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Press Office

Press release

European Medicines Agency recommends conditional approval of Pixuvri (pixantrone) for relapsed or refractory aggressive non-Hodgkin's B-cell lymphoma

Company to supply additional data on patients pretreated with rituximab

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended that Pixuvri be granted conditional approval for the cancer non-Hodgkin's B-cell lymphoma. The new medicine, which contains the active substance pixantrone, is to be used on its own in patients whose cancer is aggressive and has come back after multiple rounds of previous chemotherapy or is not responding to other treatments.

The Committee recommended conditional approval, because the data supplied show that the medicine's benefits outweigh its risks but are not yet comprehensive, and that more information is needed on the benefits of the medicine in patients who have received rituximab in the past.

At the same time, the Committee concluded that Pixuvri satisfies an unmet medical need, because there are no approved and standard treatments for this stage of the disease. Therefore, the benefits of making this medicine available on the market immediately outweigh the risks inherent in the fact that additional data are required.

The main study showed that a greater proportion of patients responded to Pixuvri than a comparator chemotherapy medicine (20% versus 6%) and that patients receiving Pixuvri survived for longer without their disease getting worse (an average of 10.2 versus 7.6 months). The Committee also noted that the benefit of Pixuvri appeared to be lower in patients who had received rituximab in the past, and that its benefit was not established in patients when used as the fifth or later round of chemotherapy in patients whose disease did not respond to the last treatment.

The conditional approval will be renewed on a yearly basis until the obligation to provide additional data on rituximab-pretreated patients has been fulfilled. The applicant, CTI Life Sciences Ltd., has informed the Committee that it expects to be able to provide the results of the additional study by mid-2015.

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The most frequent side effect seen in the clinical studies was suppression of the bone marrow, resulting in low levels of white blood cells, platelets and red blood cells. Infections were common, but were only serious in a few patients.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The CHMP's recommendation will now be sent to the European Commission for the adoption of an EU-wide decision.
3. All other opinions and documents adopted by the CHMP at its February 2012 plenary meeting will be published on Friday, 17 February 2012 at 12.00 noon United Kingdom time on a dedicated web page.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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