

COPD phenotypes and history of pneumonia can impact on exacerbation of COPD in Korea. We need to investigate further prospective studies to reach the concrete conclusion.

PRS3

REAL WORLD EFFECTIVENESS AND RELATIVE EFFECTIVENESS OF OMALIZUMAB. AN HISTORIC-PROSPECTIVE DESIGN STUDY

Grimaldi-Bensouda L¹, Abenheim L²

¹LA-SER, Paris, Paris, France, ²LA-SER Europe Ltd., London, UK

OBJECTIVES: Omalizumab has been shown to decrease the risk of hospitalisation or emergency visits in patients with uncontrolled severe allergic asthma as compared to placebo. This longitudinal study observed the conditions under which omalizumab is prescribed in real-life settings; and assessed whether its use, as an add-on therapy alongside standard treatments, decreases the risk of severe asthmatic exacerbations. **METHODS:** A cohort of adult patients with uncontrolled severe asthma despite optimal treatment with inhaled and oral corticosteroids and a long-acting beta2-agonist, but no treatment with omalizumab upon entry, was assembled. Risk of hospitalisation and/or emergency room visits for asthma exacerbation was assessed using the Andersen-Gill extension of the Cox model for repeated events controlling for age, gender, smoking history, body mass index, gastro-oesophageal reflux, allergic status, allergic rhinitis, treatment, and hospitalisation or emergency room visits for asthma in the 2 months prior to omalizumab treatment. **RESULTS:** Overall, 163 physicians recruited 767 patients, of whom 374 took omalizumab at least once (mean observation period: 20.4 months). Omalizumab use was associated with an adjusted relative risk of hospitalisation and/or emergency room visits for asthma of 0.57 (95% confidence interval: 0.43–0.78). In omalizumab users, the adjusted relative risk of hospitalisation and/or emergency room visits for asthma during omalizumab treatment versus non-treatment periods was 0.40 (95% confidence interval: 0.28–0.58). **CONCLUSIONS:** Add-on omalizumab significantly decreases the risk of hospitalisation/emergency room visits in patients with uncontrolled severe asthma in the real-life practice.

PRS4

COMPARATIVE EFFICACY OF ACLIDINIUM BROMIDE 400 MCG BID VERSUS TIOTROPIUM 18 MCG AND 5 MCG QD AS MAINTENANCE BRONCHODILATOR TREATMENT TO RELIEVE SYMPTOMS IN ADULT PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): A NETWORK META-ANALYSIS

Karabis A¹, Lindner L², Mocarski M³, Bouwmeester W¹, Karakurum C², Prior M², Bergman G⁴

¹MAPI Consultancy, Houten, The Netherlands, ²Almirall S.A., Barcelona, Spain, ³Forest Research Institute, Jersey City, NJ, USA

OBJECTIVES: To estimate the relative efficacy of a new long-acting muscarinic antagonist (LAMA), aclidinium bromide 400 µg BID (AB400), to tiotropium bromide 18 µg (TIO18) and 5 µg (TIO5) QD in patients with COPD. **METHODS:** A systematic literature search using a predefined strategy in MEDLINE[®], EMBASE[®] and the Cochrane Library identified 21 unique placebo-controlled RCTs: TIO18 (16 trials), TIO5 (3 trials) and AB400 (2 trials). Outcomes were change from baseline (CFB) in lung function (trough FEV₁), disease-specific health status by St. George's Respiratory Questionnaire (SGRQ) total score, and breathlessness by Transition Dyspnea Index (TDI) focal score, at 12 and 24 weeks. All trials were analysed simultaneously using a Bayesian network meta-analysis and relative treatment effects between all regimens were obtained. Meta-regression techniques were included to investigate dissimilarities in study design and patient characteristics across trials. **RESULTS:** In line with the pivotal trials, AB400 was shown to be more efficacious than placebo on all evaluated endpoints. AB400 showed comparable but numerically greater improvements at 12 weeks compared to TIO18 in trough FEV₁ [difference in CFB (95% Credible Interval) 0.001L (-0.03,0.03)], SGRQ total score [-0.85 (-3.41,1.75)] and TDI focal score [0.06 (-0.41,0.52)]. Similar but numerically greater differences were also seen for AB400 versus TIO18 at 24 weeks in trough FEV₁ [-0.02L (-0.02,0.08)], SGRQ total score [-1.84 (-4.21,0.51)] and TDI focal score [0.10 (-0.53,0.73)]. Additionally, AB400 showed similar improvements on these same endpoints versus TIO5 (where data was available). Meta-regression analyses, correcting for differences in treatment patterns (concurrent ICS, LABA treatment) and COPD severity (baseline FEV₁ percent predicted) across the trials, showed comparable findings as the base case analysis. **CONCLUSIONS:** This meta-analysis suggests that maintenance treatment with aclidinium 400 µg BID results in comparable improvements in lung function, health status, and breathlessness as tiotropium 18 µg and 5 µg QD in COPD patients.

