

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

*Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting*  
January 10, 2025

**QUESTIONS**

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1. **DISCUSSION:** Comment on the significance of Study 1131 (negative study) in the context of the other two positive studies with respect to establishing the efficacy of condoliase.
2. **DISCUSSION:** Discuss what concepts might be included in the prescribing information to help clinicians identify patients who would have a favorable benefit-risk profile if treated with condoliase. The Applicant's proposed indication states that condoliase “is indicated for the treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults.” Does this indication reflect the most appropriate patient population for condoliase, and if not, what modifications could be made?
3. **DISCUSSION:** The data support that condoliase reduces radicular leg pain in a subset of patients. However, digestion of chondroitin sulfate in the nucleus pulposus subsequent to condoliase injection results in a decrease in disc height and Modic changes. Given the known function of a healthy disc, reduction in disc height/volume may result in disc-related complaints, such as axial back pain, or might affect surgical options/outcomes. Discuss the clinical significance of these potential unintended consequences related to the mechanism of action of this product, or whether additional data are needed to adequately assess this risk.
4. **DISCUSSION:** Given the route of administration, the narrow population in which the drug has been established to be effective, and potential risks of both the product and the procedure, discuss appropriate proceduralist and setting requirements to support safe administration of the drug.
5. **DISCUSSION:** Discuss the level of concern for immune-related adverse reactions, including hypersensitivity, anaphylaxis, and SCARs, as well as appropriate mitigation and monitoring strategies.
6. **VOTE:** Do the benefits of condoliase injection for treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults with radicular leg pain outweigh the risks?

Provide a rationale for your vote.

- a. If you voted yes, specify the evidence that establishes condoliase’s effectiveness and safety.
- b. If you voted no, provide recommendations for additional data that may support a conclusion that condoliase is safe and effective.