

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

***Oncologic Drugs Advisory Committee (ODAC)***

May 20-21, 2025

**QUESTIONS**

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**May 20, 2025 - Morning Session**

1. **DISCUSSION:** Discuss how the differential results observed in the Asian and Non-Asian regions impact the overall interpretation of the STARGLO trial results and the generalizability to a U.S. patient population.
2. **VOTE:** Are the STARGLO population and trial results applicable to the proposed U.S. patient population?

**May 20, 2025 - Afternoon Session**

1. **DISCUSSION:** Discuss the clinical meaningfulness of the efficacy endpoints assessed in the AQUILA trial.
2. **DISCUSSION:** Discuss the benefit-risk of daratumumab hyaluronidase (Dara SC) for the intended high-risk smoldering multiple myeloma (SMM) population.
3. **VOTE:** Do the results from the AQUILA trial provide sufficient evidence to support a favorable benefit-risk profile for Dara SC for patients with high-risk SMM?

**May 21, 2025 - Morning Session**

1. **DISCUSSION:** Given uncertainty regarding interpretation of duration of response in low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC), discuss whether randomized trials should be required in the future to assess the effectiveness of therapies in this disease setting.
2. **VOTE:** Is the overall benefit-risk of the investigational therapy UGN-102 favorable in patients with recurrent LG-IR-NMIBC?

**May 21, 2025 - Afternoon Session**

1. **DISCUSSION:** Discuss whether efficacy should be formally evaluated in a biomarker-negative population when the biomarker is predictive of response and the prevalence of the biomarker-negative group is high.
2. **VOTE:** Are the results from TALAPRO-2 sufficient to conclude a favorable benefit-risk profile for adding talazoparib to enzalutamide in patients with non-homologous recombination repair mutated (non-HRRm) metastatic castration-resistant prostate cancer (mCRPC)?