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Press Office

Press release

EMA fast-tracks antidote to anticoagulant Pradaxa

Praxbind to reverse anticoagulant effect of Pradaxa in life-threatening or emergency situations

The European Medicines Agency (EMA) has recommended granting a marketing authorisation, following accelerated assessment, for Praxbind (idarucizumab) as a specific antidote to the anticoagulant medicine Pradaxa (dabigatran etexilate), when rapid reversal of its effect is required. Praxbind is to be used when a patient taking Pradaxa needs to undergo an emergency surgery or when life-threatening or uncontrolled bleeding occurs.

Pradaxa belongs to a new generation of oral anticoagulants (medicines that prevent the blood from clotting) approved over the past few years, which have given doctors and patients a wider range of options to prevent and treat thromboembolic disorders in adults. Praxbind is the first medicine designed to specifically neutralise the anticoagulant effect of Pradaxa.

Bleeding is a well-known complication of all anticoagulants, and information on how to address this risk has been included in Pradaxa's product information since it was first authorised in the European Union (EU) in March 2008. Although low in frequency in patients treated with Pradaxa, major and sometimes life-threatening bleeding may occur. However, unlike older oral anticoagulants such as warfarin, up until now there has been no specific means of rapidly neutralising Pradaxa’s effect. Praxbind could help patients in some emergency cases where a quick reversal of the anticoagulant effect of Pradaxa is needed.

The Committee for Medicinal Products for Human Use (CHMP) decided to speed up the evaluation of this medicine and recommended granting a marketing authorisation following an accelerated assessment, given its potential to respond to an unmet medical need.

In clinical studies carried out in 283 healthy volunteers and 123 patients who had uncontrolled bleeding or required emergency surgery or procedures, Praxbind enabled complete reversal of Pradaxa's anticoagulant effect within 5 minutes of administration with a long-lasting action allowing emergency management of patients as needed, and an overall good safety profile.

The applicant received scientific advice on quality, non-clinical and clinical aspects of Praxbind's application from the CHMP. This is one of the Agency’s main tools to facilitate and stimulate research and development within the EU.

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The opinion adopted by the CHMP at its September 2015 meeting is an intermediary step on Praxbind's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, each Member State will take a decision on price and reimbursement based on the potential role/use of this medicine in the context of its national health system.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The marketing-authorisation applicant for Praxbind is Boehringer Ingelheim International GmbH.
3. Pradaxa is authorised in the European Union:
   - to prevent the formation of blood clots in the veins in adults who have had an operation to replace a hip or knee;
   - to prevent stroke and the formation of clots in adults who have an abnormal heart beat called 'non-valvular atrial fibrillation' and are considered to be at risk of stroke;
   - to treat deep vein thrombosis (a blood clot in a deep vein, usually in the leg) and pulmonary embolism (a clot in a blood vessel supplying the lungs), and to prevent these conditions from reoccurring in adults.
4. More information on Pradaxa is available here.
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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