Who sponsored this study?

GSK

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A study to compare the effects of a new medicine with regular medicine in participants with advanced lung cancer

GSK would like to thank all those who took part in this clinical study. We think it is important that you know the study results. We hope it helps you understand and feel proud about your important role in medical research.

General information about the clinical study

This is a “platform study” made up of many smaller studies called sub-studies. In these types of studies, researchers use the same plan to test different medicines to treat a disease.

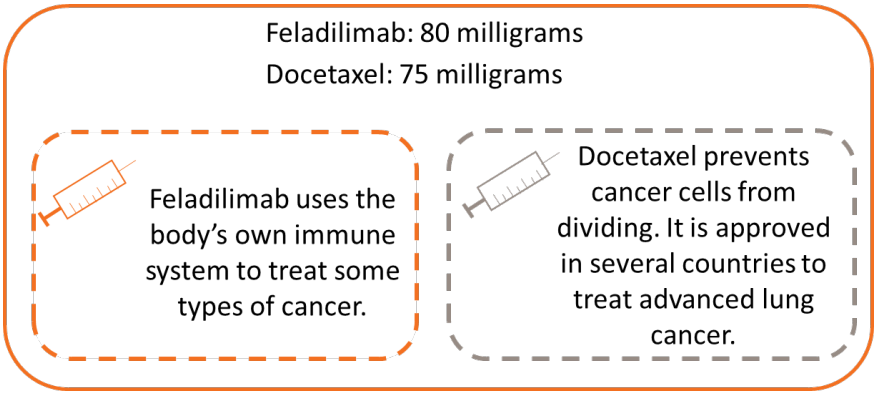
When was this study done?

The first sub-study started in January 2019 and ended in September 2021. The results of this sub-study are presented in this summary.

An additional sub-study was also started; however, researchers could not draw any conclusion as this sub-study ended early. Other sub-studies are ongoing and more are planned. Results of each sub-study will be presented in a separate summary when they are finished.

Which medicines were studied?

Feladilimab and docetaxel are the two medicines studied in this sub-study.



What was the main reason for this study?

Non-small cell lung cancer (NSCLC) is the most common type of lung cancer. Common symptoms include cough that does not go away, chest pain, and tiredness. When NSCLC has spread beyond the lungs into other areas of the body, it is considered as advanced NSCLC.

Some cancer cells have a type of protein called programmed cell death ligand 1 (PD-L1) on their surface. These are called PD-L1 positive cancers. Current treatment options include chemotherapy with platinum-based medicines and medicines that block PD-L1 protein. Some people may respond to treatment while some do not. Of those who respond, the cancer may come back after being treated.

For these reasons, researchers are looking for a better way to treat advanced NSCLC. In this sub-study, they wanted to know if feladilimab + docetaxel compared with docetaxel alone improved survival.

Who took part in this study?

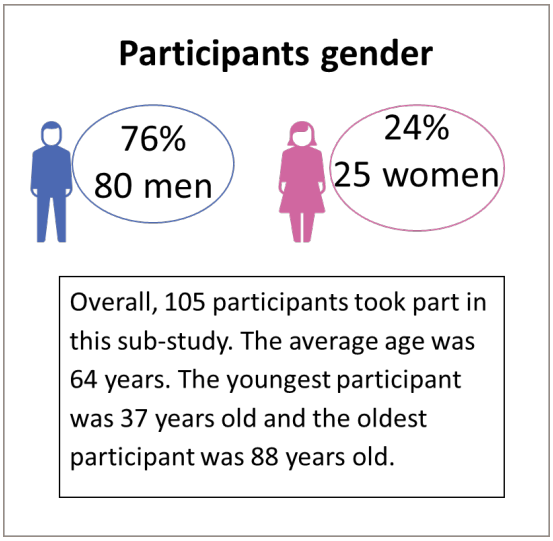
Studies have a list of requirements for participants who can enter (inclusion criteria) and those who cannot enter (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Men and women with advanced NSCLC were included in the study if they:

- Were at least 18 years old (participants in Republic of Korea were at least 19 years old).
- Had a tumour that the study doctor could measure with the help of scans.
- Were capable of self-care as determined by a scoring scale before starting the study.
- Had tumour tissue samples (biopsy) or were willing to undergo a fresh biopsy before starting the study.

