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 the summary is provided at the end of this document.

Study names

Short Title: A study to assess long-term safety of triple therapy in Japanese patients with asthma.

Full Scientific Title: A Phase III, 52-week, open-label study to evaluate long-term safety of fixed dose combination therapy fluticasone furoate/umeclidinium bromide/ vilanterol trifenatate in Japanese patients with asthma.

Study Number: 207236

Who sponsored this study?

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

General information about the clinical study

When and where was this study done?

The study started in June 2017 and ended in June 2019. All study sites were in Japan.

What was the main objective of this study?

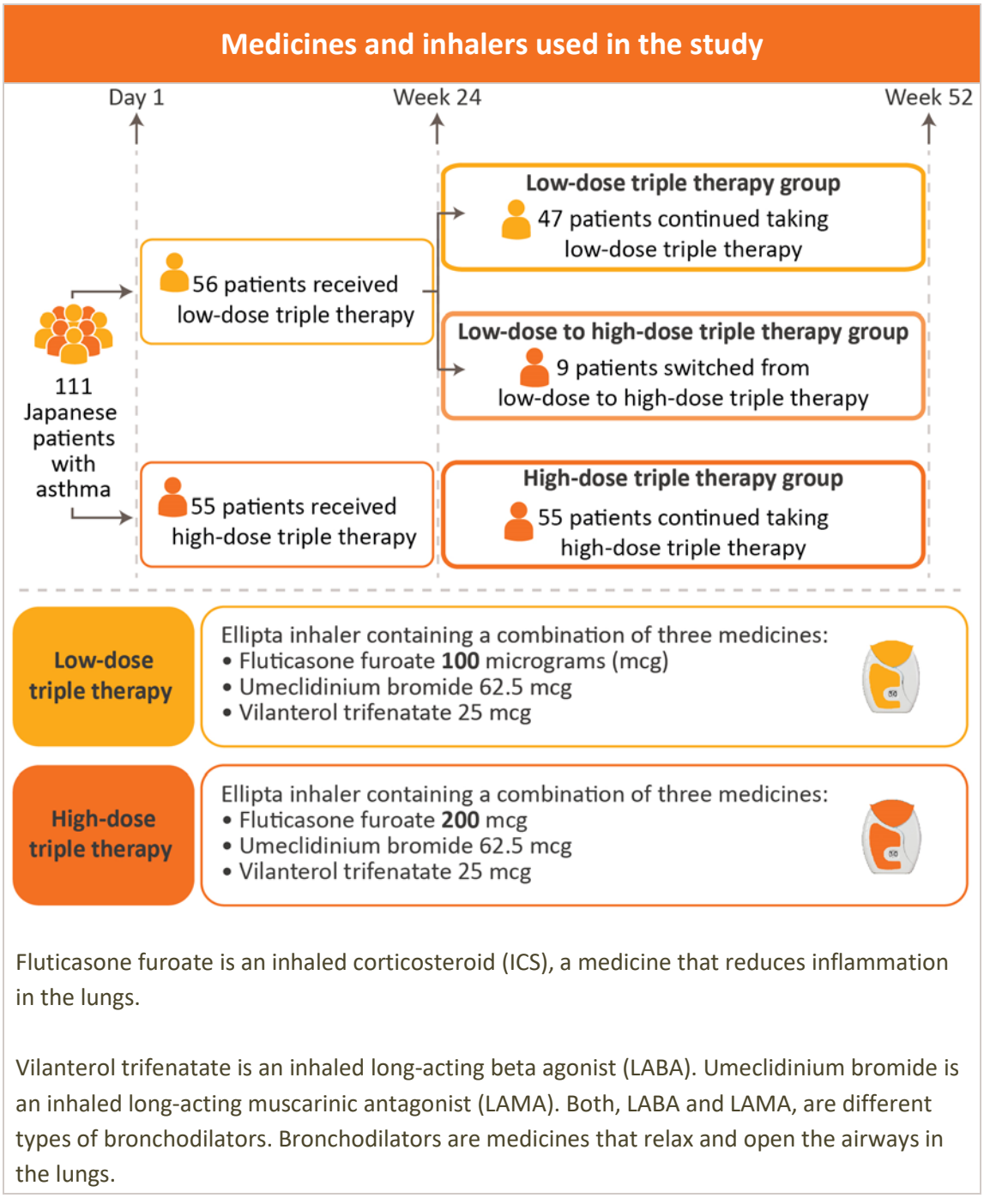
Asthma is a long-term condition of the airways. When airways are inflamed, they become narrow. This narrowing can cause coughing, wheezing, chest tightness, and shortness of breath.

