Introduction

- Double-blind treatment period
  - RR: 0.25 (0.12 to 0.52)
- Baseline characteristics
  - 72.7 ± 7.61
- 371 (91.8)
  - 20.7 ± 11.79
- 0.149 (0.064 to 0.234)
  - 33 (8.2)
- 1 (0.1)
  - -0.26 (−0.37 to −0.14)
  - 27.2 (22.1 to 32.4)
  - 163 (40.3)
  - 367 (92.2)

FAS included all randomised patients who received at least one dose of study treatment

Methods

- **Patients**
  - **Key inclusion criteria**
    - Men and women (adult and adolescent patients) aged ≥12 and ≤75 years
    - Patients with history of a long QT syndrome, and a prolonged QTc interval
    - ATS/ERS criteria after withholding bronchodilators at the start and end of run-in period
    - Men and women (adult and adolescent patients) aged ≥12 and ≤75 years
    - Patients with history of a long QT syndrome, and a prolonged QTc interval
  - **Key exclusion criteria**
    - Kishiwada City Hospital, Kishiwada, Japan;
    - Efficacy and safety of once-daily low-dose indacaterol/mometasone via Breezhaler
    - Indacaterol acetate/mometasone furoate (IND/MF, a LABA/ICS combination) 150/80 μg once-daily (o.d.) delivered via Breezhaler
    - Superiority of IND/MF (150/80 μg o.d.) to MF 200 μg o.d. in terms of trough FEV₁ after 12 weeks of treatment
    - One serious asthma outcome (asthma-related hospitalisation) was reported in the MF group and none in the IND/MF group
    - No death was reported in any treatment group throughout the study

- **Treatment**
  - IND/MF 150/80 µg o.d.
  - MF 200 µg o.d.

- **Endpoints**
  - **Pre-randomisation period**
    - Pre-randomisation period
    - Follow-up period
  - **Pre-randomisation period**
  - **Follow-up period**
  - **Primary endpoint**
    - Trough FEV₁ at 12 weeks
  - **Key secondary endpoint**
    - ACQ-7 at Week 12

- **Results**
  - Table 1: Baseline demographic and clinical characteristics (randomised set)
    - **Group**
      - **IND/MF (n = 387)**
        - Age (years): 47.8 ± 12.7
        - Sex: Male (62.6%), Female (37.4%)
        - Asthma control: Yes (75.9%), No (24.1%)
      - **MF (n = 384)**
        - Age (years): 48.2 ± 12.6
        - Sex: Male (62.4%), Female (37.6%)
        - Asthma control: Yes (76.1%), No (23.9%)

- **Conclusion**
  - Overall, results support the use of IND/MF 150/80 µg o.d. as a potential treatment in patients with inadequately controlled asthma
  - To our knowledge, this is the first study to compare a low-dose ICS/LABA FDC o.d. to once-daily ICS in asthma and patients with inadequately controlled asthma
  - No death was reported in any treatment group throughout the study

- **References**

- **Acknowledgements**
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  - The study was conducted at the Novartis Institute for Biomedical Research in Basel, Switzerland. No financial support. No role in data analysis, interpretation, or writing.

- **Figure 1: Study design**
  - figure showing the study design

- **Figure 2: Primary endpoint**
  - Trough FEV₁ at 12 weeks

- **Figure 3: Key secondary endpoint**
  - ACQ-7 at Week 12

- **Figure 4: At Week 12, IND/MF treatment showed statistically significant improvements in trough FEV₁ compared with MF treatment**
  - Data presented as LSM ± 95% CI. Error bars represent 95% CI

- **Figure 5: Higher proportion of patients attained improvement of at least 0.5 units (MIN) in ACQ score with IND/MF compared with MF after 12 weeks**
  - Data presented as LSM ± 95% CI. Error bars represent 95% CI

- **Figure 6: At Week 12, IND/MF treatment showed statistically significant improvements in primary and key secondary endpoints**
  - Data presented as LSM ± 95% CI. Error bars represent 95% CI