

Abstract P222 Table 1

Characteristic	
VAS score baseline, mean (SD)	5 (3)
Anti-depressant use, n (%)	4 (13)
Stress/anxiety stated as trigger of cough, n (%)	17 (53)
LCQ total score, median (IQR)	14.3 (10.4; 17.8)
LCQ Physical score, median (IQR)	5.2 (3.7; 5.9)
LCQ Psychology score, median (IQR)	4.4 (3.3; 6.3)
LCQ Social score median, (IQR)	4.3 (2.9; 6.0)
GAD-7 score median, (IQR)	3.0 (0.3; 6.8)
PHQ-9 score median, (IQR)	4.0 (2.0, 8.0)

**Results** Data from 32 patients (24 female) with a median (range) age of 57 (31–73) years and average cough duration of 10 (2–40) years who attended the clinic between April and June 2019 were analysed (table). Other relevant co-morbidities included asthma (16%), inducible laryngeal obstruction (13%), reflux (38%) and nasal disease (28%). Several patients were taking (38%) or had taken (38%) anti-tussive medications for their cough.

On the GAD-7, 12 patients reported anxiety symptoms (38%); seven mild (22%), three moderate (9%) and two severe (6%). On the PHQ-9, 15 patients reported depression symptoms (47%); ten mild (31%), four moderate (13%) and one severe (3%). Several patients who recognised stress to be a trigger of their cough scored highly on the anxiety and depression questionnaires (12/17, 70%). Cough scores (VAS and LCQ) correlated strongly with each other, as did GAD7 and PHQ9 scores. PHQ9 also correlated with the LCQ-physical domain (Spearman’s rho=-0.397, p=0.025) supporting the relationship between depression and increased physical symptoms related to cough.

**Conclusion** A high proportion of patients with cough hyper-sensitivity syndrome had symptoms of anxiety and depression. The direction of cough and psychological problems is difficult to determine from these results. When taking a medical history from a patient, physicians should note psychological as well as physical complications. Failure to recognise this may influence treatment outcomes. Clinical psychology input into cough multi-disciplinary teams may be beneficial.

## Asthma and inhalers: all the colours of the rainbow

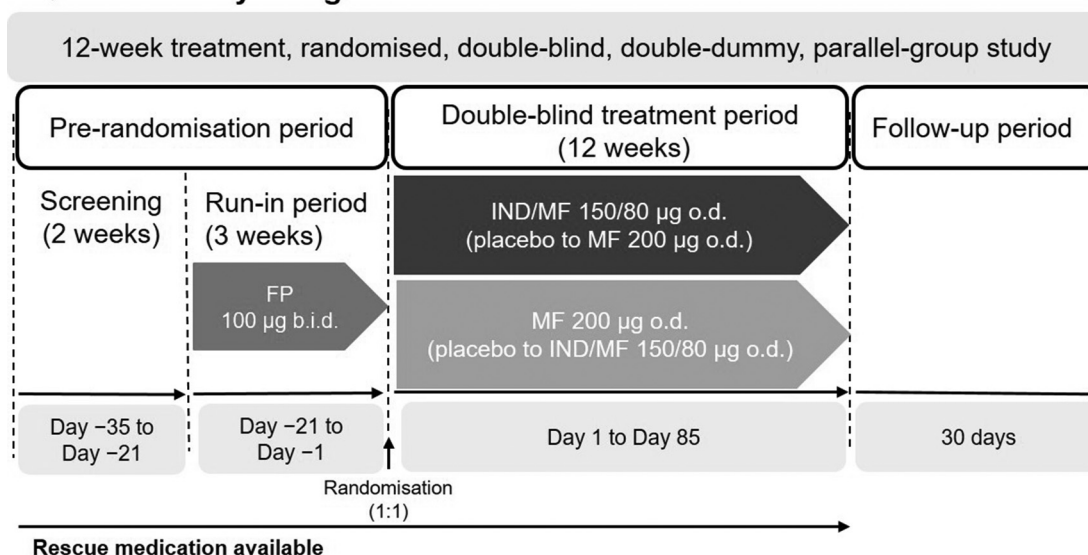
### P223 ONCE-DAILY LOW-DOSE INDACATEROL/MOMETASONE VIA BREEZHALER® REDUCES EXACERBATIONS IN PATIENTS WITH INADEQUATELY CONTROLLED ASTHMA: PHASE III QUARTZ STUDY

