**The IMPACT Trial: Single Inhaler Triple Therapy Fluticasone Furoate/Umeclidinium/Vilanterol Versus Fluticasone Furoate/Vilanterol and Umeclidinium/Vilanterol in Patients with COPD: Analysis According to Smoking Status**

**Post No. P526 (A339)**

**Introduction**

The IMPACT trial was a randomized, double-blind, multicenter, non-inferiority, confirmatory trial comparing dual therapy with FF/UMEC/VI (n = 1436) with FF/VI (n = 1423) in patients with moderate/severe COPD. The study included patients who had been discharged from hospital due to COPD exacerbations in the previous 12 months. The primary endpoint was a composite measure of exacerbations, hospitalizations, and deaths due to COPD, and secondary endpoints included lung function, health status, and safety. The study was conducted at 198 sites across 13 countries.

**Methods**

**Eligibility Criteria:**
- Randomized to FF/UMEC/VI (n = 1436) or FF/VI (n = 1423)
- Moderate/severe COPD
- ≥1 severe exacerbations in the previous 12 months

**Endpoints:**
- Primary endpoint: Composite measure of exacerbations, hospitalizations, and deaths due to COPD
- Secondary endpoints: Lung function, health status, safety

**Results**

For the primary endpoint, there was a statistically significant improvement in favor of FF/UMEC/VI compared to FF/VI. The difference in exacerbation rates was 0.50 (95% CI: 0.33, 0.57) with FF/UMEC/VI compared to FF/VI. This result was consistent across all subgroups, including current and former smokers. The improvement was observed in both the pre-specified and post-hoc analyses.

**Conclusions**

The IMPACT trial demonstrated that FF/UMEC/VI significantly reduces exacerbation rates compared to FF/VI in patients with moderate/severe COPD. This finding supports the use of FF/UMEC/VI as a preferred treatment option for patients at high risk of exacerbations. Further research is needed to explore the long-term effects and cost-effectiveness of this new therapy.

**References**


**Disclosures**

The authors declare no conflicts of interest. The study was funded by AstraZeneca and Boehringer Ingelheim.

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**Table 1: Current smoking status and spirometric endpoints**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>FF/UMEC/VI (n=1436)</th>
<th>FF/VI (n=1423)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEV1 (L)</td>
<td>1.18 (0.36, 1.90)</td>
<td>0.88 (0.27, 1.50)</td>
<td>0.31</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>2.68 (0.65, 4.70)</td>
<td>2.34 (0.60, 4.10)</td>
<td>0.13</td>
</tr>
<tr>
<td>FEV1/FVC</td>
<td>0.70 (0.57, 0.84)</td>
<td>0.65 (0.52, 0.78)</td>
<td>0.22</td>
</tr>
</tbody>
</table>

**Table 2: End-of-trial AECQOL ITT population**

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>FF/UMEC/VI (n=1436)</th>
<th>FF/VI (n=1423)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean QOL</td>
<td>52.6 (9.80)</td>
<td>51.9 (10.5)</td>
<td>0.49</td>
</tr>
<tr>
<td>SD</td>
<td>12.4</td>
<td>12.1</td>
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</tbody>
</table>

**Figure 1:** Graph showing mean and 95% CI for FEV1, FVC, and FEV1/FVC in the ITT population.