Introduction

Chronic obstructive pulmonary disease (COPD) is characterized by airflow limitation and persistent symptoms and is a major cause of chronic morbidity and mortality worldwide.

The Global Initiative for Chronic Obstructive Lung Disease (GOLD) report recommends stepwise escalation from monotherapy (long-acting bronchodilators (LABA) or long-acting muscarinic (LAMA)) to dual therapy (LABA/LAMA) or triple therapy (LABA/LAMA) based on symptoms and exacerbations.

In clinical practice, escalation from monotherapy directly to triple therapy occurs; however, recommendations are lacking from treatment guidelines.

Study 207626 (NCT03474081) evaluated the impact of once-daily single-inhaler fluticasone furoate/umeclidinium/vilanterol (FF/UMEC/VI) in an inhaled LABA/LAMA combination versus once-daily tiotropium (TIO; a LAMA) on lung function and health status in patients with symptomatic COPD and moderate/severe airflow limitation.

Methods

- **Study design**: Double-blind, double-dummy, randomized, placebo-controlled, double-treatment, parallel-group study with a 12-month treatment period.
- **Objectives**: Evaluate the safety and efficacy of FF/UMEC/VI compared with TIO in COPD patients who are at risk of exacerbations.

Results

Baseline characteristics and demographics were similar between the two treatment groups (ITT population).

<table>
<thead>
<tr>
<th>FF/UMEC/VI (N=400)</th>
<th>TIO (N=400)</th>
<th>Total (N=800)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age, years</strong></td>
<td>70.6 (5.9)</td>
<td>70.1 (6.0)</td>
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<tr>
<td><strong>BMI, kg/m²</strong></td>
<td>27.9 (4.5)</td>
<td>27.4 (4.7)</td>
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<td><strong>Forced expiratory volume in 1 second (FEV₁)</strong></td>
<td>1.71 (0.57)</td>
<td>1.74 (0.58)</td>
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</table>

**Change from baseline in trough FEV₁:**

- **FF/UMEC/VI**: 1.62 (1.22, 2.17) L
- **TIO**: 1.61 (1.20, 2.15) L

**P-value**: 0.354

**Conclusions**

- One-once-daily single-inhaler FF/UMEC/VI triple therapy significantly improved lung function versus once-daily TIO monotherapy.
- FF/UMEC/VI led to significantly greater improvements in SGRQ total score and CAT score versus TIO at both Day 28 and Day 84 (ITT population).

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