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

Pediatric Subcommittee of the Oncologic Drugs Advisory Committee (pedsODAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
June 21-22, 2017

QUESTIONS

Day 2, Topic 1: Olaratumab, Eli Lilly and Company

1. **DISCUSSION:** Based on the non-clinical and clinical data presented, please comment on the relevant cancers that should be studied and potential endpoints that could be used in future clinical trials designed to evaluate the efficacy of olaratumab in pediatric patients.

2. **DISCUSSION:** Please comment on the safety profile of single-agent olaratumab and possible toxicities that may be seen when olaratumab is added to multi-agent combination therapy in pediatric patients.

3. **DISCUSSION:** Please comment on the feasibility of or requirement for international cooperative group collaboration in a future efficacy study.

4. **DISCUSSION:** Please comment on the sponsor's plan to evaluate platelet-derived growth factor receptor expression in pediatric cancers during their proposed development program.

5. **DISCUSSION:** Given the recent approval of this product in adults with soft tissue sarcoma, please discuss whether evaluation of olaratumab in pediatric non-rhabdomyosarcoma soft tissue sarcoma should be considered.

QUESTIONS (cont.)

Day 2, Topic 2: Prexasertib, Eli Lilly and Company

1. **DISCUSSION:** Please consider the preclinical data and rationale for the development of prexasertib in neuroblastoma and rhabdomyosarcoma. Additionally, please discuss other tumor types that may benefit from the development of prexasertib.

2. **DISCUSSION**: Please consider the planned pediatric study of prexasertib in neuroblastoma and rhabdomyosarcoma and provide an opinion regarding the overall study design, including the patient population eligible for enrollment and the tumor types that are planned to be evaluated.

3. **DISCUSSION:** Please address the plans for administering prexasertib in combination with cytotoxic chemotherapy regimens. Please address plans for administering prexasertib in combination with other targeted therapies.

4. **DISCUSSION:** Please comment on whether rhabdomyosarcoma should be considered one disease or divided into two disease entities for embryonal and alveolar rhabdomyosarcoma given the different pathology and clinical courses of these tumors.

5. **DISCUSSION:** Please address any short-term and potential long-term or late toxicities that may be associated with the use of this drug in children.