14 November 2019
EMA/CHMP/402512/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Polivy

polatuzumab vedotin

On 14 November 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Polivy[3], intended for the treatment of relapsed/refractory diffuse large B-cell lymphoma (DLBCL) in combination with bendamustine and rituximab. The applicant for this medicinal product is Roche Registration GmbH.

Polivy will be available as a 140 mg powder for concentrate for solution for infusion. The active substance of Polivy is polatuzumab vedotin (ATC code: L01XC37) is a CD79b targeted antibody-drug conjugate that preferentially delivers a potent anti-mitotic agent (monomethyl auristatin E, or MMAE) to B cells, which results in the killing of malignant B-cells.

The benefits with Polivy in combination with bendamustine and rituximab are its ability to elicit higher rates of complete responses as compared to bendamustine – rituximab alone. The most common side effects are infections neutropenia, thrombocytopenia, anaemia, leukopenia, lymphopenia, neuropathy, dizziness, cough, gastrointestinal disorders, fatigue, pyrexia, asthenia, chills and infusion-related reactions.

The full indication is: "Polivy in combination with bendamustine and rituximab is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant." It is proposed that Polivy must only be administered under the supervision of a healthcare professional experienced in the diagnosis and treatment of cancer patients.

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.

[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
[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.
[3] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union