A study to test different doses of BI 836826 with gemcitabine and oxaliplatin in patients with diffuse large B-cell lymphoma

This is a summary of a clinical study about cancer. This summary describes the results of the study. 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 diffuse large B-cell lymphoma (DLBCL). The purpose of this study was to find the highest dose of a medicine called BI 836826 that the patients could tolerate when given with medicines called gemcitabine and oxaliplatin.

Why was this study needed?

When a new medicine is developed, researchers need to learn more about what the best dose is for patients. DLBCL is a type of non-Hodgkin lymphoma, which is a type of cancer. DLBCL 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 help find the best dose of BI 836826 for patients and how it works with other medicines.

Which medicines were studied?

BI 836826 was 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.

Oxaliplatin and gemcitabine are anticancer chemotherapy drugs. They were given as an infusion into a vein.

Who took part in this study?

Adult patients with DLBCL that had not responded to treatment or whose disease had returned could take part in this study.

A total of 21 patients took part in the study. This included 11 women and 10 men. The average age was 58 years. The youngest patient was 22 years old and the oldest patient was 86 years old.

This study was done in Belgium, Italy, and Spain.

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 given were 25 milligrams (mg), 50 mg, and 100 mg.

Patients were also given gemcitabine plus oxaliplatin. The dose given of these 2 drugs depended on the body size of the patient.

Treatment was given in cycles. Each treatment cycle lasted 2 weeks. Patients received 1 dose of gemcitabine plus oxaliplatin on Day 1 of the cycle and 1 dose of BI 836826 on Day 8 of the cycle. If the patient tolerated the drugs, this treatment cycle could be repeated 5 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?

We decided to stop this study early. Because the study was stopped early, the maximum tolerated dose could not be determined.

Did patients have any unwanted effects?

Yes, patients had unwanted effects. Unwanted effects are health problems that the doctors think were caused by the study medicines. In this study, 16 out of 21 patients (76%) had unwanted effects related to BI 836826.

The table below shows the 4 most common unwanted effects.

Unwanted effect	**BI 836826** **(21 patients)** 
Reduced number of neutrophils, a type of white blood cell (neutropenia)	11 patients (52%) 
Reduced number of red blood cells (anaemia)	10 patients (48%) 
Reduced number of platelets, a type of blood-clotting cell (thrombocytopenia)	10 patients (48%) 
Infusion-related reactions	8 patients (38%) 

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, 6 patients had serious unwanted effects that were related to BI 836826.

Where can I find more information about this study?

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

1. Go to http://www.trials.boehringer-ingelheim.com/ and search for the study number 1270.11.
2. Go to www.clinicaltrialsregister.eu/ctr-search and search for the EudraCT number 2014-004794-16.
3. Go to www.clinicaltrials.gov and search for the NCT number NCT02624492.

Boehringer Ingelheim sponsored this study.

The full title of the study is: ‘An open label multicenter Phase Ib/II trial to determine the dose of BI 836826 in combination with gemcitabine and oxaliplatin (GemOx) and the efficacy of BI 836826-GemOx versus rituximab (R)- GemOx (R-GemOx) in patients with relapsed/ refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for, or have relapsed/progressed after autologous/allogeneic stem cell transplant’.

This study started in March 2016 and finished in March 2018.

Are there additional studies?

No further studies are planned.

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.