**Center for Drug Evaluation and Research**

**Pulmonary-Allergy Drugs Advisory Committee Briefing Document**

# Gefapixant

## Oral Treatment for Refractory or Unexplained Chronic Cough

APPLICATION NUMBER: NDA 215010

November 17, 2023

Merck Sharp & Dohme LLC

Rahway, NJ USA

ADVISORY COMMITTEE BRIEFING MATERIALS:

AVAILABLE FOR PUBLIC RELEASE

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# 1 ERRATUM

Merck notes that in the Sponsor briefing document for the November 17, 2023 Advisory Committee Meeting, the values in the columns for "Estimated Difference vs. Placebo" and "Estimated Odds Ratio vs. Placebo" are swapped in Table 11. As such, we are providing the corrected column labels in the table below:

**Table 1**
**Posthoc Analysis of Subjects on Point Increase From Baseline in LCQ Total Score Over Time**
**Study P043**
**Full Analysis Set – Logistic Regression Model**

| Treatment | N | n | (%) | Estimated Difference† vs. Placebo (95% CI) | Estimated Odds Ratio† vs. Placebo (95% CI) |
|---|---|---|---|---|---|
| **P043 (Week 6) – Threshold of ≥ 1.3** | | | | | |
| Placebo | 197 | 130 | 66.0 | | |
| MK-7264 45 mg BID | 197 | 147 | 74.6 | 7.8 (-13.13, 27.45) | 1.46 (0.92, 2.31) |
| **P043 (Week 6) – Threshold of ≥ 3.3** | | | | | |
| Placebo | 197 | 83 | 42.1 | | |
| MK-7264 45 mg BID | 197 | 94 | 47.7 | 3.8 (-17.43, 25.98) | 1.18 (0.76, 1.82) |
| **P043 (Week 6) – Threshold of ≥ 4.1** | | | | | |
| Placebo | 197 | 68 | 34.5 | | |
| MK-7264 45 mg BID | 197 | 79 | 40.1 | 4.1 (-18.40, 23.60) | 1.20 (0.77, 1.88) |
| **P043 (Week 12) – Threshold of ≥ 1.3** | | | | | |
| Placebo | 193 | 126 | 65.3 | | |
| MK-7264 45 mg BID | 193 | 154 | 79.8 | 13.8 (-4.49, 35.18) | 2.02 (1.25, 3.26) |
| **P043 (Week 12) – Threshold of ≥ 3.3** | | | | | |
| Placebo | 193 | 92 | 47.7 | | |
| MK-7264 45 mg BID | 193 | 118 | 61.1 | 12.4 (-11.92, 33.59) | 1.65 (1.08, 2.53) |
| **P043 (Week 12) – Threshold of ≥ 4.1** | | | | | |
| Placebo | 193 | 79 | 40.9 | | |
| MK-7264 45 mg BID | 193 | 100 | 51.8 | 9.2 (-15.75, 29.89) | 1.46 (0.95, 2.24) |

N = Number of subjects with available data at the time point; n = Number of responders at the time point.
CI = Confidence Interval. LCQ = Leicester Cough Questionnaire
†Based on the logistic regression model. The covariates include treatment, visit, treatment-by-visit interaction, gender, region, baseline LCQ total score, and the interaction of baseline LCQ total score by visit.

Source: [P043MK7264: adam-adqs]