EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 February 2017
EMA/CHMP/103918/2017
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Roteas

edoxaban

On 23 February 2017, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Roteas, intended for prevention of stroke and systemic embolism in adults with atrial fibrillation, and for treatment and prevention of deep vein thrombosis and pulmonary embolism. The applicant for this medicinal product is Daiichi Sankyo Europe GmbH.

Roteas will be available as film-coated tablets (15, 30 and 60 mg). The active substance of Roteas is edoxaban, an antithrombotic agent (ATC code: B01AF03). Roteas is a highly selective, direct and reversible inhibitor of factor Xa. Inhibition of factor Xa in the coagulation cascade reduces thrombin generation, prolongs clotting time and reduces the risk of thrombus formation.

The benefits with Roteas are its ability to:

- reduce the combined risk of stroke and systemic embolic events in patients with nonvalvular atrial fibrillation who are at risk of stroke and systemic embolic events;
- treat and reduce the risk of recurrence of symptomatic venous thromboembolism in patients who had acute symptomatic deep vein thrombosis and/or pulmonary embolism.

The most common side effects are cutaneous soft tissue haemorrhage (up to 5.9%), epistaxis (up to 4.7%) and vaginal haemorrhage. Bleeding can occur at any site and may be severe and even fatal. Other common adverse reactions for edoxaban are anaemia, rash and abnormal liver function tests.

The application for Roteas was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Roteas is Lixiana.

The full indication is:

> "Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation (NVAF) with one or more risk factors, such as congestive heart failure, hypertension, age ≥ 75

[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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years, diabetes mellitus, prior stroke or transient ischaemic attack (TIA).

Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults (see section 4.4 for haemodynamically unstable PE 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.