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

Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee (pedsODAC) Meeting
May 22, 2024

QUESTIONS

1. **DISCUSSION:** Please discuss your perspectives on how the 2017 FDA Reauthorization Act (FDARA) is impacting pediatric oncology and development of new molecularly targeted therapies for pediatric patients with cancer.

   Describe positive effects or challenges associated with the legislation, and thoughts regarding how to improve its implementation.

2. **DISCUSSION:** Please discuss factors that should be considered when determining whether nonclinical proof-of-concept studies should be conducted prior to initiating a molecularly targeted pediatric cancer investigation in pediatric patients with cancer.

   Also discuss the degree of preclinical antitumor activity that would be considered sufficient to warrant clinical development.

3. **DISCUSSION:** Please discuss the role of pediatric clinical trial networks and international collaboration in efficient development of new medical products for pediatric patients with cancer including identification of relevant molecular targets, specific efforts that have been most valuable, and ideas for improved collaboration.

   Additionally, please discuss barriers to the conduct of international trials in pediatric oncology and potential ways to address these barriers.