Abstract Presentations

5. Alberto Papi, Italy

Lung Function Improvement and Asthma Exacerbation Reduction with Indacaterol/Glycopyrronium/Mometasone Furoate in Uncontrolled Asthma: IRIDIUM Study

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Breathing and feeling well through universal access to right care

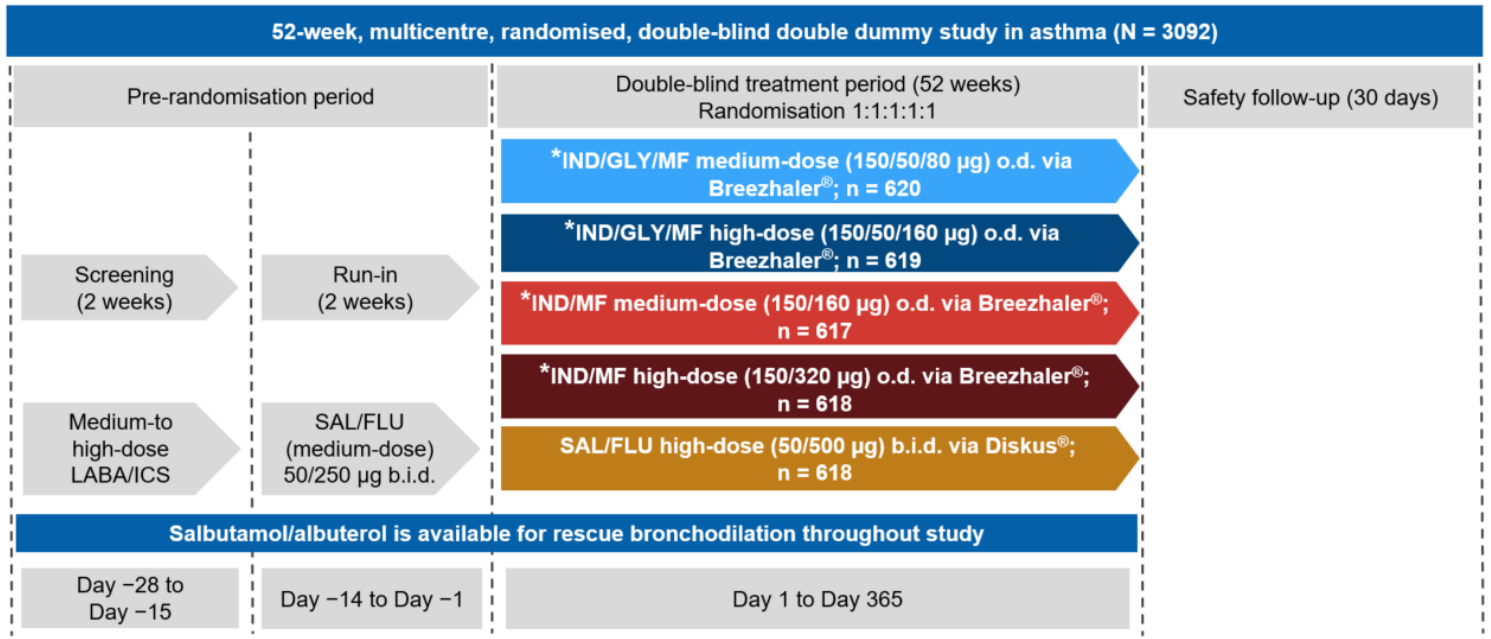
Introduction

- Patients with asthma inadequately controlled by medium- or high-dose LABA/ICS therapy could benefit from treatment with LABA/ICS+LAMA[1,2]
- The Phase III IRIDIUM study evaluated the efficacy and safety of IND/GLY/MF medium- and high-dose o.d. (delivered via the Breezhaler®) versus IND/MF medium- and high-dose o.d. and salmeterol/fluticasone (SAL/FLU) high-dose b.i.d. in adult patients with inadequately controlled asthma
- Here, we present the results of pre-specified and post-hoc analyses of the IRIDIUM study evaluating the efficacy of IND/GLY/MF medium-dose o.d. versus SAL/FLU high-dose b.i.d. and IND/MF high-dose o.d. in terms of lung function and asthma exacerbations
  - Pre-specified analysis: IND/GLY/MF medium-dose versus SAL/FLU high-dose
  - Post-hoc analysis: IND/GLY/MF medium-dose versus IND/MF high-dose

b.i.d., twice-daily; ICS, inhaled corticosteroid; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist; o.d., once-daily;

