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

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)
February 15, 2022

QUESTIONS

1. **DISCUSSION**: Discuss the importance of time to onset of action and risks related to delayed onset of action for intravenous tramadol proposed for the management of moderate to severe acute pain in the inpatient setting, such as post-operative or acute severe injury setting.

2. **DISCUSSION**: Discuss the benefits and risks of intravenous tramadol for acute pain management in the inpatient setting considering its mechanism of analgesia, drug pharmacokinetics, and complex metabolism.

3. **DISCUSSION**: Discuss the relevance of tramadol's abuse potential as a Schedule IV substance in the context of the proposed use for the management of acute pain in an inpatient setting with consideration of the following issues:

    a. Any impact on a patient's subsequent risk of abuse, misuse, or development of opioid use disorder in the outpatient setting.

    b. Any comparative advantage over currently available Schedule II intravenous opioids approved for the management of acute pain in an inpatient setting.

4. **VOTE**: Has the Applicant submitted adequate information to support the position that the benefits of their product outweigh the risks for the management of acute pain severe enough to require an opioid analgesic in an inpatient setting?

    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.