

A study to test whether afatinib helps people with advanced bladder cancer

This is a summary of results from one clinical study.

We thank all study participants. You helped us to answer important questions about afatinib and the treatment of bladder cancer.



What was this study about?

The purpose of this study was to test if treatment with a medicine called afatinib helps people whose bladder cancer has worsened. Afatinib is used to treat certain types of lung cancer that grow because of changes to the EGFR gene. Afatinib works by blocking several growth signals like EGFR, ERBB2, or ERBB3. We wanted to see if using afatinib also helps people with bladder cancer who have changes to the EGFR, ERBB2, or ERBB3 genes.

This study examined whether the bladder cancer stopped worsening when participants took afatinib alone. This study was stopped before the planned end.



Who took part in this study?

Adults with bladder cancer that had worsened or spread could be in this study. They had to have previously received treatment with platinum-based chemotherapy. They could not be candidates for further platinum chemotherapy or surgery. They also needed to have changes to the EGFR, ERBB2, or ERBB3 genes.

There were 2 groups of participants in this study.

There was a main group (Group A). 34 participants were in this group. 30 were men and 4 were women. The youngest participant was 40 years old and the oldest participant was 84 years old. The average age was 66 years. This group had changes to the ERBB2 or ERBB3 genes. This is the main group of participants that we discuss in this lay summary.

There was a second group (Group B). 8 participants were in this group. 6 were men and 2 were women. The youngest participant was 58 years old and the oldest participant was 78 years old. The average age was 70 years. This group had changes to the EGFR gene. Information about this group is included only in the section on unwanted effects.

The study took place in Spain, France, and Italy.



How was this study done?

All participants in the study took 40 mg of afatinib once a day. Afatinib was a tablet that was taken by mouth. The participants and doctors knew what they were taking.

To find out if taking afatinib helps people with certain types of bladder cancer, we studied participants in Group A. We wanted to see if their cancer grew further or they died. The study results were determined at 6 months after start of treatment. We also kept in touch with participants so we would know if they were still alive.

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



What were the results of this study?








After 6 months, 4 of the 34 participants in Group A did not have cancer growth and were still alive. This did not indicate that the treatment helped. We decided to stop the study before the planned end.




Did participants have any unwanted effects?

Participants in Group A and Group B had unwanted effects. Unwanted effects are health problems that the doctors think were caused by afatinib. 38 out of 42 participants (91%) 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 42 participants	
Diarrhoea	32 participants (76%)	
Weakness (asthenia)	13 participants (31%)	
Inflammation of mucous membranes (mucosal inflammation)	13 participants (31%)	
Rash	10 participants (24%)	
Decreased appetite	10 participants (24%)	
Inflamed and sore mouth (stomatitis)	10 participants (24%)	

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 8 participants (19%) 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 1200.261.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2015-005427-10.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02780687.

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'LUX-Bladder 1: Phase II open label single arm exploratory trial of oral afatinib monotherapy following platinum failure for patients with advanced/metastatic urothelial tract carcinoma with genetic alterations in *ERBB* receptors'.

This study started in November 2015 and finished in October 2019.



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 and BIBW 2992.

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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