For patients with asthma, inhalers are an important part of treatment. An inhaler is a handheld device that delivers medicine(s) to the lungs. Patients with asthma who need to take three inhaled medicines (triple therapy) may use two or three inhalers. GSK has developed the Ellipta inhaler that can deliver three medicines in one inhaler.

The main objective of this study was to assess the long-term safety of triple therapy using an Ellipta inhaler once daily for a year (up to Week 52) in Japanese patients with asthma. The safety was assessed by comparing the number of patients who had unwanted medical events (adverse events).

Which medicines were studied?

Patients were put into one of the two treatment groups based on the dose of asthma medicines they were taking before starting the study (see figure below).



Fluticasone furoate is an inhaled corticosteroid (ICS), a medicine that reduces inflammation in the lungs.

Vilanterol trifenatate is an inhaled long-acting beta agonist (LABA). Umeclidinium bromide is an inhaled long-acting muscarinic antagonist (LAMA). Both, LABA and LAMA, are different types of bronchodilators. Bronchodilators are medicines that relax and open the airways in the lungs.

At Week 24, the study doctor assessed patients' asthma control. Patients taking low-dose triple therapy could switch to high-dose triple therapy if their asthma was not well controlled. The doctors and patients knew which treatment they received. This is called an open-label 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.

Japanese men and women were included in the study if they:

- Were at least 18 years old.
- Had been diagnosed with asthma at least one year before starting the study.
- Were taking asthma treatment with medium to high-dose of ICS and LABA with or without LAMA for at least four weeks before starting the study.
- Had controlled or not well-controlled asthma as scored using an asthma scoring scale.

Men and women were excluded from the study if they:

- Had worsened asthma symptoms that required a change in their regular asthma medicine within six weeks before starting the study.
- Had chronic obstructive pulmonary disease or any other lung disease.
- Were current smokers or former smokers with a history of smoking at least 20 cigarettes daily for 10 years.
- Had pneumonia within six weeks before starting the study.
- Had a risk of developing pneumonia during the study.
- Had unstable liver or heart disease or any other disease that the study

