This document provides a short summary of this study for a general audience. You can find more information in scientific summaries of the study. Links to those summaries are provided at the end of this document.

**Study Identification**

**Short Title:** The Salford Lung Study of Chronic Obstructive Pulmonary Disease (COPD).

**Full Scientific Title:** A 12-month, open label, randomised, effectiveness study to evaluate fluticasone furoate (FF, GW685698)/vilanterol (VI, GW642444) Inhalation Powder delivered once daily via a Novel Dry Powder Inhaler (NDPI) compared with the existing COPD maintenance therapy in subjects with Chronic Obstructive Pulmonary Disease (COPD).

**Name and Contact Details of the Sponsor**

GlaxoSmithKline (GSK)
GSK Clinical Support Help Desk
Website: [http://www.clinicalsupporthd.gsk.com](http://www.clinicalsupporthd.gsk.com)
Email: GSKClinicalSupportHD@gsk.com

**General Information about the Study**

**Study Dates:** This study started in March 2012 and ended in November 2015.

**The Main Objective(s) of the Study:** The objective of the study was to compare the results from patients starting a new treatment for Chronic Obstructive Pulmonary Disease (COPD) with results from patients taking their usual COPD maintenance treatment.

**The Reasons for Conducting the Study:** COPD is a long-term lung disease that makes it hard to breathe and gets worse over time. Researchers wanted to test a new combination of medicines for COPD in a broad selection of patients with the disease, including patients with all severities of disease and even if they have other diseases in addition to COPD. Patients in this study saw their general practitioners/family doctors in a routine clinical practice setting as they usually would. Medications were prescribed and dispensed in the usual way and patients were not supervised in taking their medicines.
Most studies are done in research settings. Patients in research settings may be carefully chosen based on such things as age and severity of disease. They may also be excluded from a study if they are taking other medicines or have other diseases. Placing very similar types of patients in each group of a study helps researchers compare the effect of a medicine on patients when one group is compared with another.

Research settings are different from routine practice in that patients usually see study doctors more often, may get more reminders to take their medicine, and may receive more detailed instructions on how to take it. This study was designed to provide information to complement the results from more standard types of studies.

**Study Site Locations:** All study sites were located in Salford and parts of Manchester in the United Kingdom (UK). The study sites were the medical clinics of General Practitioners/Family Doctors where patients got their medical care.

**Investigational Medicinal Products Used**

**Medicines used**

Patients who took part in this study were placed into one of two groups based on chance. The medicines taken by both groups were breathed in through a device called an inhaler.

**Group A** = New combination inhaler (used once daily) containing two powders:
1. Fluticasone furoate - works by decreasing swelling and redness (inflammation) in the lungs.
2. Vilanterol - works by helping to relax and open the muscles of the airways.

Patients in Group A continued taking a Long-Acting Muscarinic Antagonist (LAMA) if they were taking it before the study started.

**Group B** = Usual-care group continued taking the same daily medicines they were taking before the study started as prescribed by their doctor.

Doctors could adjust a patient’s maintenance treatment like they would in normal clinical practice. Patients in Group A could switch back to their Usual Care if they wanted, but patients assigned to Group B were not permitted to switch to Group A. The results presented are based on the treatment group that they were assigned to even if they did switch.
All patients were able to use a rescue inhaler for quick relief if they had trouble breathing. The rescue inhaler works like the vilanterol part of the study drug, but is faster acting.

Participants

Patients Included

The study included 2799 patients. All of these patients were included in the safety portion of the study.

The treatment effect was measured in the group of patients who had one or more moderate or severe exacerbations (sudden worsening of COPD symptoms) in the year before the study started. This was 2269 (81%) of the patients.

A **moderate exacerbation** means that a patient’s COPD symptoms got worse and the patient needed antibiotics and/or oral corticosteroids but did not need to go to the hospital.

A **severe exacerbation** means that the patient needed hospital treatment.

Patients included in this study were:

- Already taking daily medicines for COPD
- 40 years old or older
- Diagnosed with at least one COPD flare-up in the 3 years before starting the study
- Able to participate no matter how well their lungs were working
- Smokers and non-smokers.

Patients could not enter the study if their COPD symptoms were getting much worse before the study started, if they took oral corticosteroids for a long time, or if they had another life-threatening disease.

For more information about the patients included in this study, see the scientific summary on the GSK Clinical Study Register (Link provided at the end of this document).
Results of the Study

Results

Researchers measured the average rate of moderate and severe exacerbations of COPD in a year to understand the effect of the starting a new treatment (Group A) compared with continuing usual care (Group B).

Researchers looked at patients who had a moderate or severe exacerbation in the year before starting the study. There were 2269 of the 2799 (81%) patients in this population.

Table 1 shows the results.
Table 1. Results
The Rate of Moderate or Severe COPD Exacerbations

<table>
<thead>
<tr>
<th>Patients who had an exacerbation within a year prior to the study</th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group A: Fluticasone Furoate-Vilanterol Group</td>
<td>1135 patients</td>
<td>1134 patients</td>
</tr>
<tr>
<td>The Average Rate of Exacerbations per year during the one year study</td>
<td>1.74</td>
<td>1.90</td>
</tr>
</tbody>
</table>

For patients who had an exacerbation within the year prior to the study, the rate of moderate or severe exacerbations per year was 8.4% lower in the patients who were started on fluticasone furoate and vilanterol (new treatment) compared with patients who stayed on usual care. This result was confirmed in the entire study population of 2799 patients too.