PRS5

DUAL BRONCHODILATION WITH INDACATEROL AND TIOTROPIUM IN COMBINATION VERSUS TRIPLE THERAPY, FIXED-DOSE COMBINATIONS, AND MONOTHERAPY IN COPD – A NETWORK META-ANALYSIS OF FEV₁

Kraemer M¹, Ellis A², Baldwin M³, Jansen J², Capkun-Niggli G¹, Cope S²

¹Novartis Pharma AG, Basel, Switzerland, ²MAPI Consultancy, Boston, MA, USA, ³Novartis Pharmaceuticals UK Limited, Horsham, West Sussex, UK

OBJECTIVES: To evaluate the relative efficacy of indacaterol 150µg + tiotropium 18µg (IND/TIO) versus triple therapies (i.e. tiotropium plus a fixed-dose combination [FDC] of a long-acting beta2-agonist [LABA] and inhaled corticosteroid [ICS]), a LABA/ICS FDC alone, and monotherapies, including indacaterol, tiotropium, aclidinium, salmeterol, formoterol, and placebo in patients with moderate to severe chronic obstructive pulmonary disease (COPD) in terms of trough FEV₁ at 12 weeks. **METHODS:** Several of the treatments to be compared include ICS as part of the study treatment. Therefore the evidence base was restricted to RCTs not allowing for concomitant ICS use (for Novartis studies subgroup data for non-ICS users were included). For this population 23 RCTs were identified based on a systematic liter-

ature review, which were analysed simultaneously using a Bayesian network meta-analysis. Treatment-by-covariate interactions were included for the proportion of current-smokers to improve similarity of the trials. **RESULTS:** IND/TIO resulted in a higher change from baseline (CFB) in FEV₁ by 0.24L (95%CrI: 0.20, 0.27) versus placebo at 12 weeks. IND/TIO is likely to be favourable versus salmeterol/fluticasone 50/500µg + tiotropium 18µg [difference 0.03L (95%CrI: -0.01, 0.07); probability better: 94%] and comparable to formoterol/budesonide 9/320µg + tiotropium 18µg [difference 0.02L (95%CrI: -0.02, 0.06); probability better: 80%]. IND/TIO has a larger CFB than the FDCs alone with an advantage of 0.07L (95%CrI: 0.03, 0.12) to 0.09L (95%CrI: 0.04, 0.15). IND/TIO also has a higher CFB than the monotherapies assessed. Out of the 13 regimens evaluated, there is a 77% probability that IND/TIO is the most efficacious treatment in terms of CFB in FEV₁. Results were not sensitive to adjustment for smokers or to the exclusion of RCTs with concomitant anticholinergics or an exacerbation history. **CONCLUSIONS:** IND/TIO is expected to be comparable to triple therapies and more efficacious than FDCs and monotherapies in terms of FEV₁ at 12 weeks.