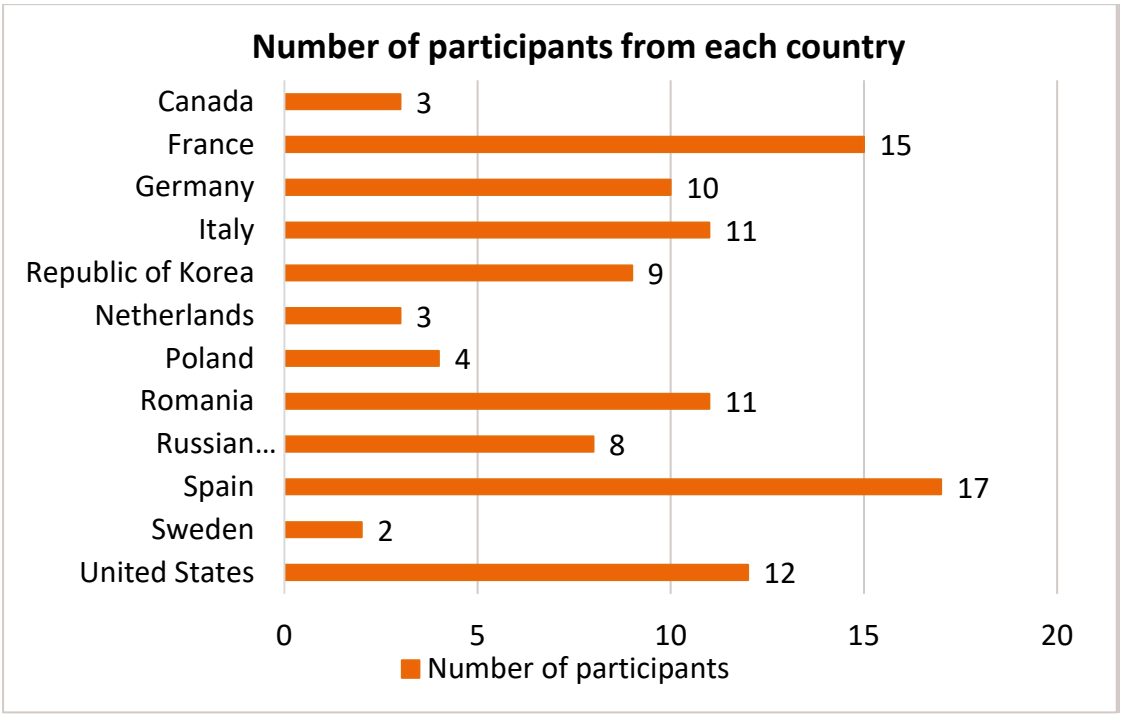
Men and women were excluded from the study if they:

- Received docetaxel or a medicine similar to feladilimab before starting the study.
- Received more than two types of cancer treatments for NSCLC before starting the study.
- Had a history of any other lung disease or needed medicines to reduce lung inflammation.
- Underwent any major surgery within a month before receiving study medicine.



Where was this study done?

