A study to test how people with non-Hodgkin lymphoma that has returned or spread tolerate different doses of BI 836826

This is a summary of a clinical study in non-Hodgkin lymphoma. It describes how researchers did the study and what the results were. We have written this summary for the general public.

We thank all patients who took part in this study. You helped to answer important questions about BI 836826 and the treatment of cancer.

What was this study about?

We tested a medicine called BI 836826 in patients with non-Hodgkin lymphoma. The purpose of the study was to find the highest dose of BI 836826 that the patients could tolerate.

Why was this study needed?

When a new medicine is developed, researchers need to learn more about what the best dose is for patients. Non-Hodgkin lymphoma is a type of cancer. Some forms of non-Hodgkin lymphoma can be difficult to treat. Even if treatment works, the cancer can return after some time. Therefore, new treatments are needed. This study was needed to learn more about the best dose of BI 836826 for patients.

Which medicines were studied?

BI 836826 is being developed to treat people with non-Hodgkin lymphoma or with chronic lymphocytic leukaemia. In this study, BI 836826 was given as an infusion into a vein.

Who took part in this study?

Adult patients with B-cell non-Hodgkin lymphoma that had not responded to treatment or had returned could take part in this study.

A total of 48 patients took part in the study. This included 30 men and 18 women. The average age was 66 years. The youngest patient was 25 years old and the oldest patient was 83 years old.

2 groups of patients are described in this lay summary. One group consisted of 37 Caucasian patients who were treated in France and Germany. The other group consisted of 11 Korean patients treated in the Republic of Korea.

How was this study done?

We wanted to find the highest dose of BI 836826 that patients could tolerate. This dose is called the maximum tolerated dose. To find the maximum tolerated dose, we looked at how many patients had certain severe health problems that might have been caused by the treatment. These are called dose-limiting toxicities.

The patients were all given BI 836826 but at different doses. The first patients to enter the study received a low dose and patients who started the study later received a higher dose. The doses ranged between 1 milligram (mg) and 200 mg.

Patients received one dose of BI 836826 per week during the first 4 weeks of the study. This 4-week period was followed by 27 days of no doses. If the patient tolerated BI 836826, this treatment cycle could be repeated 2 more times.

Patients visited their doctors regularly. During the visits, the doctors collected information on each patient's health.

What were the results of this study?

4 of the 37 Caucasian patients (11%) had dose-limiting toxicities. The maximum tolerated dose for Caucasian patients was 100 mg of BI 836826 once-weekly for 4 weeks.

The Korean patients did not tolerate the maximum tolerated dose for Caucasian patients. 4 (36%) of the 11 Korean patients had dose-limiting toxicities. The study ended before the maximum tolerated dose for Korean patients was found.

Were there any unwanted effects?

Unwanted effects are any health problems that the doctors thought were caused by the study medicines. In this study, 35 out of 37 patients (95%) in the Caucasian group had unwanted effects. All patients (100%) in the Korean group had unwanted effects.

The following table shows the most common unwanted effects seen in either group.

	Caucasian patients (37 patients)	Korean patients (11 patients)
Reduced number of neutrophils, a type of white blood cell (neutropenia)	21 patients (57%)	8 patients (73%)
Reduced number of leukocytes, a type of white blood cell (leukopenia)	21 patients (57%)	0 patients
Fever with reduced number of neutrophils (febrile neutropenia)	0 patients	6 patients (55%)
Reduced number of platelets, a type of blood-clotting cell (thrombocytopenia)	15 patients (41%)	5 patients (46%)
Infusion-related reaction	15 patients (41%)	3 patients (27%)
Chills	13 patients (35%)	3 patients (27%)

Some unwanted effects were serious because they required a visit to hospital or a longer stay in hospital, or were life-threatening. Unwanted effects were also serious if the doctor thought they were serious for any other reason. In this study, 4 patients (11%) in the Caucasian group had serious unwanted effects. 6 patients (55%) in the Korean group had serious unwanted effects.

Are there additional studies?

If we do additional clinical studies with BI 836826, you will find them on the websites listed in the next section. To search for these studies, use the following names: BI 836826.

Where can I find more information about this study?

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

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number **BI 1270.2.**
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number **2010-024456-29.**
3. Go to www.clinicaltrials.gov and search for the NCT number **NCT01403948.**

Boehringer Ingelheim sponsored this study.

The full title of the study is: 'A Phase I, open-label, dose-escalation trial with BI 836826 in patients with relapsed or refractory non-Hodgkin lymphoma of B cell origin'.

This study started in January 2012 and finished in February 2018.

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.