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

Study names

Short Title: A study to learn about the effect of otilimab in participants with severe COVID-19 related lung disease.

Full Scientific Title: A randomised, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV in patients with severe pulmonary COVID-19 related disease (OSCAR study).

Study Number: 214094 (Part 1)

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 was this study done?

This study had two parts. Part 1 of the study was followed by Part 2. Part 1 of the study started in May 2020 and ended in January 2021. The results of Part 1 of this study have been presented in this summary.

What was the main reason for this study?

Coronavirus disease 2019 (COVID-19) is a rapidly spreading disease caused by a virus. It can cause lung inflammation, which leads to difficulty in breathing, resulting in very low levels of oxygen in the blood. This condition is called COVID-19 related lung disease and can be life-threatening. Patients may need a breathing machine called a ventilator to help them breathe.

Otilimab is a medicine also being tested to treat inflammation in patients with other diseases like rheumatoid arthritis. It is thought to be able to reduce lung inflammation caused by COVID-19 related lung disease.

Patients who were hospitalised with severe COVID-19 related lung disease (such as pneumonia) and were receiving standard-of-care (SoC) treatment took part in this study. The SoC treatment includes the normal hospital care and usual treatments that are given to patients with the same condition. Researchers wanted to see if otilimab would improve these participants' recovery and chances of survival when added to SoC treatment, compared with SoC treatment alone. Researchers also assessed the safety of this medicine.

Which medicines were studied?

Participants who decided to take part in the study continued to receive SoC. In addition, participants received one of the following two study medicines:

- Otilimab
  (or)
- Placebo

Placebo, also known as a dummy medicine, looked like otilimab but did not contain actual medicine. A computer decided which study medicine the participants would receive by chance, as if by tossing a coin. Neither participants nor study doctors knew who was receiving which study medicine. This is to make sure the results of each treatment group were handled in the same way. This is called a double-blind study.

Participants received the study medicine directly through a vein on Day 1. Study doctors monitored participants daily in the hospital until they were discharged. After being discharged, the study doctors regularly contacted the participants to check on how they were doing for up to two months after they were first admitted to the hospital.

Which participants took part in this study?

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

Men and women were included in the study if they:

- Were 18 to 79 years old.
- Were hospitalised with COVID-19 related pneumonia.
- Required high oxygen supply through an oxygen mask, nasal tubes, breathing tube, or ventilator.

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

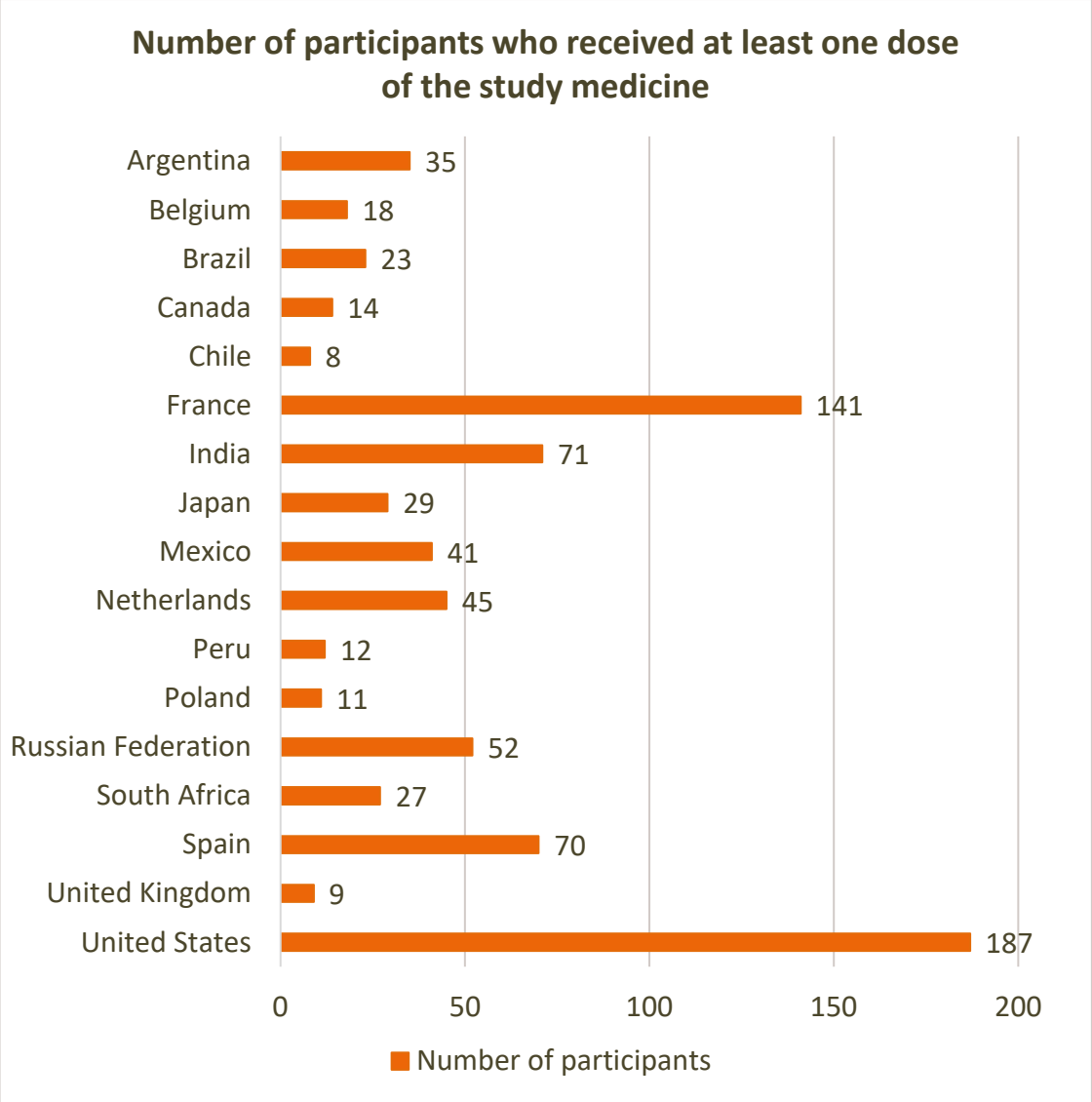
- Less than 48 hours left to live regardless of getting any treatment, in the opinion of the study doctor.
- Multiple organ failure in the opinion of the study doctor.
- A requirement for life support using a heart-lung machine (blood pumped from the body to a machine that adds oxygen to it and removes carbon dioxide) or kidney dialysis (a treatment that removes waste from the body and filters blood when kidneys do not work well).
- Taken or had planned to start taking medicines that suppress the immune system or medicines similar to otilimab within three months of Day 1.
- Any other untreated infection or disease(s), abnormal blood test results, or taken any treatment(s) that the study doctor thought would affect the results of the study.