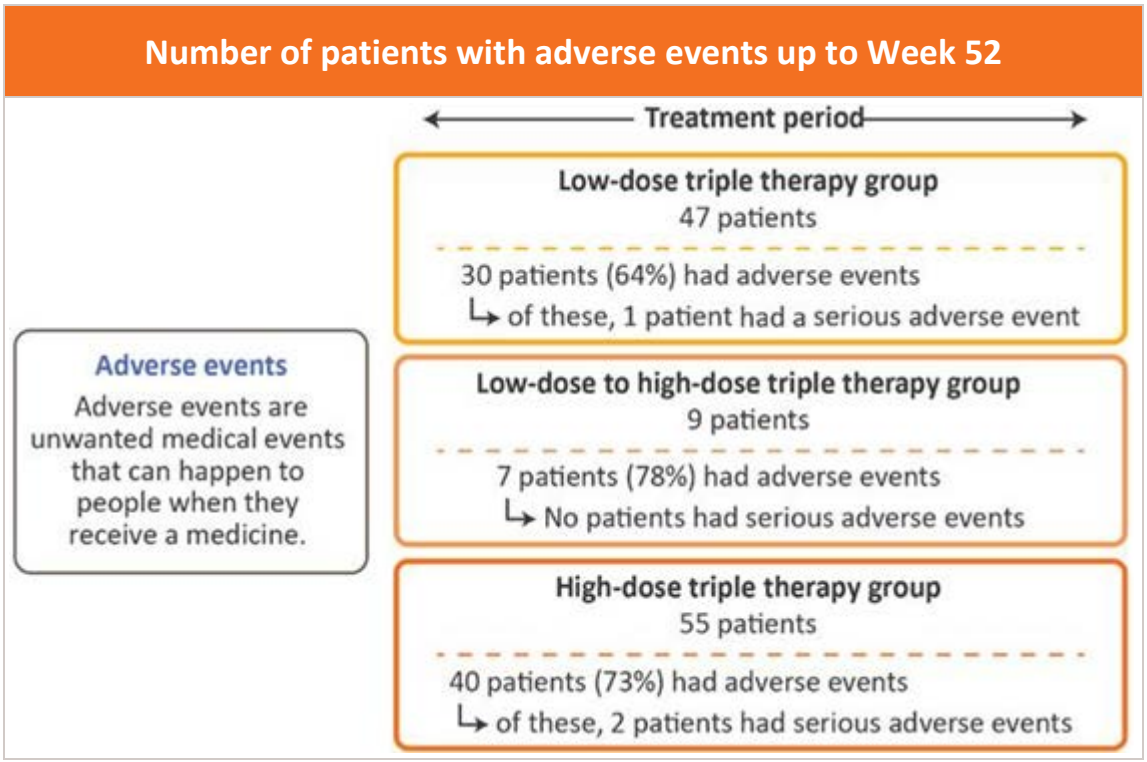
A total of 111 patients received at least one dose of the study medicines. The table below shows the gender and age of these patients.

Patients who received at least one dose of the study medicines			
	Low-dose triple therapy group 47 patients	**Low-dose to high-dose triple therapy group 9 patients**	**High-dose triple therapy group 55 patients**
Female	23 (49%)	5 (56%)	36 (65%)
Male	24 (51%)	4 (44%)	19 (35%)
Age range (years)	20 to 74	41 to 66	26 to 78
Average age (years)	48	48	54

For more detailed information about the patients included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

What were the overall results of the study?

This study focused on safety results only, other studies have assessed how well triple therapy works in patients with asthma. The figure below shows the number of patients (percentage) who had adverse events up to Week 52.



Details of these adverse events can be found in the scientific results summary (a link to the summary is provided at the end of this document).

What were the side effects?

In this summary, “side effects” refer to those adverse events that the study doctor thinks may have been caused by the study medicine, as shown in the figure below.

The side effects in this section may be different to those in the Informed Consent or other documents related to the study medicines.

No serious side effects were reported up to Week 52.

The tables below show the total number of patients (percentage) with non-serious side effects and the number of patients (percentage) that were reported by two or more patients in any treatment group up to Week 52.

Total number of patients with non-serious side effects up to Week 52		
Low-dose triple therapy group 47 patients	**Low-dose to high-dose triple therapy group 9 patients**	**High-dose triple therapy group 55 patients**
6 (13%)	2 (22%)	8 (15%)

Number of patients with non-serious side effects reported by two or more patients in any treatment group up to Week 52			
	Low-dose triple therapy group 47 patients	**Low-dose to high-dose triple therapy group 9 patients**	**High-dose triple therapy group 55 patients**
Bitter taste	2 (4%)	1 (11%)	4 (7%)
Hoarse voice	2 (4%)	0	2 (4%)

How has this study helped patients and researchers?

The main objective of this study was to assess the long-term safety of triple therapy by recording adverse events in Japanese patients with asthma. Three serious adverse events were reported during the study; none of these serious events were caused by the study medicines. The non-serious side effects reported in this study were limited in number.

Are there plans for further studies?

Other studies of fluticasone furoate, umeclidinium bromide, and vilanterol trifenatate in patients with asthma have been conducted and more are underway.

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 numbers associated with this study are shown below with an internet link to the scientific summary and other information.

The scientific summary include 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	NCT03184987[1]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. 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 asthma.

The content for this document was finalised by GSK on the 4th of March 2020. The information in this summary does not include additional information available after this date.

[1] https://clinicaltrials.gov/ct2/show/study/NCT03184987