20 November 2014
EMA/CHMP/666694/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zontivity

vorapaxar

On 20 November 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zontivity, 2 mg, film-coated tablet, intended for the reduction of atherothrombotic events in adult patients with a history of myocardial infarction (MI). Zontivity should be co-administered with acetylsalicylic acid (ASA) and, where appropriate with clopidogrel.

The applicant for this medicinal product is Merck Sharp & Dohme Limited. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Zontivity is vorapaxar a selective and reversible inhibitor of the Protease Activated Receptor-1 present on platelets that are activated by thrombin.

The benefits with Zontivity are its ability to inhibit thrombin-induced platelet aggregation in vitro and inhibit thrombin receptor agonist peptide (TRAP)-induced platelet aggregation without affecting coagulation parameters.

Vorapaxar does not inhibit platelet aggregation induced by other agonists such as adenosine diphosphate (ADP), collagen or a thromboxane mimetic.

The most common side effects are related to bleedings (haematoma, epistaxis, increased tendency to bruise, haematuria and contusion).

A pharmacovigilance plan for Zontivity will be implemented as part of the marketing authorisation.

The approved indication is:
"Zontivity, co-administered with acetylsalicylic acid (ASA) and, where appropriate, clopidogrel, is indicated for the reduction of atherothrombotic events in adult patients with a history of myocardial infarction (MI)."

[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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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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Zontiviy and therefore recommends the granting of the marketing authorisation.