<sup>1</sup>O Kornmann, <sup>2</sup>J Mucsi, <sup>3</sup>N Kolosa, <sup>4</sup>L Bandelli, <sup>4</sup>LC Satlin, <sup>5</sup>B Sen, <sup>4</sup>P D’Andrea. <sup>1</sup>IKF Pneumologie Frankfurt, <sup>2</sup>Clinical Research Centre Respiratory Diseases, Frankfurt, Germany; <sup>3</sup>Erzsébet Gondozóház, Gödöllő, Hungary; <sup>4</sup>Daugavpils Regional Hospital LTD, Daugavpils, Latvia; <sup>5</sup>Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA; <sup>6</sup>Novartis Healthcare Pvt. Ltd, Hyderabad, India

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**Introduction** GINA 2019 recommends LABA/ICS as preferred controller therapy in patients with inadequately controlled asthma despite low-dose ICS treatment. This Phase-III study (NCT02892344; the QUARTZ Study) is part of the PLATINUM clinical program which supports the development of both indacaterol acetate/mometasone furoate (IND/MF) and indacaterol acetate, glycopyrronium bromide and mometasone furoate (IND/GLY/MF). Specifically, in QUARTZ we evaluated efficacy and safety of low-dose IND/MF 150/80 µg once daily (o.d.) via Breezhaler® versus MF 200 µg o.d. via Twisthaler® in

### QUARTZ study design



IND/MF was administered via Breezhaler® and MF via Twisthaler®  
 MF 200 µg o.d. via Twisthaler® is equivalent to MF 80 µg o.d. via Breezhaler®  
 b.i.d., twice-daily; FP, fluticasone propionate; IND/MF, indacaterol acetate/mometasone furoate; MF, mometasone furoate; o.d., once daily

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symptomatic asthma patients, both adults and adolescents. IND/MF demonstrated significant improvements in trough FEV<sub>1</sub> and ACQ-7 in these patients. Here, we present exacerbation data, a secondary endpoint from QUARTZ study.

**Methods** This Phase III, 12-week, double-blind study randomised (1:1) asthma patients (≥12yrs) receiving low-dose ICS (with or without additional controller medication) prior to study, to IND/MF or MF (Figure). Patients were symptomatic (ACQ-7 ≥1.5) prior to randomisation and were not required to have a history of exacerbations prior to the study. The rate and time-to-first moderate-to-severe and all exacerbations (mild, moderate and severe) were evaluated as secondary endpoints comparing IND/MF versus MF. Safety was assessed.

**Results** Of 802 patients randomised, 768 completed the study. Lower rates of moderate-to-severe [Rate ratio (RR) 0.25, 95% CI: 0.12, 0.52] and all exacerbations (RR: 0.30, 95% CI: 0.18, 0.50) were observed in IND/MF versus MF. Further IND/MF treatment, delayed time-to-first exacerbation vs MF for moderate-to-severe (Hazard ratio (HR): 0.29, 95% CI: 0.14, 0.59), and all asthma exacerbations (HR: 0.30, 95% CI: 0.18, 0.50). Safety was comparable between the two groups.

**Conclusion** In symptomatic asthma patients, IND/MF showed greater effect on reducing rate (75% of moderate-to-severe and 70% of all exacerbations) and time-to-first exacerbations vs MF. The result was apparent even in patients with a low history of exacerbations. These results demonstrate additive benefit of IND in a fixed combination with MF in terms of reduction in exacerbations and supports the use of IND/MF as efficacious maintenance therapy for asthma versus MF alone.

