INPULSIS®-ON: The long-term safety of nintedanib in patients with idiopathic pulmonary fibrosis (IPF)

This is a summary of a clinical study in patients with IPF. It is written for the general public. It includes information about how researchers did the study and what the results were.

We thank all patients who took part in this study. Through your participation, you helped researchers answer important questions about nintedanib and the treatment of IPF.

What was this study about?

This study looked at the long-term safety of a medicine called nintedanib in patients with IPF. IPF is a rare disease that causes scarring of the tissue inside the lungs. The scarring makes the lungs become thick and stiff (fibrotic). This makes breathing difficult. The word 'idiopathic' means that doctors do not know the cause of the disease.

The patients in this study had already participated in previous nintedanib studies.

This study started in July 2012. Some patients are still in the study. The final analysis shown in this summary was done in September 2017.

Why was the study needed?

This study allowed patients from previous nintedanib studies to receive nintedanib for a longer period of time. Researchers wanted to see the long-term safety of nintedanib in patients with IPF.

Which medicines were studied?

Researchers studied the medicine nintedanib (also known as BIBF 1120). Nintedanib is a medicine that is used to treat IPF. Nintedanib can help to slow down the worsening of the disease. Researchers think that nintedanib blocks biological signals that take place in the lung-scarring process. Nintedanib is given as a capsule taken by mouth.

Who participated in the study?

Patients with IPF who completed 1 year of treatment in the previous nintedanib studies could enter the study.

A total of 734 patients were treated with nintedanib in the study. The patients were mostly men (80%). The average age was 67 years. The youngest patient was 43 years old. The oldest patient was 89 years old.

The table below shows the number of patients in different regions who took part in the study.

Region	Countries	Number of Patients
European Union	Belgium, Czech Republic, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, United Kingdom	334 patients
Asia	China, India, Japan, Korea	204 patients
Other countries	Australia, Canada, Chile, Israel, Mexico, Russia, Turkey, United States	196 patients

How was this study done?

In this study, patients with IPF received long-term nintedanib treatment. Most patients started treatment on a dose of 150 milligrams (mg) twice a day. If patients had side effects that they could not tolerate, the doctors could lower the dose to 100 mg twice a day. Patients could also stop taking nintedanib for a while. The patients and their doctors knew which dose of nintedanib the patients were taking.

On average, patients took nintedanib for 2 years and 7 months. The longest time a patient took nintedanib in this study was 4 years and 8 months. Overall, 36% of patients had at least 1 dose reduction and 38% had at least 1 treatment interruption.

Patients visited their doctors regularly. During the visits, the doctors collected information about health problems the patients had during the study. In this way, researchers could determine the long-term safety of nintedanib. Health problems included those caused by IPF, other diseases, other medicines, and unwanted effects of nintedanib. Unwanted effects of nintedanib are described in a separate section below.

What were the results of this study?

In this long-term study, 723 out of 734 patients (99%) had health problems. Some patients had to stop taking nintedanib because of health problems. Overall, 313 patients (43%) stopped treatment because of health problems.

Some health problems were serious because they required a visit to hospital or a longer stay in hospital, were life-threatening, or fatal. Health problems were also serious if they led to disability or the doctor thought they were serious for any other reason. In this study, 506 patients (69%) had serious health problems. This included 175 patients (24%) who died from serious health problems.

The health problems were similar to those seen in previous studies of nintedanib in patients with IPF. The most common health problems were with the stomach and bowel. Researchers found no new safety concerns in this study.

Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by nintedanib. In this study, 552 out of 734 patients (75%) had unwanted effects. The most common unwanted effects seen in at least 5% of patients are shown in the table below.

	Nintedanib (734 patients)
Patients with any unwanted effect	552 patients (75%)
Diarrhoea	465 patients (63%)
Nausea	96 patients (13%)
Decreased weight	78 patients (11%)
Decreased appetite	60 patients (8%)
Vomiting	54 patients (7%)
Stomach pain (Abdominal pain)	38 patients (5%)

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, were life-threatening, or fatal. Unwanted effects were also serious if they led to disability or the doctor thought they were serious for any other reason. In this study, 44 patients (6%) had serious unwanted effects. This included 1 patient who died from a sudden worsening of IPF.

Are there follow-up studies?

If more clinical studies with nintedanib are done, they may be found on the public websites listed in the section below. To search for these studies, use the following names: BIBF 1120, nintedanib, OFEV®.

Where can I find more information?

You can find the scientific summaries of the study results at these websites:

www.trials.boehringer-ingelheim.com	search for the study number: BI 1199.33
www.clinicaltrialsregister.eu	search for the EudraCT number: 2011-002766-21
www.clinicaltrials.gov	search for the NCT number: NCT01619085

The sponsor of this study is Boehringer Ingelheim.

The full title of the study is:

'An open-label extension trial of the long term safety of oral BIBF 1120 in patients with idiopathic pulmonary fibrosis (IPF)'.

This is a Phase 3 study.

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.