



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Withdrawal of application for a change to the marketing authorisation for Zydelig (idelalisib)

On 30 January 2018, Gilead Sciences International Ltd. officially notified the Committee for Medicinal Products for Human Use (CHMP) that it wishes to withdraw its application to use the cancer medicine Zydelig in combination with the cancer medicines rituximab and bendamustine for the treatment of chronic lymphocytic leukaemia (CLL).

What is Zydelig?

Zydelig is used to treat two types of blood cancer: CLL and follicular lymphoma (cancers that affect a type of white blood cells called B lymphocytes).

In CLL, Zydelig is used in combination with another medicine (rituximab or ofatumumab) in patients who have received at least one previous treatment and in patients who have genetic mutations in their cancer cells called 17p deletion or TP53 mutation who cannot be treated with any other therapy.

In follicular lymphoma, Zydelig is used on its own in patients whose disease has not responded to two previous treatments.

Further information on Zydelig's current uses can be found on the Agency's website: ema.europa.eu/Find/medicine/Human/medicines/European_public_assessment_reports.

What was Zydelig expected to be used for?

Zydelig was also expected to be used in combination with rituximab and bendamustine to treat adults with CLL who had received at least one previous treatment.

How does Zydelig work?

The active substance in Zydelig, idelalisib, blocks the effects of an enzyme called PI3K-delta. This enzyme plays a role in the growth, migration and survival of white blood cells but is overactive in blood cancers, where it enables the survival of the cancer cells. By targeting this enzyme and blocking its effects, idelalisib causes death of the cancer cells, thereby delaying or stopping the progression of the cancer.



What did the company present to support its application?

The company presented data from one main study comparing Zydelig with placebo (a dummy treatment) both used in addition to bendamustine and rituximab. The study involved 416 patients with CLL who had received previous treatment. The main measure of effectiveness was how long patients lived without their disease getting worse.

How far into the evaluation was the application when it was withdrawn?

The application was withdrawn after the CHMP had evaluated the documentation provided by the company and formulated lists of questions. The company had not responded to the last round of questions at the time of the withdrawal.

What was the recommendation of the CHMP at that time?

Based on the review of the data and the company's response to the CHMP lists of questions, at the time of the withdrawal, the CHMP had some concerns and was of the provisional opinion that Zydelig could not have been approved for use with rituximab and bendamustine in patients with CLL.

The CHMP noted that patients treated with Zydelig in addition to rituximab and bendamustine lived longer without their disease getting worse than those receiving placebo in addition to rituximab and bendamustine. However, because of the design of the study and the side effect profile of Zydelig, the CHMP considered that more longer term data were needed to show that the benefits of Zydelig outweighed its risks in this combination.

What were the reasons given by the company for withdrawing the application?

In its letter notifying the Agency of the withdrawal of application, the company stated that the withdrawal is based on CHMP's opinion that the data supplied did not provide sufficient evidence to conclude that the medicine's benefits outweigh its risks.

The withdrawal letter is available [here](#).

What consequences does this withdrawal have for patients in clinical trials?

The company informed the CHMP that this withdrawal does not impact ongoing clinical trials with Zydelig.

If you are in a clinical trial and need more information about your treatment, contact the doctor who is giving it to you.

What is happening with Zydelig in its authorised uses?

There are no consequences on the use of Zydelig in its authorised uses.