

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

***Meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory  
Committee (pedsODAC)***

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
November 19, 2015

**DRAFT QUESTIONS**

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**Session 1: ABT-414**  
**Sponsor: AbbVie, Inc.**

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1. **DISCUSSION:** Please consider whether ABT-414 is a viable drug candidate for study in pediatric patients? Comment on the feasibility of a trial of ABT-414 in pediatric patients with high grade glioma (HGG) given both the rarity of the disease and the low frequency of pediatric HGG with epidermal growth factor receptor (EGFR).
2. **DISCUSSION:** Please address the plans for administering ABT-414 in combination with temozolomide.
3. **DISCUSSION:** Please comment on the proposal for a pediatric trial embedded in the adult trial and other components of the study design including expected numbers of pediatric patients, age, range, and dose selection. Consider the need for and/or the extent of a statistical analysis plan for evaluation of the response and pharmacokinetic endpoints.
4. **DISCUSSION:** Given the incidence of HGG in children, please discuss how accrual to the pediatric substudy might be increased and accelerated by opening this amended protocol to a broader group of institutions or clinical trials networks.
5. **DISCUSSION:** Please comment on any concerns relating to the use of ABT-414 in pediatric patients. Specifically address any considerations for monitoring and/or preventing the known ocular toxicity.