Description of Adverse Reactions and Their Frequency

**Adverse Reactions**

Researchers collect information about the safety of study medicines.

- *An adverse reaction* means a medical problem that develops during the study that the doctor thinks could have been caused by the patient’s study medicines.

- *A serious adverse reaction* means a medical problem that is life threatening, requires hospitalisation, or results in death or permanent damage that develops during the study that the doctor thinks could have been caused by the patient’s study medicines.

In this study, patients in Group A could switch to Group B if they preferred the medicines they were taking before. For patients who switched, any adverse reaction would be listed under Group A even if they were taking a usual care medicine when it occurred.

Table 2 lists the *serious* adverse reactions that were reported by 2 or more patients in either treatment group.
Table 2. Serious Adverse Reactions

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fluticasone Furoate-Vilanterol Group</td>
<td>Usual-Care Group</td>
</tr>
<tr>
<td></td>
<td>1396 patients</td>
<td>1403 patients</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>3 of 1396 (Less than 1%)</td>
<td>4 of 1403 (Less than 1%)</td>
</tr>
<tr>
<td>Worsening Symptoms of COPD (COPD)</td>
<td>4 of 1396 (Less than 1%)</td>
<td>1 of 1403 (Less than 1%)</td>
</tr>
<tr>
<td>Chest Infection (Lower Respiratory Tract Infection)</td>
<td>2 of 1396 (Less than 1%)</td>
<td>1 of 1403 (Less than 1%)</td>
</tr>
<tr>
<td>Abnormal Rapid, Irregular Heartbeat (Atrial Fibrillation)</td>
<td>2 of 1396 (Less than 1%)</td>
<td>1 of 1403 (Less than 1%)</td>
</tr>
</tbody>
</table>

One patient in each treatment group died from a serious adverse reaction. In Group A, one patient died from a blood clot that went to the lung (pulmonary embolism). In Group B, one patient died from pneumonia.

Table 3 lists the adverse reactions that were not considered serious (also called the non-serious adverse reactions) reported by 1 percent or more of patients in either treatment group.
Table 3. Non-Serious Adverse Reactions

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th>Group B</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Fluticasone Furoate-Vilanterol Group</td>
<td>Usual-Care Group</td>
</tr>
<tr>
<td></td>
<td>1396 patients</td>
<td>1403 patients</td>
</tr>
<tr>
<td>Yeast Infection in Mouth</td>
<td>56 of 1396 (4%)</td>
<td>40 of 1403 (3%)</td>
</tr>
<tr>
<td>(Oral Candidiasis)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shortness of Breath</td>
<td>30 of 1396 (2%)</td>
<td>1 of 1403 (Less than 1%)</td>
</tr>
<tr>
<td>(Dyspnoea)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on these results, no new concerns were raised related to the safety of these types of medicines.

**Comments on the Outcome of the Study**

**What did this study tell researchers?**

The Salford Lung Study on COPD was a large study comparing the effect of a new medicine to usual care in a regular medical clinic setting. This was a Phase IIIB study. Phase IIIB studies gather information about how well a new medicine (or combinations of medicines) works and how safe it is. When physicians are making treatment decisions for patients, they want to know how the new medicine compares with other treatments. They also want to know if their patients will do as well as patients in research studies.

The results of this study suggest that patients who had one or more moderate or severe exacerbations in the previous year and started on fluticasone furoate and vilanterol in combination (new treatment) had fewer moderate and severe exacerbations in the following year compared with patients who stayed on their usual-care medications. This summary shows the results from one study. Other studies using these medicines may have different results.

We would like to thank the patients who contributed. The results of this study will help answer important scientific questions in patients with COPD.
Further Studies

The Salford Lung Study on asthma is currently in progress. Other studies of fluticasone furoate and vilanterol in patients with COPD are currently planned and others are ongoing. The results of these studies will also be available on GlaxoSmithKline’s Clinical Study Register after the studies end and the results are analysed (See link below).

Where Additional Information Can Be Found

Clinical studies have unique study numbers which are included in publications and other information about the study. Below are the unique study numbers that go with this study. The hyperlink text connects to scientific summaries and other information on the Internet.*

<table>
<thead>
<tr>
<th>Organization</th>
<th>Website</th>
<th>Study Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>United States National Institutes of Health (NIH)</td>
<td><a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a></td>
<td>NCT01551758</td>
</tr>
<tr>
<td>GlaxoSmithKline (GSK)</td>
<td><a href="http://www.gsk.clinicalstudyregister.com">www.gsk.clinicalstudyregister.com</a></td>
<td>115151</td>
</tr>
</tbody>
</table>

Your doctor can help you understand more about this study and the results. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed to change by your doctor.

This document was developed and approved by GSK on 20 December 2016. The information in this summary does not include additional information available after this date.

* For readers of this document in text form, the websites that go with the hyperlinks above are
http://www.gsk-clinicalstudyregister.com/study/115151?study_ids=115151#rs
https://clinicaltrials.gov/ct2/show/NCT01551758?term=115151&rank=1