

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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
January 16, 2020

QUESTIONS

1. **DISCUSSION:** Discuss whether the Applicant has provided sufficient information to support the proposed indication.
2. **DISCUSSION:** Discuss whether there are issues with this Complete Response resubmission that warrant additional studies and, if so, should these studies be conducted before or after approval.
3. **DISCUSSION:** Discuss whether the efficacy, safety, and overall risk-benefit profile of Posimir support the approval of this application.
4. **VOTE:** Do you recommend approval of Posimir, bupivacaine extended-release solution, 660 mg/5 mL (132 mg/mL), for the proposed indication of single-dose instillation into the surgical site to produce post-surgical analgesia?
 - a. If you voted “Yes,” please discuss the rationale for your vote and specify whether any post-approval studies should be required.
 - b. If you voted “No,” please discuss the rationale for your vote and what additional data are needed for approval.