# Supplementary Materials

## Indacaterol acetate/mometasone furoate (IND/MF, QMF149) provides sustained improvements in lung function and reduces exacerbations, symptoms and rescue medication use compared with salmeterol xinafoate/fluticasone propionate in patients with moderate-to-very severe COPD: results from a Phase II randomized, double-blind 12-week study

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### Methods: Other exacerbation-related parameters

A worsening of symptoms that either did not meet the exacerbation symptom definition, but which was treated by the investigator with systemic corticosteroids or antibiotics, or that met the symptom definition, but did not receive antibiotics and/or systemic corticosteroids, was not considered a moderate or severe COPD exacerbation for the study. However, these events were recorded as mild exacerbations.

### Results: Other exacerbation-related parameters

Exacerbation rates were low, with a mean of 0.39 and 0.73 exacerbations per patient per year in the IND/MF (QMF149) and Sal/Flu groups, respectively. For all the COPD exacerbation-related parameters reported below, no significant differences between treatment groups were noted for mild COPD exacerbations.

Time to first COPD exacerbation during the 12-week treatment

Patients in the IND/MF (QMF149) group demonstrated a significantly longer time to 'any' (mild, moderate, severe) first exacerbation compared with patients in the Sal/Flu group: HR=0.48 (95% CI 0.289, 0.807; p=0.005), with a reduction in HR of 52%.

Annual rate of COPD exacerbations

The annualized exacerbation rates were compared between groups and the reductions in annual rate of any (mild, moderate, severe) (46%; p=0.015) COPD exacerbation were significantly in favor of IND/MF (QMF149) (**Table S1**).

Duration (total days) of COPD exacerbations over the 12-week treatment period

Most patients did not experience a COPD exacerbation during the treatment period. IND/MF (QMF149) significantly reduced the mean (±SD) number of exacerbation days per patient compared with Sal/Flu for any COPD exacerbation (1.4±6.59 versus 2.0±6.28, p=0.008).

**Table S1. Analysis of exacerbation rates (other exacerbation-related parameters) during the 12-week treatment period**

| | IND/MF (QMF149) | Sal/Flu |
|---|---|---|
| **Patients with any COPD exacerbation, n (%)** | 24 (7.6) | 44 (14) |
| **Event-free rate at week 12, % (95% CI)** | | |
| Mild | 99.3 (98.4–100.0) | 98.7 (97.4–100.0) |
| Any (mild, moderate, severe) | 92.2 (89.2–95.2) | 85.8 (81.9–89.8) |
| **Rate of exacerbations per year** | | |
| Mild | 0.03 | 0.07 |
| Any (mild, moderate, severe) | 0.39 | 0.73 |
| **Rate ratio (95% CI)** | **IND/MF (QMF149) versus Sal/Flu** | |
| Mild | 0.36 (0.068, 1.867) | |
| Any (mild, moderate, severe) | 0.54 (0.325, 0.888)* | |

**Notes:** *p=0.015.

**Abbreviations:** CI, confidence interval; COPD, chronic obstructive pulmonary disease; IND/MF, indacaterol acetate/mometasone furoate; Sal/Flu, salmeterol xinafoate/fluticasone propionate.