PRS6

PREVALENCE OF SELECTED CONDITIONS IN RUSSIA ACROSS SOURCES

Vietri J¹, Matveev N², Bhounsule P³, Isherwood G⁴

¹Kantar Health, Princeton, NJ, USA, ²Russian National Research Medical University, Moscow, Russia, ³Kantar Health, New York, NY, USA

OBJECTIVES: To compare the prevalence of selected medical conditions in Russia as estimated using the National Health and Wellness Survey (NHWS) with those from the medical literature. **METHODS:** This study used data from the 2011 Russian NHWS, a cross-sectional survey administered to 10,039 adults living in large Russian cities recruited through both online and offline methods. All data were self-reported. Weighted prevalence was estimated through self-report and validated scales embedded in the questionnaire. Conditions included depression, restless legs syndrome, and sleep difficulties, among others. Gender differences were also assessed. NHWS estimates were compared with prevalence estimates taken from published studies. **RESULTS:** Twelve-month prevalence estimates of depression according to self-report were 20% in men and 25% in women, and depression of moderate or greater severity was identified through Patient Health Questionnaire (PHQ-9) in 17% of men and 21% of women, both slightly higher than the approximately 10% and 20% estimates of clinically significant depression in men and women, respectively, reported by Akarachkova and Vershinina (2010). In NHWS, restless leg syndrome was reported by 6% and 10% of men and women respectively, and found to affect 8% of men and 10% of women by Romanova (2008). Difficulty falling asleep was estimated at 25% of men and 32% of women in NHWS, and 30% of men and 28% of women (Romanova, 2008). Prevalence for all conditions among urban Russian adults was much lower across conditions when limited to patients reporting a diagnosis confirmed by a doctor. **CONCLUSIONS:** Prevalence estimates and gender differences calculated from NHWS Russia data were generally similar to those taken from previous literature, providing initial evidence for its use in estimating prevalence of disease in urban Russia. Reports of experiencing a condition were much more common than reports of confirmed diagnosis, suggesting substantial unmet medical need.

PRS7

PATTERNS OF INTRANASAL CORTICOSTEROID USE AMONG INDIVIDUALS DIAGNOSED WITH ALLERGIC RHINITIS: EVIDENCE FROM A LARGE CLAIMS DATABASE

Lage MJ¹, Gross GN², Buck PO³, Lepore MS³

¹HealthMetrics Outcomes Research, Delray Beach, FL, USA, ²Dallas Allergy and Asthma Center, Dallas, TX, USA, ³Teva Pharmaceuticals, Frazer, PA, USA

OBJECTIVES: Examine patient characteristics and patterns of intranasal corticosteroid (INS) use among individuals diagnosed with allergic rhinitis (AR) from a large, US retrospective claims database. **METHODS:** The i3 Invention™ Data Mart was used from January 1, 2006 through December 31, 2010. AR patients aged ≥12 years were included if they received an aqueous INS formulation (with first such date identified as index date) and had continuous insurance coverage from 6 months before through 24 months after index date. Patients diagnosed with chronic rhinitis or nasal polyps were excluded. Data are descriptive in nature. **RESULTS:** The sample consisted of 163,473 individuals with a mean age of 41 years (SD=15), 59% female, and 55% residing in the southern US. Patients were most commonly prescribed generic fluticasone propionate (44%), mometasone (34%), or triamcinolone (10%) and had a high degree of related comorbidities, including sinusitis (40%), asthma (15%), and otitis media (12%). Treatment patterns during the first year after index date: a mean of 2.1 INS prescriptions were filled (median=1.0; SD=1.8), adherence as measured by the medication possession ratio averaged 18% (median=8; SD=16), and persistence averaged 135 days (median=30; SD=134). Furthermore, 7% of patients switched INS products during their first year of use, with 5% of patients who initially received generic INS switching to a branded INS product. **CONCLUSIONS:** Although INs are considered the gold standard for symptomatic treatment of AR, this examination of a large US claims database demonstrated that patients with AR who filled at least 1 aqueous INS prescription generally did not use their INS for an extended period of time.

PRS8

BURDEN OF EXACERBATIONS IN PATIENTS WITH COPD IN THE NETHERLANDS: A REAL-LIFE STUDY

Overbeek JA¹, Balp MM², Penning FJA¹, Dekhuijzen PNR³, Herings RMC¹

¹PHARMO Institute for Drug Outcomes Research, Utrecht, The Netherlands, ²Novartis Pharma AG, Basel, Basel, Switzerland, ³Radboud University Medical Centre, Nijmegen, Gelderland, The Netherlands