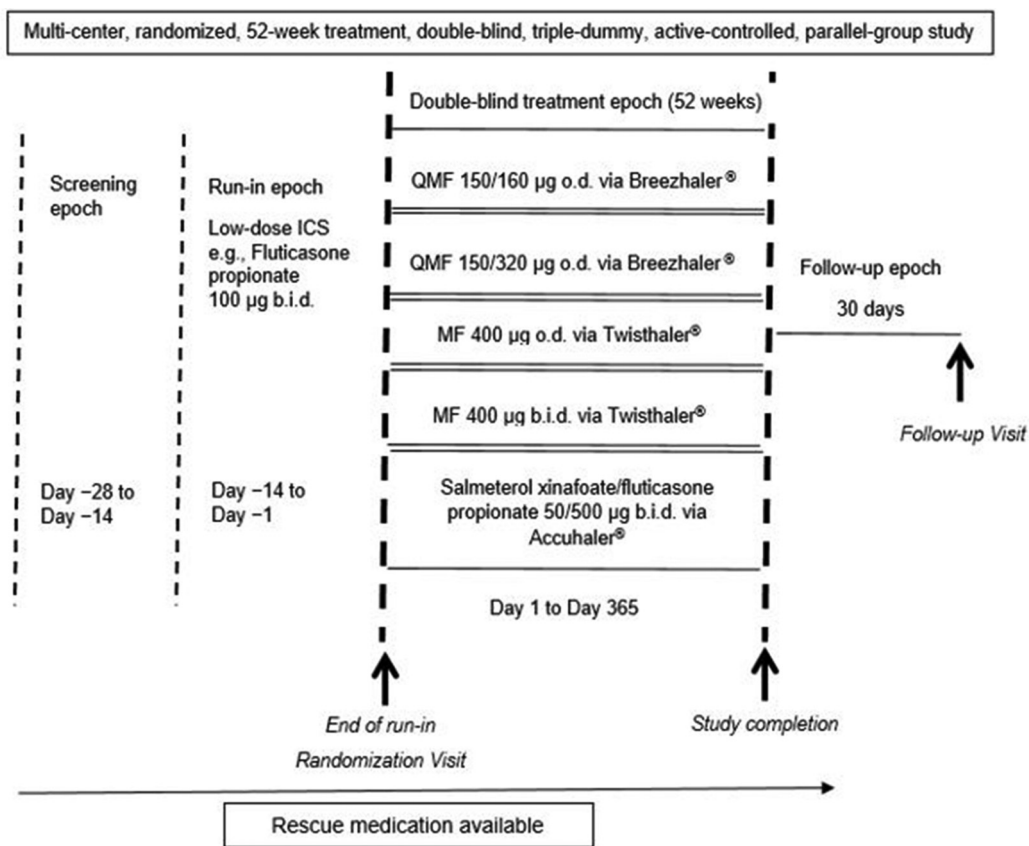
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**EFFICACY AND LONG-TERM SAFETY OF QMF149 (INDACATEROL ACETATE/MOMETASONE FUROATE) VERSUS MOMETASONE FUROATE AND VERSUS SALMETEROL XINAFOATE/FLUTICASONE PROPIONATE IN PATIENTS WITH INADEQUATELY-CONTROLLED ASTHMA: THE PALLADIUM STUDY**

<sup>1</sup>R van Zyl-Smit, <sup>2</sup>M Krull, <sup>3</sup>C Gessner, <sup>4</sup>Y Gon, <sup>5</sup>A Richard, <sup>6</sup>A de los Reyes, <sup>6</sup>X Shu, <sup>6</sup>A Pethe, <sup>6</sup>P D'Andrea. <sup>1</sup>Division of Pulmonology and UCT Lung Institute, University of Cape Town, Cape Town, South Africa; <sup>2</sup>Institut für Allergie- und Asthmaforschung Berlin IAAB, Berlin, Germany; <sup>3</sup>Universitätsklinikum Leipzig, Germany POIS Leipzig GbR, Leipzig, Germany; <sup>4</sup>Division of Respiratory Medicine, Department of Internal Medicine, Nihon University School of Medicine, Tokyo, Japan; <sup>5</sup>Novartis Pharma AG, Basel, Switzerland; <sup>6</sup>Novartis Pharmaceuticals Corporation, East Hanover, New Jersey, USA

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**Rationale** Long-Acting Beta2-Agonist/Inhaled Corticosteroids (LABA/ICS) Fixed-Dose Combinations (FDCs) have been found to be safe and effective in asthma management; however, most of the available therapies require twice-daily(b.i.d.) dosing to achieve an optimum therapeutic effect. QMF149 is a once-daily(o.d.) FDC of indacaterol acetate(LABA) and mometasone furoate(MF, an ICS) delivered by the Breezhaler® device. This Phase-III study(NCT02554786; The PALLADIUM Study) is part of the PLATINUM clinical program which supports the development of both QMF149 and QVM149 (indacaterol acetate, glycopyrronium bromide and mometasone furoate). Specifically, the PALLADIUM study evaluates the efficacy and safety of once-daily QMF149 150/160µg and 150/



b.i.d., twice daily; QMF149, indacaterol acetate/mometasone furoate; MF, mometasone furoate; o.d., once daily

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