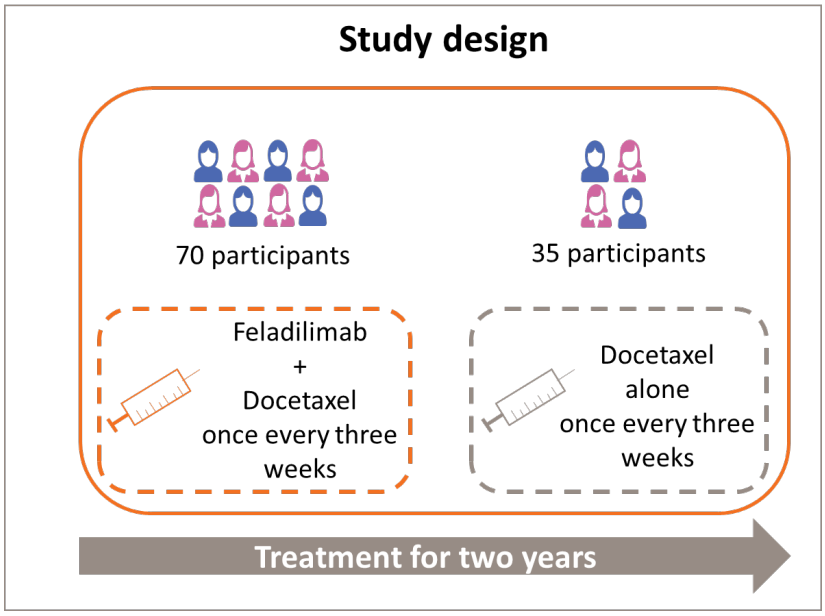
Study sites were in 12 countries.



How was the study done?

This was an open-label study, which means the participants and study doctors knew which treatment they received.

As shown in the study design figure, participants either received feladilimab + docetaxel or docetaxel alone. Twice as many participants were included in the feladilimab + docetaxel group as compared with the docetaxel alone group.



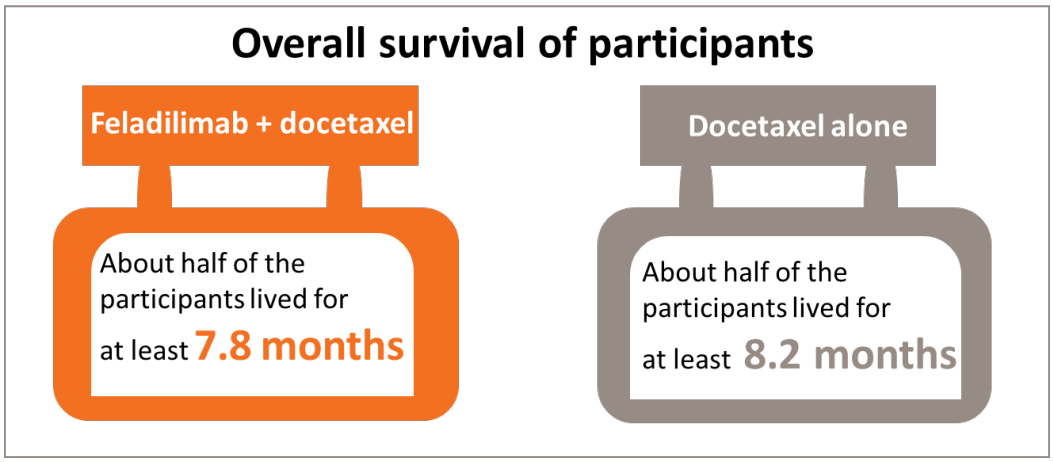
What were the main results of the study?

Study doctors assessed each participant's cancer using physical examinations, scans, and blood tests. They recorded the time in months from the day the participant entered the study until the participants' death. This is called Overall Survival (OS).

How long did the participants live after starting the treatment?

The median OS was calculated for each treatment group as shown in the 'Overall survival of participants' figure. Median is the number in the middle of the ordered list, with equal values above and below this number.

Participants in the feladilimab + docetaxel group received treatment ranging from 1 day to 2 years. Participants in the docetaxel alone group received treatment ranging from 1 day to about 6 months. The results showed that the median OS between the two groups was similar.



What were the side effects?

Unwanted medical problems (adverse events) can happen to people when they receive a medicine. Study doctors record these events.

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 other documents related to the study medicine.