1. Kew KM and Dahri K. Cochrane Database Syst Rev 2016; (1): CD011721; 2. Munoz-Cano R, et al. Eur Respir J 2017;49: 1501885

Study Design and Key Inclusion and Exclusion Criteria



ClinicalTrials.gov number: NCT02571777

Inclusion

- Aged ≥18 and ≤75 years
- Patients receiving LABA/ICS medium- or high-dose for ≥3 months and at a stable dose for ≥1 month prior to screening
- Pre-bronchodilator FEV_1 <80% of predicted normal and an increase in FEV_1 of ≥12% and 200 mL after administration of salbutamol/albuterol
- ACQ-7 score ≥1.5 at run-in visit
- History of ≥1 asthma exacerbation 12 months prior to screening

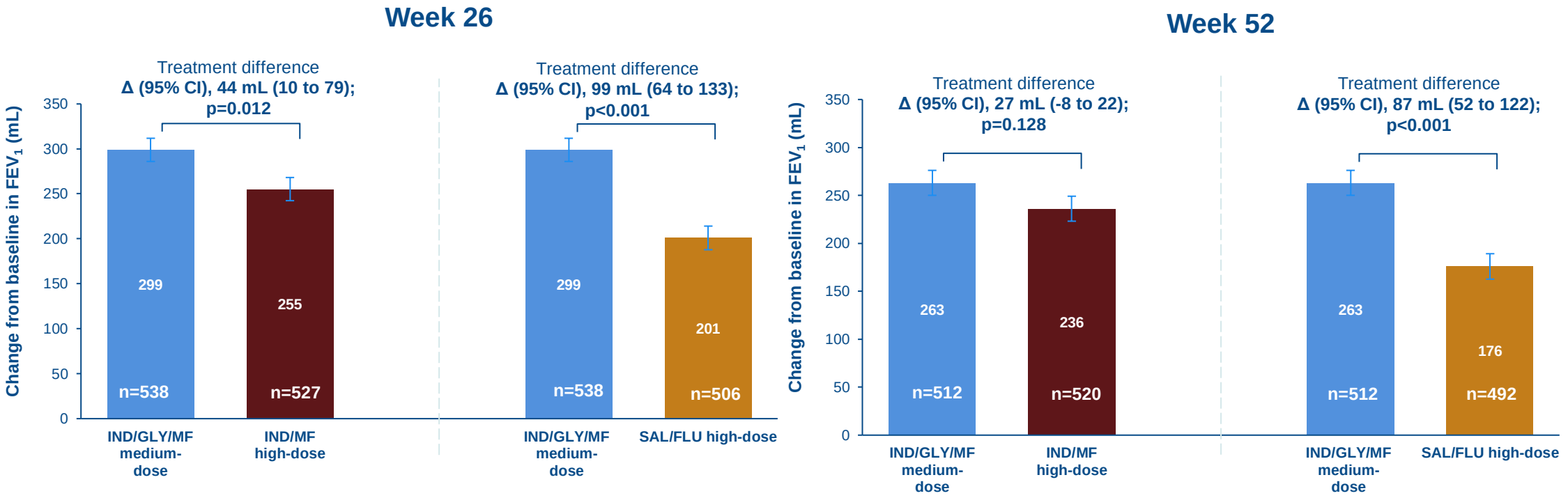
Exclusion

- Inhaled tobacco products in 6 months before screening or >10 pack-year smoking history
- History of chronic lung disease
- An asthma exacerbation requiring SC or hospitalisation or ER visit within 6 weeks of screening
- Patients with a RTI or asthma worsening within 4 weeks prior to screening, or during the run-in period, and clinically significant comorbidities

