13 October 2016
EMA/CHMP/561089/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Venclyxto

venetoclax

On 13 October 2016, 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 Venclyxto, intended for the treatment of chronic lymphocytic leukaemia (CLL). Venclyxto was designated as an orphan medicinal product on 6 December 2012. The applicant for this medicinal product is AbbVie Ltd.

Venclyxto will be available as 10-mg, 50-mg and 100-mg film-coated tablets. The active substance of Venclyxto is venetoclax, an antineoplastic agent, which acts by inhibiting BCL-2 (B cell lymphoma-2), an anti-apoptotic protein overexpressed by B-cells in CLL, thus inducing tumour cell apoptosis.

The benefits shown in single arm studies with Venclyxto are its ability to produce responses in patients unsuitable for or refractory to B-cell receptor pathway inhibitors and other anticancer medicines. The most common side effects are neutropenia / neutrophil count decreased, diarrhoea, nausea, anaemia, upper respiratory tract infection, fatigue, hyperphosphataemia, vomiting, and constipation.

The full indication is: "Venclyxto monotherapy is indicated for the treatment of chronic lymphocytic leukaemia (CLL) in the presence of 17p deletion or *TP53* mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor. Venclyxto monotherapy is indicated for the treatment of CLL in the absence of 17p deletion or *TP53* mutation in adult patients who have failed both chemoimmunotherapy and a B-cell receptor pathway inhibitor."

It is proposed that Venclyxto be prescribed by physicians experienced in the treatment of CLL and the use of anticancer medicines.

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

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