Abstract P158 Table 1 Treatment comparisons for % patients with ≥50% symptom free nights over the study duration

HZA106827 (Weeks 1–12) REF	Placebo (n = 203)	FF 100 (n = 204)	FF/VI 100 (n = 201)
% of patients	35%	46%	59%
Odds Ratio (95% CI)		FF vs PbO: 2.29 (1.41, 3.73)	FF/VI vs PbO: 4.66 (2.84, 7.66)
Odds Ratio (95% CI)			FF/VI vs FF 100: 2.04 (1.29, 3.22)
Time (days) when 50% of patients achieved 7 nights without symptoms	Did not occur during study	70	44
HZA106863 (Weeks 1–12) REF	**FF 100 (n = 346)**	**FF/VI 100 (n = 345)**	**FF/VI 200 (n = 345)**
% of patients	42%	43%	48%
Odds Ratio (95% CI)		FF/VI 100 vs FF 100: 1.33 (0.93, 1.91)	FF/VI 200 vs FF/VI 100: 1.23 (0.87, 1.74)
Time (days) when 50% of patients achieved 7 nights without symptoms	86	64	48
HZA106829 (Weeks 1–24) REF	**FF 200 (n = 193)**	**FF/VI 200 (n = 197)**	**FP 500 (n = 195)**
% of patients	41%	51%	46%
Odds Ratio (95% CI)		FF/VI 200 vs FF 200: 1.59 (0.99, 2.55)	
Odds Ratio (95% CI)			FF/VI 200 vs FP 500: 1.09 (0.69, 1.74)
Time (days) when 50% of patients achieved 7 nights without symptoms	111	72	84

P159 THERAPEUTIC BENEFIT OF MEPOLIZUMAB IN THE SCOTTISH MEDICINES CONSORTIUM (SMC) RESTRICTED SUB-POPULATION – A POST-HOC META-ANALYSIS OF PHASE IIB/III TRIALS

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Rationale The Scottish Medicines Consortium provides advice to NHS boards and Area Drug and Therapeutics Committees across Scotland about the status of newly licensed medicines. In June 2016 positive advice was issued for mepolizumab, an anti-IL-5 mAb licensed for adult severe refractory eosinophilic asthma, for use in a restricted sub-population: patients who have eosinophils of ≥150 cells per microlitre (0.15 × 109/L) at initiation of treatment and had ≥4 asthma exacerbations in the preceding year or are receiving maintenance treatment with oral corticosteroids (mOCS). Here we present the results for this sub-population comparing the effect of mepolizumab with placebo in this subgroup.

Methods Three randomised, double-blind, placebo-controlled studies of mepolizumab in severe eosinophilic asthma were identified, which used the licensed 100 mg SC dose or the corresponding 75 mg IV dose of mepolizumab. For analysis purposes, these two treatment arms were combined. A post-hoc meta-analysis assessing the key outcome measures in the three phase IIb/III trials (DREAM [NCT01000506] and MENSA [NCT01691521] with a sensitivity analysis including SIRIUS [NCT01691508]) were run for the sub-population using individual patient data.

Results The post-hoc meta-analysis included 197 patients from DREAM and MENSA and 251 when including the SIRIUS trial. The mean age was 51.2 and 51.3 years of which 62% and 64% were female, respectively. A 59% (95% CI: 0.31, 0.55; $p < 0.001$) reduction in clinically significant exacerbations was seen in the meta-analysis of DREAM and MENSA (50% [95% CI: 0.40, 0.64, $p < 0.001$] sensitivity analysis with SIRIUS). The ACQ score showed an improvement of −0.56 (95% CI: −0.79,−0.33; $p < 0.001$) and −0.58 (95% CI: −0.79,−0.38; $p < 0.001$, sensitivity analysis with SIRIUS). The SGRQ was only used in MENSA and SIRIUS and showed an improvement in total score of −8.0 (−12.0, −3.9, $p < 0.001$).

Conclusion Mepolizumab treatment was effective in SMC advice population (adult severe refractory eosinophilic asthma patients with a blood eosinophil count of ≥150 cells/μL at initiation of treatment, and ≥4 exacerbations in the previous year or dependency on mOCS). The use of a post-hoc meta-analysis is a helpful approach to increase our understanding of mepolizumab's treatment effect in the SMC restricted sub-population.

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P160 USE OF OMALIZUMAB IN FUNGAL ALLERGIC ASTHMA

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Background The monoclonal anti-IgE agent Omalizumab holds an established place in the management of severe allergic asthma patients (GINA Step 5). Fungal allergic asthma possesses added complexity as fungi are ubiquitous in our environment and are capable of not only triggering asthma, but may grow, colonise and infect host tissue. Current treatment approaches include: Allergen avoidance, mucus reduction, control of bacterial infection, control of inflammation, reducing fungal burden and recently blockade of allergy using Omalizumab.