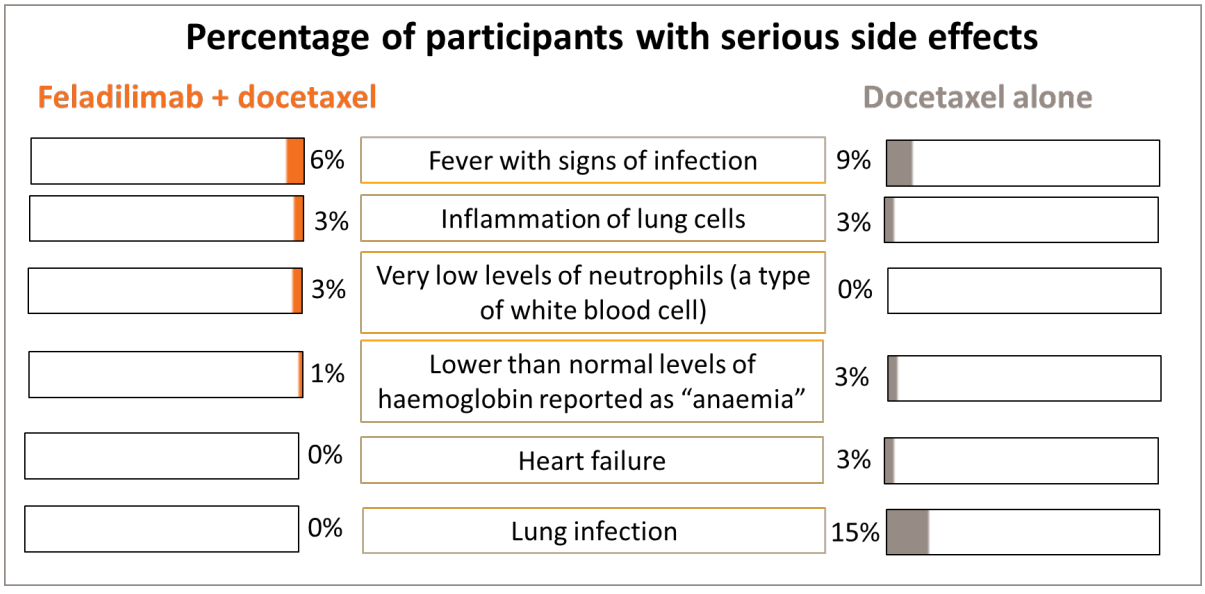
A summary of all events reported in this study may be found in the clinical results summary.

A total of 104 out of 105 participants received at least one dose of study medicine. Side effects were reported for these participants.

What were the serious side effects?

The side effects are considered "serious" if they cause death, are life threatening, cause lasting problems or require hospital care.

