

## A study to test different doses of nintedanib combined with weekly docetaxel in patients with advanced lung cancer who have had chemotherapy

This is a summary of results from one clinical study.

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We thank all study participants. You helped us to answer important questions about nintedanib and the treatment of advanced lung cancer.

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### What was this study about?

Nintedanib is a medicine that helps to stop cancer from growing and spreading. It is used to treat lung cancer in combination with chemotherapy (docetaxel). However, treatment with these 2 medicines is associated with unwanted effects. Therefore, we wanted to find the highest dose of nintedanib that people could tolerate together with a lower dose of chemotherapy (docetaxel) taken less often.

The study was stopped early because we could not find enough participants.

### Who took part in this study?

Participants could take part in this study if they had advanced lung cancer which did not respond to another kind of therapy.

This study was planned for 30 participants. The study was stopped early; therefore, only 14 participants took part in the study. 10 were men and 4 were women. On average, participants were 64 years old. The youngest participant was 48 years old and the oldest participant was 77 years old. This study was done in France and Germany. There were 9 participants from France and 5 participants from Germany.



## How was this study done?

The participants received different doses of nintedanib. The first 7 participants received 150 mg capsules of nintedanib twice a day. Participants who started the study later received 200 mg capsules of nintedanib twice a day. The participants also received docetaxel one day each week for 3 weeks during each 28-day cycle. On those days, the participants did not take nintedanib.

The participants and doctors knew which dose each participant was receiving. Participants could continue to receive the medicine as long as it was safe and their cancer was not becoming worse.

We wanted to find out the highest dose of nintedanib participants could tolerate when taken together with docetaxel.

Participants visited the doctors regularly. During these visits, the doctors collected information about the participants' health.



## What were the results of this study?

The study was stopped early. We could not find enough participants to determine the highest dose participants could tolerate.



## 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 nintedanib or docetaxel. In this study, 6 out of 7 participants in the nintedanib 150 mg and docetaxel group had unwanted effects. 5 out of 7 participants in the nintedanib 200 mg and docetaxel group had unwanted effects.

The most common unwanted effects were:

- diarrhoea: 5 participants in the nintedanib 150 mg and docetaxel group and 4 participants in the nintedanib 200 mg and docetaxel group
- reduced number of red blood cells (anaemia): 3 participants in the nintedanib 150 mg and docetaxel group and no participants in the nintedanib 200 mg and docetaxel group

None of the unwanted effects were serious. This means that the unwanted effects did not lead to a hospital stay, that they were not life-threatening, and that they did not lead to a disability.



## 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 1199-0224.
2. Go to [www.clinicaltrialsregister.eu/ctr-search](http://www.clinicaltrialsregister.eu/ctr-search) and search for the EudraCT number 2015-000317-52.
3. Go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov) and search for the NCT number NCT02668393.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'An open-label Phase I of oral nintedanib plus weekly docetaxel therapy in patients with locally advanced or metastatic lung adenocarcinoma after failure of platinum-based first-line chemotherapy.'

This study started in June 2016 and finished in November 2019.



## Are there additional studies?

If we do more clinical studies with nintedanib, you will find them on the websites listed above. To search for these studies, use the words nintedanib and BIBF 1120.

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## 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.

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