*treatments were administered in the evening *SFC 50/250µg b.i.d.
ACQ, asthma control questionnaire; b.i.d., twice daily; ER, emergency room; FEV_1, forced expiratory volume in 1 second; GLY, glycopyrronium bromide; ICS, inhaled corticosteroid; IND, indacaterol acetate; LABA, long-acting β_2-agonist; MF, mometasone furoate; o.d., once daily; RTI, respiratory tract infection; SC, systemic corticosteroids
Sal/Flu, salmeterol xinafoate/fluticasone propionate combination

Trough FEV_1 at Weeks 26 and 52

- IND/GLY/MF medium-dose demonstrated greater improvements in trough FEV_1 versus IND/MF high-dose and SAL/FLU high-dose at Week 26; the improvements were maintained at Week 52



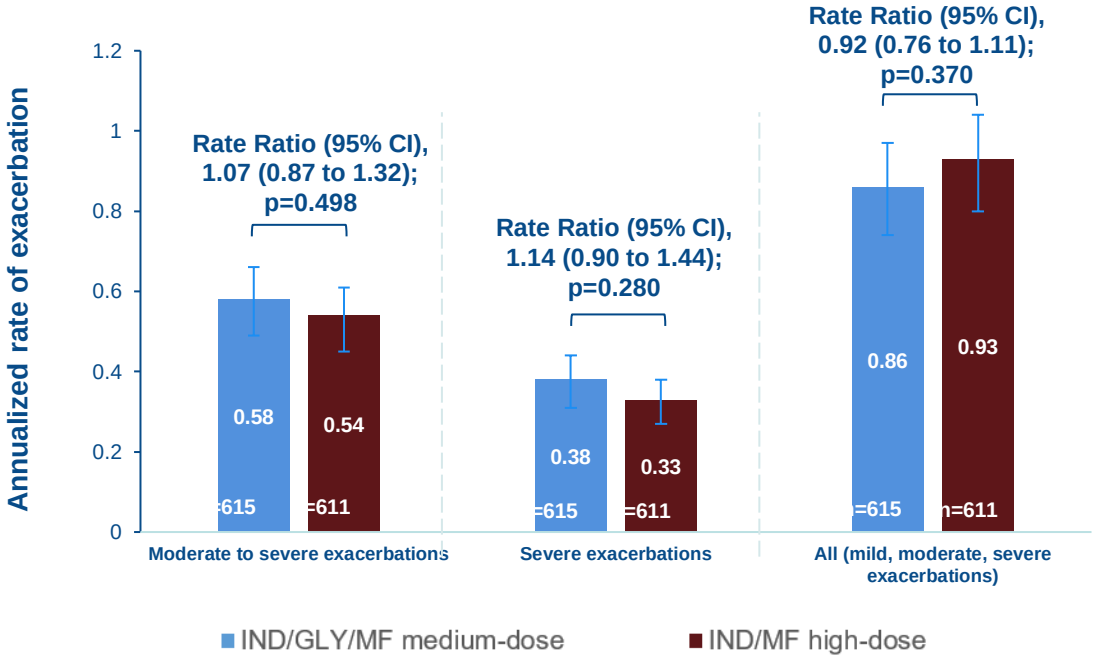
Data presented as LS mean ± SE, error bars represent SE values

