incomplete block, placebo-controlled, 2-way crossover study. *Post hoc* data analysis from patients who received both FP/FORM doses is presented.

Methods 62 patients (33M, 29F; =18yrs; reversible FEV_1 =60% pred.) discontinued maintenance ICS medication for 2 - 3wks; those showing a provocative dose of AMP producing a 20% decline in FEV_1 (AMP PD_{20} FEV_1) of <60 mg were randomised to receive 2 of 3 treatments (FP/FORM high-, low-dose or placebo) during 2 periods of 28 ± 3 days each, separated by 2 - 3wks. AMP challenges were performed pre-dose and repeated 12h after last dose at the end of each treatment period. The difference in changes in AMP PD_{20} FEV_1 (day 1 vs day 28) between treatments were compared by an ANCOVA.

Results 15 patients were randomised to receive both high- and low-dose FP/FORM. The change in AMP PD_{20} FEV_1 was greater with FP/FORM high- compared with low-dose (LS means: high dose = 11 mg; 95% CI 4.3, 27.9; low dose = 4.6 mg, 95% CI 1.8, 11.8), with a statistically significant 2.4 fold difference in AMP PD_{20} FEV_1 (1.2 doubling doses) between doses (LS mean: 2.4; 95% CI 1.3, 4.5; p = 0.012). FP/FORM was well-tolerated; only few (mild or moderate) AEs occurred.

Conclusions A significant dose-response was found between low- and high-dose FP/FORM with the higher dose demonstrating a greater reduction in airway responsiveness to AMP.

P167 EFFICACY AND SAFETY OF OMALIZUMAB IN REAL–WORLD CLINICAL PRACTICE IN INDIAN PATIENTS WITH ALLERGIC (IGE-MEDIATED) ASTHMA: ANALYSIS BY BASELINE SEVERITY OF ASTHMA

[1]Z Udwadia, [2]R Narasimhan, [3]VK Ratnavelu, [4]M Kotnis; *[1]P D Hinduja National Hospital and Medical Research Centre, Mumbai, India; [2]Apollo Hospitals (Main), Chennai, India; [3]Yashoda Super Specialty Hospital, Secunderabad, India; [4]Novartis India Ltd, Mumbai, India*

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Omalizumab (OMA) is a humanised anti-immunoglobulin E (IgE) monoclonal antibody, indicated as add-on therapy for moderate-to-severe persistent allergic (IgE–mediated) asthma. Here, we report the interim results of a 52-week observational study of OMA in patients in India, stratified by baseline severity of asthma.

In this open-label, non-comparative, non-interventional study, patients (age =12 years) with moderate-to-severe persistent allergic asthma, inadequately controlled despite ICS + LABA (GINA step 4) treatment, were recruited. All patients were receiving OMA at baseline. Outcomes were assessed every 4 weeks, and included exacerbations, days missed at college or work, hospitalizations, and mean change (D) in FEV_1, ACQ5 score, ACT score and oral corticosteroid (OCS) dose versus baseline. Adverse events were also recorded. Asthma severity was assessed at baseline, in accordance with GINA guidelines, and classified as either moderate (group 1) or severe (group 2). Data were analysed using chi-squared and paired t-tests. All parameters were compared between baseline and Week 28 post-OMA treatment.

To date, 100 patients have completed 28 weeks of follow-up (36 patients in group 1 and 64 in group 2). Results are presented in the Table. The proportion of patients with =1 exacerbation, missing any day at work/college and requiring hospitalisation decreased appreciably in both groups. There was also significant improvement in lung function and asthma control, and a reduction in OCS need. Overall, 5 patients (5%) reported adverse events (AEs), of whom 2 (2%) reported serious AEs (SAEs). The most frequent non-serious AEs were gastrointestinal (GI) and nervous system disorders and were suspected to be related to omalizumab. GI, respiratory, thoracic and mediastinal SAEs were reported, but were not suspected to be related to omalizumab. All reported AEs and SAEs resolved with treatment. 28 weeks' treatment with omalizumab was associated with reductions in asthma exacerbations and OCS requirements, and improvements in lung function and asthma control, that were comparable between patients with moderate or severe asthma at baseline

Abstract P167 Table 1.

Parameter	Group 1 (n=36)		Group 2 (n=64)		Group 1 vs. 2	
	baseline	28 weeks	baseline	28 weeks	p-Value	
Patients with ≥1 exacerbation	9.5%	0.0%	9.3%	1.1%	0.530	
Patients missing any day at work/college	23.8%	0.0%	25.9%	7.4%	0.200	
Hospitalization rate	19.0%	0.0%	27.8%	0.0%	-	
	D vs. baseline	p-Value	D vs. baseline	p-Value	Mean difference	p-Value
FEV_1 (L)	+1.1	0.000	+1.0	0.000	0.1	0.244
ACQ5 score (composite)	-7.5	0.000	-7.3	0.000	-0.2	0.786
ACQ5 score (mean)	-1.5	0.000	-1.5	0.000	0.0	0.981
ACT score(mean)	+9.4	0.000	+10.2	0.000	-0.8	0.396
OCS dose (mg/day)	-11.3†	0.002	-18.8‡	0.000	7.5	0.099

†13 and ‡16 patients were receiving OCS at baseline in group 1 and 2, respectively.

P168 THE EFFECT OF FLUTICASONE PROPIONATE/FORMOTEROL FUMARATE COMBINATION THERAPY ON QUALITY OF LIFE SCORES IN ASTHMA PATIENTS

T McIver, S Dissanayake; *Mundipharma Research Limited, Cambridge, UK*

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Introduction The Asthma Quality of Life Questionnaire (AQLQ) is a validated questionnaire which measures the effect of asthma on patient's lives. AQLQ data from four phase III studies were pooled to assess how AQLQ scores are affected by treatment with fluticasone propionate (FP)/formoterol fumarate (FORM) in a single MDI (FP/FORM; ***flutiform***) compared with other combination treatments.

Method AQLQ data from a pooled analysis of two phase III open-label studies in patients with mild-moderate/severe asthma [pool 1; FP/FORM 50/5 or 125/5 (n = 206) vs. FP 50 + FORM 12 given together in separate inhalers and FP/salmeterol 50/25 or 125/25 (n = 206)], and a pooled analysis of two phase III double-blind studies in patients with moderate/severe asthma [pool 2; FP/FORM 250/10 (n = 294) vs. FP 250 + FORM 12 given together in separate inhalers and budesonide/FORM 200/6 (n = 295)] were analysed. AQLQ scores range from 1–7; a low score indicates the most severe impairment. Change in AQLQ from baseline to end of study was analysed using an ANCOVA. The proportion of subjects achieving a clinically relevant change of = 0.5 units was analysed using a logistic regression model.

Results In pool 1, both groups had a similar increase in overall AQLQ score from baseline to end of study (0.635 in the FP/FORM group and 0.771 in the combination group) and the percentage of patients with a clinically relevant change in overall AQLQ score was 56% and 59%, respectively. In pool 2, the mean increase in overall AQLQ score from baseline to end of study was 0.837 in the FP/