This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to this summary is provided at the end of this document.

Study names

Short Title: A study to assess how well umeclidinium works and how safe it is in patients with chronic obstructive pulmonary disease.

Full Scientific Title: A 24-week randomised, double-blind and placebo-controlled study to evaluate the efficacy and safety of 62.5 mcg Umeclidinium Inhalation Powder delivered once-daily via a Novel Dry Powder Inhaler in subjects with Chronic Obstructive Pulmonary Disease.

Study Number: 117410

Who sponsored this study?

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

General information about the clinical study

When was this study done?

The study started in May 2016 and ended in November 2017.

What was the main reason for conducting this study?

Chronic obstructive pulmonary disease (COPD) is a long-term disease of the lungs that makes it hard to breathe and gets worse over time. Umeclidinium is an inhaled long-acting bronchodilator (a medicine that opens the airways in the lungs). It is approved in many countries for the treatment of COPD. However, umeclidinium is not yet approved in China. More information is needed to understand how this medicine works in Chinese and Korean patients with COPD.

What was the main objective of this study?

In this study, the study doctors wanted to see if umeclidinium improved the lung function of Chinese and Korean patients with COPD. They also studied the safety of umeclidinium in these patients.

Which medicines were studied?

During the study, patients were included in one of the following two treatment groups by chance (randomisation).

- Placebo (containing no active medicine)
- Umeclidinium (62.5 micrograms)

Twice as many patients were included in the umeclidinium group compared with the placebo group.

Patients took the study medicine through an inhaler once daily in the morning for 24 weeks. An inhaler is a handheld device that delivers medicine to the lungs. Neither patients nor study doctors knew who was receiving which treatment. This is called a double-blind study.

Which patients were included in this study?

Studies have a list of requirements for patients who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Main Inclusion Criteria

Men and women were included in the study if they:

- Were at least 40 years old.
- Were of Chinese or Korean origin.
- Had COPD.

Main Exclusion Criteria

Men and women were excluded from the study if they had:

- Asthma or any other respiratory problem.
- Been hospitalised for COPD or pneumonia within the last 12 weeks.

For more detailed information about the patients included in this study, see the scientific summary on the ClinicalTrials.gov website (see link provided at the end of this document).

A total of 306 patients took part in this study. The table below shows the gender and age of patients who were included in the study.

Patients included in the study		
	Placebo **101 patients**	**Umeclidinium** **205 patients**
Gender		
Female	4 (4%)	12 (6%)
Male	97 (96%)	193 (94%)
Age - In years		
Range	47 to 87	41 to 81
Average	66	66

Where was this study done?

The study sites were in two countries. A total of 260 patients were from China and 46 patients were from the Republic of Korea.

What were the overall results of the study?

Lung function tests measure how well a patient's lungs are moving air in and out of the body. Doctors can use the results of these tests to see if the lung function is stable, getting better, or getting worse.
One measure of lung function is Forced Expiratory Volume in one second (FEV_1). FEV_1 measures the amount of air that a patient can breathe out in the first second when asked to blow as hard as possible into a tube connected to a machine (spirometer). Higher values of FEV_1 mean more air is flowing out of the lungs, and that lung function is better. FEV_1 is measured in millilitres (mL).

In this study, the lung function of patients receiving umeclidinium was compared with those receiving placebo. Study doctors measured each patient's lung function at the

beginning of the study (baseline FEV_1) and after 24 weeks of treatment (FEV_1 after treatment) on Day 169. The difference between these two FEV_1 values is called the change from baseline.

The results from patients in each treatment group were combined and averaged. The difference in average FEV_1 change from baseline between the two groups was compared. The results are shown in the table below.

Lung function results		
	Placebo	**Umeclidinium**
Number of patients with FEV_1 values at baseline and at Day 169 (so change could be measured)	80 patients	176 patients
Average FEV_1 change from baseline to Day 169	22 mL lower	131 mL higher
Difference in average FEV_1 on Day 169 of treatment between umeclidinium group and placebo	154 mL	

After 24 weeks of treatment, the average lung function of patients in the umeclidinium group improved, and it worsened for the placebo group. The difference in FEV_1 between the two groups was statistically significant. This means that the difference was not likely due to chance alone.

What were the side effects?

Study doctors collect information about the safety of study medicine. Any medical events including symptoms reported by patients in the clinical study are called adverse events. These adverse events can be found in the scientific summary (see link provided at the end of this document).

The study doctors record if they think any of these events may be caused by the study medicine. If the study doctor believes that the event was caused by the study medicine, they record this adverse event as a possible side effect. In a clinical study, these are

called **adverse reactions**. A **serious adverse reaction** is an adverse reaction that is life threatening, requires hospitalisation or results in death or permanent damage. In blinded studies, the study doctor does not know which study medicine the patient is taking. In some cases, adverse reactions may be related to placebo.

This plain language summary describes those side effects (adverse reactions including serious adverse reactions) recorded by study doctors.

The table below shows all serious adverse reactions reported in this study.

Serious adverse reactions up to Week 24		
	Placebo 101 patients	**Umeclidinium 205 patients**
Worsening symptoms of COPD	2 (2%)	1 (less than 1%)
Pneumonia	0	1 (less than 1%)

Non-serious adverse reactions were reported by fewer than one percent of patients in either treatment group.

For further information about safety, including details about the adverse events that the study doctors did not think were related to the study medicine, please see the scientific summary using the link at the end of this document.

How has this study helped patients and researchers?

This information will help regulators make decisions about whether to approve umeclidinium to treat patients with COPD in China.

Are there plans for further studies?

Other studies of umeclidinium in patients with COPD are ongoing as of October 2018.

Where can I find more information about this study?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study number associated with this study is shown below with an internet link to the scientific summary and other information.

The scientific summary includes more details about the requirements for study enrolment, the study visit schedule, results from other endpoints and more detailed information about adverse events.

Organisation	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02184611[1]

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 by your doctor.

We would like to thank the patients who contributed to this study. The results of this study will help answer scientific questions about treating patients with COPD.

The content for this document was finalised by GSK on 30 October 2018. The information in this summary does not include additional information available after this date.

[1] The link is: https://clinicaltrials.gov/ct2/show/NCT02184611?term=NCT02184611&rank=1