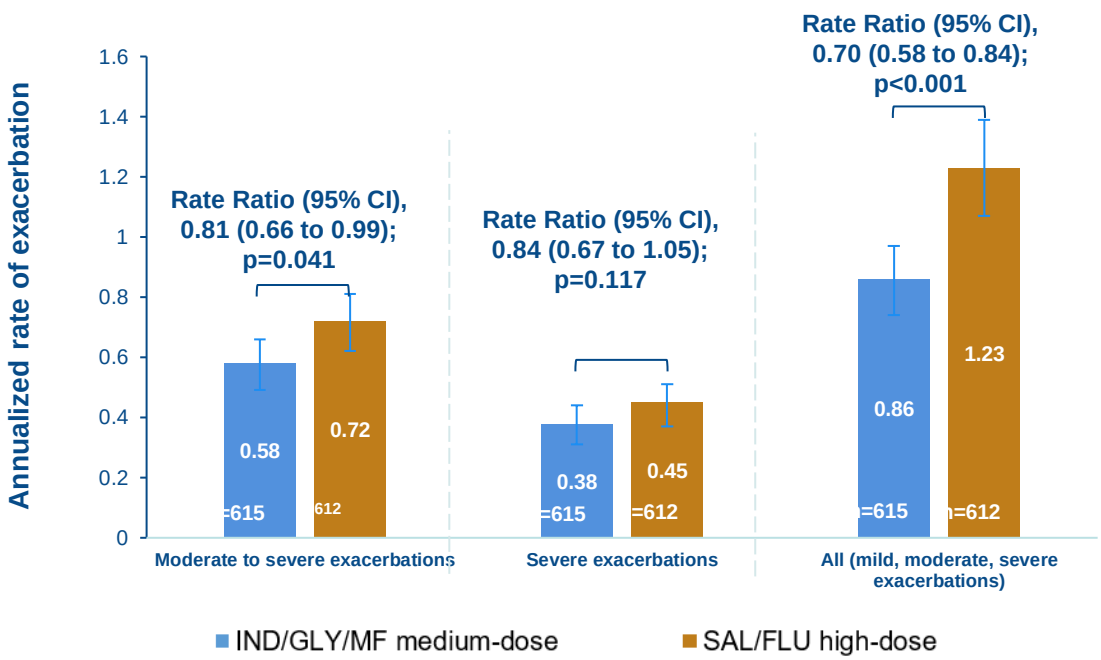
IND/GLY/MF medium-dose, IND/GLY/MF 150/50/80 µg o.d.; IND/MF high-dose, IND/MF 150/320 µg o.d.; SAL/FLU high-dose, SAL/FLU 50/500 µg b.i.d.
Δ, treatment difference; b.i.d., twice daily; FEV_1, forced expiratory volume in one second; IND/GLY/MF, indacaterol acetate/glycopyrronium bromide/mometasone furoate; IND/MF, indacaterol acetate/mometasone furoate; LS, least square, o.d., once daily; SAL/FLU, salmeterol/fluticasone

Annualized Rate of Asthma Exacerbation over 52 weeks

The annualised rates of exacerbations were:

- comparable between IND/GLY/MF medium-dose o.d. and IND/MF high-dose o.d. over 52 weeks;
- with greater reductions in rate of moderate to severe and all exacerbations were observed for IND/GLY/MF medium-dose versus SAL/FLU high-dose b.i.d.





Data presented as annualised rate (95% CI); error bars represent CI values

IND/GLY/MF medium-dose, IND/GLY/MF 150/50/80 µg o.d.; SAL/FLU high-dose, SAL/FLU 50/500 µg b.i.d.
b.i.d., twice daily; ER, emergency room; IND/GLY/MF, indacaterol acetate/glycopyrronium bromide/mometasone furoate; o.d., once daily; RR, rate ratio; SABA, short-acting β_2-agonist; SAL/FLU, salmeterol/fluticasone

Conclusions

In the IRIDIUM study, once-daily, single-inhaler IND/GLY/MF medium-dose demonstrated:

- Greater improvement in lung function versus once-daily IND/MF high-dose and twice-daily SAL/FLU high-dose, at a reduced steroid dose
- Greater reduction in moderate/severe and all exacerbations versus SAL/FLU high-dose
- All treatments were well tolerated