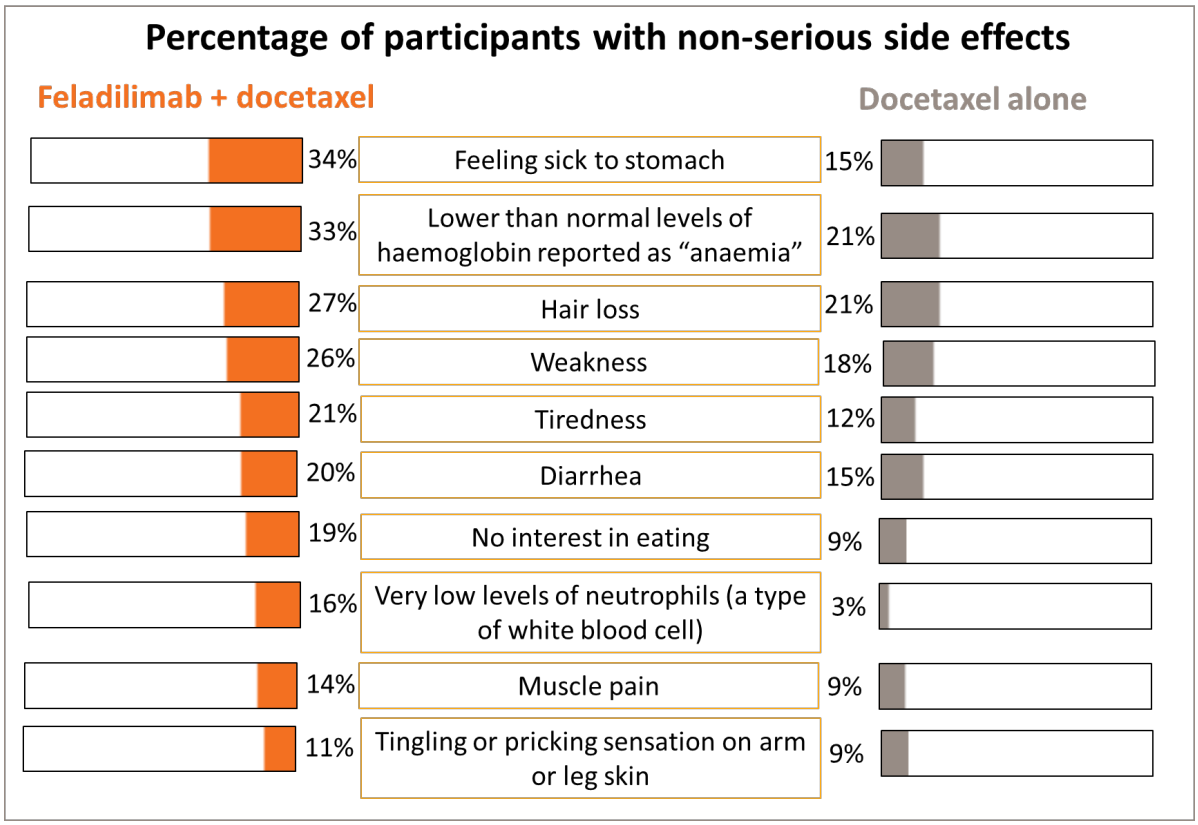
Serious side effects were reported by 11 participants (16%) in the feladilimab + docetaxel group and 10 participants (29%) in the docetaxel alone group. Serious side effects reported by one percent or more participants in either treatment group are shown below.



Fatal serious side effects of heart stopped beating and inflammation of lung cells were reported for three participants (4%) in the feladilimab + docetaxel group. No fatal serious side effects were reported by participants in the docetaxel alone group.

What were the non-serious side effects?

Non-serious side effects were reported by 59 participants (84%) in the feladilimab + docetaxel group and 24 participants (71%) in the docetaxel alone group. Non-serious side effects reported by 10% or more participants in either treatment group are shown below.



How has this study helped participants and researchers?

Researchers concluded that giving feladilimab + docetaxel did not improve overall survival in participants with advanced NSCLC compared with docetaxel alone. The side effects reported in this study were as expected.

Are there any plans for further studies?

No further studies with feladilimab are planned but other new treatments for NSCLC are either underway or being planned.

Where can I find more information about this study?

Full title of this study: A phase II, randomized, open-label platform trial utilizing a master protocol to study novel regimens versus standard of care treatment in NSCLC participants.

Clinical studies have unique study numbers. The unique study numbers associated with this study are shown below with internet links to scientific summaries.

Organisation (Website)	Study Identifier
European Medicines Agency (www.clinicaltrialsregister.eu)	2018-001316-29 [1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT05553808 [2]

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. These details will be available on the above link on Clinicaltrials.gov by November 2022.

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.

We would like to **thank the participants** who contributed to this study. The results of this study will help answer scientific questions about treating participants with advanced NSCLC.

The content for this document was finalised by GSK on 20 July 2022. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=205801
[2] https://clinicaltrials.gov/ct2/show/NCT05553808?term=NCT05553808