28 February 2019
EMA/CHMP/40684/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ondexxya

andexanet alfa

On 28 of February 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation[2] for the medicinal product Ondexxya, intended for use when reversal of anticoagulation with apixaban or rivaroxaban is needed due to life-threatening or uncontrolled bleeding. The applicant for this medicinal product is Portola Netherlands B.V.

Ondexxya will be available as a 200 mg powder for solution for infusion. The active substance is andexanet alfa, belonging to the pharmacotherapeutic group antidotes (ATC code: V03AB38). Andexanet alfa is a recombinant form of human factor Xa protein which binds to rivaroxaban or apixaban (direct factor Xa inhibitor) with high affinity, rendering them unable to exert their anticoagulant effects.

The benefits with Ondexxya are its ability to reverse the anticoagulant activity of rivaroxaban and apixaban. It can be used in conjunction with standard supportive measures as appropriate. Clinical efficacy is based upon reversal of anti-factor Xa activity in healthy volunteers and interim results in patients with life threatening bleeding. Further confirmation of the correlation between anti-factor Xa activity and haemostatic efficacy in bleeding patients and of the recommended posology is expected. Thrombotic events have been reported following treatment with Ondexxya and a pro-thrombotic effect cannot be ruled out.

The full indication is:

> "For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding."

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.

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