A phase II study that tests afatinib in combination with pembrolizumab in patients with squamous cell carcinoma of the lung

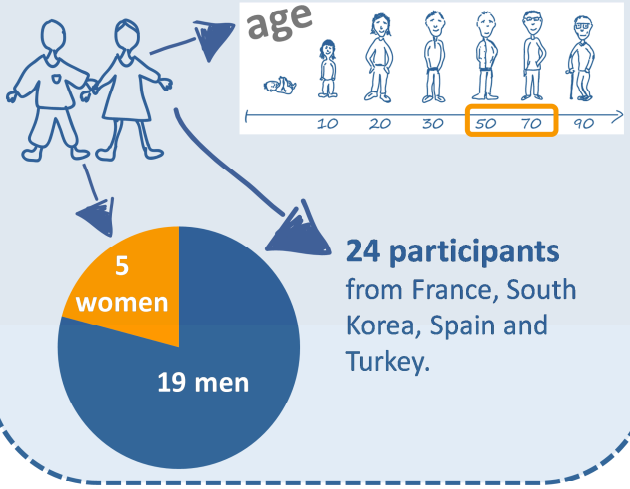
Boehringer Ingelheim

Afatinib and **pembrolizumab** are two medicines that work against cancer in different ways.

This **study** was to find out:

Does **combining afatinib and pembrolizumab** help people with **squamous cell carcinoma** of the **lung** that has advanced or spread?

Participants had squamous cell carcinoma of the lung that had worsened or spread after previously receiving chemotherapy.



24 participants from France, South Korea, Spain and Turkey.

Participants received:

1 **Afatinib** (30 mg or 40 mg) each day as a tablet

and

1 200 mg **pembrolizumab** every 3 weeks as an infusion

All participants in this study had **unwanted effects.**

The **most common** unwanted effects were:

- Diarrhoea
- Acne
- Rash
- Vomiting
- Fatigue

RESULTS

Tumours decreased for 2 participants who received **40 mg afatinib with pembrolizumab** and for 1 participant who received **30 mg afatinib with pembrolizumab.**

This study was **stopped** early **before** the planned **end** as the results were not promising.

Study: 1200-0283

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This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about afatinib in combination with pembrolizumab and the treatment of squamous cell carcinoma of the lung.

What was this study about?

The purpose of this study was to test whether combining 2 cancer medicines helps people with squamous cell carcinoma of the lung that has advanced or spread after previously receiving chemotherapy. The first medicine, called afatinib, works by permanently blocking several growth factor signals. It is used in certain types of lung cancer.

The second medicine, called pembrolizumab, helps the immune system fight cancer. It is used to treat various types of cancer.

This study was stopped early before the planned end as the results were not promising.

Who took part in this study?

Adults with squamous cell carcinoma of the lung that had worsened or spread could be part of the study. They had to have previously received platinum-based chemotherapy. They could not be candidates for further platinum chemotherapy or surgery.

24 participants took part in the study. 19 were men and 5 were women. The average age was 63 years. The youngest participant was 47 years old and the oldest was 81 years old.

The following table shows the numbers of participants in the study in different countries.

Country	Number of Participants
Spain	10
France	5
South Korea	5
Turkey	4

How was this study done?

All participants in the study took afatinib once a day. Afatinib was a tablet that was taken by mouth. The participants also received 200 mg pembrolizumab once every 3 weeks. Pembrolizumab was given by an infusion into a vein. Participants could continue to receive the medicines as long as it was safe and their cancer was not becoming worse. During the study, participants visited the doctors regularly. The doctors looked at the size and number of tumours every 9 weeks to see if the treatment helped. During the visits, the doctors also collected information about the participants' health.

The study was designed in 2 parts. The first part aimed to determine the dose of afatinib when given with pembrolizumab that was safe and kept the cancer from worsening.

The first 12 participants received a dose of 40 mg of afatinib with pembrolizumab. After each participant had received both medicines for at least 3 weeks, a safety committee reviewed the results. They decided that a lower dose of afatinib should be given.

The next 12 participants who started the study later received 30 mg of afatinib and pembrolizumab for at least 3 weeks.

The plan for the study was that the dose determined from the first part would be used for the second part of the study. But, after the safety committee reviewed the results from the first part, the study was stopped because the results were not promising.

What were the results of this study?

In the first part of the study, tumours decreased for 2 out of 12 participants (17%) who received 40 mg afatinib with pembrolizumab, and for 1 out of 12 participants (8%) who received 30 mg afatinib with pembrolizumab.

Did participants have any unwanted effects?

Yes, participants in both groups had unwanted effects. Unwanted effects are health problems that the doctors think were caused by afatinib or pembrolizumab. All participants in this study had unwanted effects.

The table below shows the most common unwanted effects. The table also shows how many participants had each of these unwanted effects.

Type of unwanted effect	**Afatinib 40 mg and Pembrolizumab** **12 participants were in this group**	**Afatinib 30 mg and Pembrolizumab** **12 participants were in this group**
Diarrhoea	11 participants (92%)	7 participants (59%)
Acne (dermatitis acneiform)	2 participants (17%)	5 participants (42%)
Rash	5 participants (42%)	1 participant (8%)
Vomiting	3 participants (25%)	4 participants (33%)
Fatigue	3 participants (25%)	3 participants (25%)

Some unwanted effects were serious because they required a stay in hospital, were life-threatening, or fatal. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 4 participants (33%) in the 40 mg afatinib with pembrolizumab group had serious unwanted effects. 4 participants (33%) in the 30 mg afatinib with pembrolizumab group had serious unwanted effects.

Where can I find more information about this study?

You can find further information about this study at these websites:

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number 1200-0283.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2016-005042-37.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT03157089**.**

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'LUX-Lung IO: A phase II, open label, non-randomised study of afatinib in combination with pembrolizumab in patients with locally advanced or metastatic squamous cell carcinoma of the lung'.
This study started in November 2017 and finished in January 2020.

Are there additional studies?

If we do more clinical studies with afatinib, you will find them on the websites listed above. To search for these studies, use the words afatinib, Giotrif®, or Gilotrif® and BIBW2992.

Important notice

This summary shows only the results from one study and may not represent all of the knowledge about the medicine studied. Usually, more than one study is carried out in order to find out how well a medicine works and the side effects of the medicine. Other studies may have different results.

You should not change your therapy based on the results of this study without first talking to your treating physician. Always consult your treating physician about your specific therapy.

Boehringer Ingelheim has provided this lay summary in accordance with European Union transparency obligations.