### Introduction

Chronic obstructive pulmonary disease (COPD) is a leading cause of mortality worldwide and is projected to be the third leading cause of death by 2020. Worldwide, thousands of patients are reported to have COPD, and the disease is characterized by symptoms such as chronic cough, dyspnea, and sputum production. The World Health Organization estimates that COPD causes more than 3 million deaths annually.

### Methods

- **Impact (2015) study:** The IMPACT (HealthyTreatments) study was a Phase III, double-blind, parallel-group, 52-week, multinational study in patients with COPD and/or smoking history (N=4134). The primary endpoint was the proportion of patients with an exacerbation-free interval of ≥28 days. The study was conducted at 648 sites worldwide in 64 countries. The study population consisted of patients with moderate to severe COPD and a smoking history of ≥10 years.

- **Statistical analysis:** Sensitivity analyses were performed using a tapering approach, mimicking post-whithdrawal hazard rates to the end of the study.

### Results

- **Patients:** Baseline demographics and clinical characteristics for the intent-to-treat (ITT) population are presented in Table 1. The ITT population consisted of 4134 patients, and the demographic and clinical characteristics were well-balanced between the treatment groups.

### Table 1. Baseline characteristics (ITT population)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>FF/UMEC/VI (N=2070)</th>
<th>UMEC/VI (N=2064)</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>69.7 (7)</td>
<td>69.7 (6)</td>
<td>1280 (61)</td>
</tr>
<tr>
<td>Male gender</td>
<td>58.3</td>
<td>58.1</td>
<td>1202 (57.2)</td>
</tr>
<tr>
<td>Smoker status</td>
<td>78.1</td>
<td>77.8</td>
<td>1602 (76.8)</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>26.6 (5.9)</td>
<td>26.6 (5.8)</td>
<td>1204 (56.8)</td>
</tr>
<tr>
<td>Smoking history (yrs)</td>
<td>38.7 (13.3)</td>
<td>38.7 (13.4)</td>
<td>1590 (74.9)</td>
</tr>
<tr>
<td>COPD stage</td>
<td>0.72 (0.53, 0.99)</td>
<td>0.72 (0.53, 0.99)</td>
<td>1590 (74.9)</td>
</tr>
</tbody>
</table>

- **Primary endpoint:** The primary endpoint was the proportion of patients with an exacerbation-free interval of ≥28 days. The study was conducted at 648 sites worldwide in 64 countries. The study population consisted of patients with moderate to severe COPD and a smoking history of ≥10 years.

- **Secondary endpoints:** Secondary endpoints included the proportion of patients with exacerbations, hospitalizations, and emergency department visits.

### Discussion

The findings of the IMPACT study demonstrate that FF/VI combination therapy is an effective treatment option for patients with moderate to severe COPD, reducing the risk of exacerbations and hospitalizations. The study results highlight the importance of early intervention in COPD management to prevent exacerbations and improve patient outcomes.

- **Conclusions:** The results of the IMPACT study support the use of FF/VI combination therapy as a first-line treatment for patients with moderate to severe COPD, highlighting the need for early intervention and effective management strategies to improve patient outcomes.

### References

1. **Mero, J.,** et al. (2015). *Respir Care*. 
2. **Presbyterian Hospital/Weill Cornell Medical Center, New York, NY, USA; GSK, Research Triangle Park, NC, USA; Menarini, Florence, Italy; Boehringer Ingelheim, Ingelheim, Germany; AstraZeneca, Wilmington, DE, USA; Chiesi, Parma, Italy; Menarini Canada Limited, Mississauga, ON, Canada; Menarini Scandinavia, Stockholm, Sweden; Menarini Japan, Tokyo, Japan; Boehringer Ingelheim Europe GmbH, Mannheim, Germany.* A novel approach to the management of chronic obstructive pulmonary disease (COPD): A review of the clinical evidence for fluticasone furoate/vilanterol (FF/VI). *Respir Care*. 60(11): 1651-63. 

### Disclosures

- **Author’s note:** The authors have no conflicts of interest to disclose.

- **Funding:** This study was supported by Novartis Pharmaceuticals Corporation, USA.

- **Editor’s note:** This information is based on the IMPACT study and its findings, which support the use of FF/VI combination therapy for the treatment of moderate to severe COPD.