testosterone concentrations (C_{max}) exceeding the prespecified targets.

    d. The adrenal-related findings, including adrenocorticotropin (ACTH) stimulation results.

2. **DISCUSSION:** Discuss whether the titration regimen proposed for marketing will appropriately identify patients who require titration or discontinuation of Jatenzo.

3. **DISCUSSION:** Discuss whether NaF/EDTA tubes are critical for the safe and effective use of Jatenzo. If you conclude that NaF/EDTA tubes are not critical, discuss how serum tubes will ensure safe and effective use given that the Phase 3 trial used NaF/EDTA tubes.

4. **VOTE:** Is the overall benefit/risk profile of Jatenzo acceptable to support approval as a testosterone replacement therapy?

    Provide a rationale for your vote.