16 February 2012
EMA/CHMP/102366/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Pixuvri

pixantrone dimaleate

On 16 February 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Pixuvri, 29mg, powder for concentrate for solution for infusion intended for the treatment of patients with multiply relapsed aggressive Non Hodgkin's Lymphoma (NHL) as monotherapy.

The applicant for this medicinal product is CTI Life Sciences Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Pixuvri is pixantrone, an anthracyclines and related substances (L01DB11) belonging to a class of drugs which antineoplastic activity is linked to inhibition of topoisomerase II and DNA intercalation.

The benefit with Pixuvri is its ability to improve the rate of complete responses and unconfirmed complete responses (CR/CRu), compared to the comparator group in adult patients with multiply relapsed or refractory aggressive Non-Hodgkin B-cell Lymphomas.

The most common side effects are neutropenia, leucopoenia, anaemia, thrombocytopenia, asthenia, pyrexia, cough, decreased ejection fraction and nausea. Haematological side effects are also the most common associated with grade 3 or 4 toxicity.

A pharmacovigilance plan for Pixuvri will be implemented as part of the marketing authorisation.

The approved indication is: "Pixuvri is indicated as monotherapy for the treatment of adult patients with multiply relapsed or refractory aggressive Non-Hodgkin B-cell Lymphomas. The benefit of pixantrone treatment has not been established in patients when used as fifth line or greater chemotherapy in patients who are refractory to last therapy."

It is proposed that Pixuvri be prescribed by physicians familiar with the use of antineoplastic agents and have the facilities for regular monitoring of clinical, haematological, and biochemical parameters during and after treatment

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

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Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR) and made available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Pixuvri and therefore recommends the granting of the marketing authorisation. The marketing authorisation is conditional[2].

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.