Comparative Efficacy and Safety of Umeclidinium/Vilanterol, Umeclidinium, and Salmeterol in Symptomatic Maintenance-Naïve and Maintenance-Treated Chronic Obstructive Pulmonary Disease: A Pre-specified Secondary Analysis of the EMAX Trial

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Background

Umeclidinium and vilanterol (UMEC/VI) are long-acting ligands. UMEC/VI bronchodilation is recommended as bronchodilatory therapy in symptomatic patients with chronic obstructive pulmonary disease (COPD). Clinical efficacy and safety studies demonstrated that UMEC/VI was well tolerated and provided effective bronchodilation in maintenance-naïve (MN) and maintenance-treated (MT) patients.1

Methods

Patients were randomized to UMEC/VI (N=348), UMEC (N=349), or SAL (N=348) in a 1:1:1 ratio. The primary endpoint was mean increase from baseline in post-albuterol FEV1 (focal score) at 24 weeks. Mean differences were compared with a two-sided alpha level of 0.05 using Mixed Effect Model for Repeated Measurements (MMRM) in the ITT population. Resulting changes in lung function and symptom outcomes were compared between UMEC/VI and SAL in the MN and MT subgroups. Safety outcomes were compared between UMEC/VI and SAL in the ITT population.

Results

In the MN subgroup, mean increase from baseline in post-albuterol FEV1 and IC at Week 24 was significantly greater with UMEC/VI versus UMEC and SAL (Table 1). Analyses in the ITT population demonstrated early and sustained improvements in lung function, symptoms, rescue medication use, exacerbation risk, and E-RS total score (Table 2).

Conclusions

In this pre-specified subgroup analysis of the EMAX trial, UMEC/VI was well tolerated and provided statistically significant, clinically important improvements in lung function versus UMEC and SAL in both MN and MT subgroups, and versus SAL in patients intensifying bronchodilation is effective and well tolerated in these patients.

Table 1. Demographics and baseline characteristics

|                | UMEC/VI (N=348) | UMEC (N=349) | SAL (N=348) | p-value
|----------------|-----------------|--------------|-------------|--------
| Age (years)    | 64.1 (14.9)     | 64.2 (14.9)  | 63.9 (14.7) | 0.693  |
| Sex (male/female) | 234/114        | 235/114      | 235/113     | 0.853  |
| E-RS focal score | 43.7 (17.6)    | 43.7 (17.6)  | 43.9 (17.8) | 0.795  |

Table 2. Symptom severity, rescue use and exacerbation outcomes

|                | UMEC/VI (N=555) | UMEC (N=554) | SAL (N=550) | p-value
|----------------|-----------------|--------------|-------------|--------
| FEV1 (L)       | 2.9 (1.1)       | 2.9 (1.2)    | 2.9 (1.2)   | 0.795  |
| IC (L)         | 60.8 (18.4)     | 60.6 (18.4)  | 60.5 (18.3) | 0.795  |

References


Disclosures

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