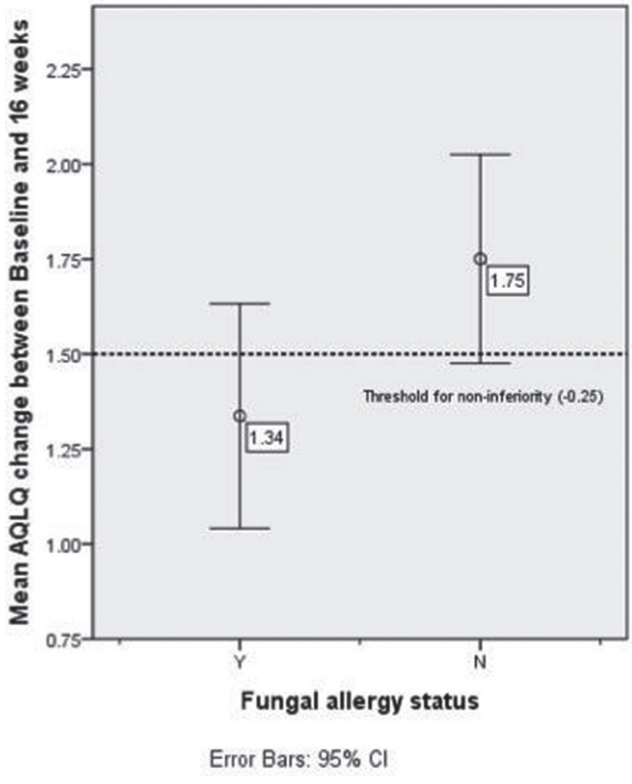
Aims/purpose Investigate the response to Omalizumab in severe asthma patients who are sensitised to fungal allergens compared to those who are non-fungal allergic. Current literature describes the use of Omalizumab in fungal allergic airways disease, though published data takes the form of case reports/series with limited total population.

Methods Retrospective cohort study of severe asthma patients treated with Omalizumab (n = 168). Patients were grouped into fungal or non-fungal allergy status, followed by a comparison of the change in a variety of clinical and physiological outcomes at 16 weeks and 52 weeks from baseline between these two groups. The change in Asthma Quality of Life Questionnaire (AQLQ) between baseline and 16 weeks was utilised as the primary outcome. Groups will be compared using an unpaired t-test or Chi-

squared test, as appropriate, to test for non-inferiority (threshold −0.25) in the fungal allergic group compared to the non-fungal allergic group.

Results The fungal allergic group (n = 76) was found to have a mean AQLQ difference between baseline and 16 weeks of +1.34 (± 1.25). When compared to the non-fungal allergic cohort, the fungal allergic group was found to have a statistically significant mean AQLQ difference between baseline and 16 weeks of −0.41 (95% CI: −0.14 – −0.81). See Figure 1.

Conclusion Fungal allergic patients have a less profound AQLQ response to Omalizumab than non-fungal allergic although the benefit is still clinically significant in the majority of cases. The reduced benefit is statistically different in terms of change, though it does not fulfil the a-priori threshold for non-inferiority.



Abstract P160 Figure 1 Comparing mean AQLQ response to Omalizumab between fungal and non-fungal allergic patients

Treating Idiopathic Pulmonary Fibrosis

P161 UNMET NEEDS IN THE TREATMENT OF IDIOPATHIC PULMONARY FIBROSIS (IPF) – INSIGHTS FROM PATIENT CHART REVIEW IN FIVE EUROPEAN COUNTRIES

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Abstract P161 Table 1 Summary of findings from the treated and untreated populations across European countries

Factor	Treated N = 828	Untreated N = 909
Average age, years	67	70**
Male,%	69	63**
MDT evaluation,%	83	57**
Lung comorbidities,%	39	51**
Emphysema	23	33**
Lung cancer	2	5**
Pulmonary hypertension	22	25
CV comorbidities,%	39	45*
High risk of coronary artery disease	16	17
Coronary artery disease without history of MI or stroke	14	16
Coronary artery disease with history of MI	11	15**
Candidate for lung transplantation,%	19	7**
Confirmed IPF,%	84	51**
Average time from diagnosis to last consultation, months	15.8	15.9
Stable IPF,%	31	51**
Mild IPF (current level),%	18	41**
Symptomatic at treatment initiation,%	90	70**
%FVC at last check-up	60.7	64.2**
%DLco at last check-up	47.4	50.6**

p values represent treated population versus untreated population. *p ≤ 0.05; **p ≤ 0.01. CV, cardiovascular; %DLco, percent predicted carbon monoxide diffusing capacity; %FVC, percent predicted forced vital capacity; IPF, idiopathic pulmonary fibrosis; MDT, multidisciplinary team; MI, myocardial infarction.

Introduction and objectives Two antifibrotic drugs, pirfenidone and nintedanib, are approved by the FDA and EMA for the treatment of IPF. We investigated treatment patterns of European patients with IPF to understand antifibrotic treatment uptake and identify unmet needs in IPF treatment practice.

Methods Between February and March 2016, respiratory physicians from France, Germany, Italy, Spain and the UK participated in an online questionnaire designed to collect information on IPF treatment patterns. Responses were collected from physicians who had consulted with ≥6 (France, Italy, Spain) or ≥10 (Germany, UK) patients with IPF (within 3 months). Patients were categorised as being in the treated population (those who had received approved antifibrotics) or the untreated population (those who had not received approved antifibrotics, but may have received other therapies). Classification of IPF diagnosis (confirmed/suspected) and severity (mild/moderate/severe) for each patient was based on the individual physician's report.

Results Overall, there were 290 respondent physicians reporting on 1838 patients. Of 1783 patients with data, 54% were not treated with an approved antifibrotic. Of patients with a confirmed IPF diagnosis, 41% were not treated. In the 1737 patients analysed, the untreated population was older than the treated population (70 versus 67 years, respectively; p ≤ 0.01) and had less frequent multidisciplinary team (MDT) evaluation (57% versus 83%, respectively; p ≤ 0.01). At diagnosis, mild, moderate and severe IPF was reported in 43%, 40% and 16% of untreated patients, and 26%, 64% and 10% of treated patients, respectively. Average forced vital capacity (FVC) at diagnosis and last check-up was significantly higher in untreated patients versus treated patients (both p ≤ 0.01; Table); however, fewer untreated patients had an FVC measurement at their most recent check-up