InforMing the PAthway of COPD Treatment (The IMPACT Study): Single Inhaler Triple Therapy (Fluticasone Furoate/Umclidinium/Vilanterol) Versus Fluticasone Furoate/Vilanterol and Umclidinium/Vilanterol in Patients With COPD: An Analysis Based on Baseline COPD Medication Use

Phisher No. 203 (A1116)


Introduction

- The current Global initiative for chronic Obstructive Lung Disease (GOLD) strategy document (GOLD 2017) suggests that COPD management should be based on the continuous reassessment of treatment needs over time, with four key treatment goals: 1) symptom control, 2) prevention of exacerbations, 3) preservation of lung function, and 4) reduction of comorbidities.
- The Global Initiative for Chronic Obstructive Lung Disease (GOLD) proposes the use of a single inhaler triple therapy (SITT) for the management of COPD, particularly in patients with persistent symptoms and/or exacerbations.
- The objective of this analysis was to evaluate the efficacy and safety of FF/UMEC/VI versus FF/VI and UMEC/VI in patients with moderate-to-severe COPD over 12 months of treatment.

Methods

- IMPACT (T1H0631, T1H0632, T1H0633) was a 52-week, randomized, double-blind, parallel group study comparing single inhaler triple therapy with FF/UMEC (100/225/125 μg) and salmeterol fixed-dose with FF (100/610 μg) in patients with moderate-to-severe COPD and persistent symptoms and/or exacerbations.
- Patients were randomized to FF/UMEC/VI or FF/VI or UMEC/VI over 52 weeks.

Results

- Objective endpoints included annual exacerbation rate, respiratory function measures (FEV1, SGRQ score), and lung function measures (FEV1, FVC).
- Secondary endpoints included SGRQ score, exacerbation rate, and lung function measures (FEV1, FVC).
- FF/UMEC/VI was non-inferior to FF/VI and UMEC/VI in the primary endpoint of annual exacerbation rate.
- FF/UMEC/VI significantly reduced the risk of severe exacerbations compared to both FF/VI and UMEC/VI.
- FF/UMEC/VI also significantly improved SGRQ score compared to both FF/VI and UMEC/VI.
- FF/UMEC/VI was well-tolerated, with a similar safety profile to FF/VI and UMEC/VI.

Conclusions

- FF/UMEC/VI significantly reduced the risk of severe exacerbations compared to both FF/VI and UMEC/VI in patients with moderate-to-severe COPD.
- FF/UMEC/VI was non-inferior to FF/VI and UMEC/VI in the primary endpoint of annual exacerbation rate.
- FF/UMEC/VI significantly improved SGRQ score compared to both FF/VI and UMEC/VI.
- FF/UMEC/VI was well-tolerated, with a similar safety profile to FF/VI and UMEC/VI.

References


Table 1. Patient demographics (ITT population)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>FF/UMEC/VI (n=387)</th>
<th>FF/VI (n=349)</th>
<th>UMEC/VI (n=1351)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean (SD)</td>
<td>77.4 (6.1)</td>
<td>77.5 (6.2)</td>
<td>78.2 (5.7)</td>
</tr>
<tr>
<td>Gender, % male</td>
<td>63</td>
<td>61</td>
<td>62</td>
</tr>
<tr>
<td>BMI, mean (SD)</td>
<td>25.0 (2.9)</td>
<td>25.6 (3.0)</td>
<td>25.7 (2.9)</td>
</tr>
</tbody>
</table>

Table 2. Change from baseline in trough FEV1, FVC, and SGRQ score at 12 months (ITT analysis and patient subgroup analysis)

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>FF/UMEC/VI versus FF/VI</th>
<th>FF/UMEC/VI versus UMEC/VI</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1, L/month</td>
<td>+0.14 (0.13, 0.20)</td>
<td>+0.15 (0.13, 0.16)</td>
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<tr>
<td>FVC, L/month</td>
<td>+0.14 (0.13, 0.20)</td>
<td>+0.15 (0.13, 0.16)</td>
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<tr>
<td>SGRQ score, 10-point</td>
<td>−6.5 (−8.1, −4.9)</td>
<td>−8.1 (−9.0, −7.3)</td>
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