Overall, 793 participants received at least one dose of the study medicine. The study included 566 men (71%) and 227 women (29%). The average age was 60 years. The youngest participant was 23 years old and the oldest participant was 80 years old.

For more detailed information about the participants included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

Where was this study done?

Study sites were in 17 countries.



What were the main results of the study?

The main focus of this study was to look at the number of participants who were alive and could breathe with minimal or no need for extra oxygen, about one month after receiving the study medicine (Day 28). Results are shown in the table below.

Number of participants (percent) who were alive and could breathe with minimal or no need for oxygen support on Day 28		
	Otilimab 395 participants	**Placebo 398 participants**
Number of participants (percent)	277 (71%)	262 (67%)

More information about the study results is available in the scientific results summaries (links to those summaries are provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of these events can be found in the scientific results summaries (links to those summaries are provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, side effects refer to those events that the study doctor thinks may have been caused by the study medicine. The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine.

In blinded studies, the doctor does not know which study medicine the participant is taking. In some cases, side effects will be associated with placebo.

The side effects included in this summary are those reported by the participants during the two-month study period.

Two participants who were randomised to the placebo group received otilimab by error. Side effects for these participants were reported in the otilimab group.

The table below shows the number of participants (percent) with side effects that were reported during the study.

Number of participants (percent) with side effects reported during the study		
	Otilimab 397 participants	**Placebo 396 participants**
Serious side effects	16 (4%)	18 (5%)
Fatal side effects (side effects that led to death)	8 (2%)	3 (less than 1%)
Non-serious side effects	40 (10%)	40 (10%)

Serious side effects

Dangerously low blood pressure caused by a life-threatening response to an infection was the only serious side effect that was reported for 1% or more of participants in any treatment group. This was reported as a fatal side effect in four participants (1%) in the otilimab group and as a non-fatal side effect in two participants (less than 1%) in the placebo group.

Non-serious side effects

Diarrhoea was the only non-serious side effect reported by 1% or more of participants in any treatment group. It was reported by four participants (1%) in the otilimab group and by none of the participants in the placebo group.

How has this study helped participants and researchers?

In Part 1 of this study, researchers concluded that the number of participants who were alive and could breathe with minimal or no need for extra oxygen on Day 28 was slightly higher in the otilimab group compared with the placebo group. Older participants (between the age of 70 and 79 years) seemed to show more improvement when treated with otilimab. However, there were not enough participants in this age group to know if the effect was real. This was studied further in Part 2 of this study.

The side effects reported were considered as expected in patients with COVID-19 related lung disease.

Are there plans for further studies?

In addition to the two parts of this study, no other studies of otilimab in participants with COVID-19 related lung disease are planned or ongoing at this time. Otilimab continues to be studied for the treatment of other diseases, such as rheumatoid arthritis.

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 internet links to scientific summaries.

The scientific summaries 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 and Website	Study Number
European Medicines Agency (www.clinicaltrialsregister.eu)	2020-001759-42[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT04376684[2]

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 participants who contributed to this study. The results of this study will help answer scientific questions about treating patients with COVID-19 related lung disease.

The content for this document was finalised by GSK on 23 February 2022. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2020-001759-42
[2] https://clinicaltrials.gov/ct2/show/NCT04376684