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

Pulmonary-Allergy Drugs Advisory Committee (PADAC) Meeting
November 17, 2023

QUESTIONS

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1. **DISCUSSION:** Discuss the evidence of effectiveness for gefapixant for the treatment of refractory or unexplained chronic cough in adults. Specifically address the following:

    a. The small reduction in cough frequency compared to placebo and the clinical meaningfulness of the reduction in cough frequency.

    b. The observed results from Patient-Reported Outcomes (PROs) and whether these results provide compelling evidence to inform the clinical meaningfulness of the reduction in cough frequency.

    c. Potential unblinding of patients due to taste disturbance and its impact on interpretation of cough frequency and PRO results.

2. **DISCUSSION:** Discuss the overall benefit/risk assessment of gefapixant for the treatment of adults with refractory or unexplained chronic cough, a symptomatic condition.

3. **VOTE**: Does the evidence demonstrate that gefapixant provides a clinically meaningful benefit to adult patients with refractory or unexplained chronic cough, given the small reduction in cough frequency and results from PROs? Provide a rationale for your vote.

    a. If you conclude that there is insufficient evidence of a clinically meaningful benefit, describe the evidence that could be collected to show a benefit that is clinically meaningful.