EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 February 2011
EMA/CHMP/124404/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Rasilamlo

aliskiren / amlodipine

On 17 February 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Rasilamlo, 150 mg/10 mg, 150 mg/5 mg, 300 mg/10 mg, 300 mg/5 mg, film-coated tablet intended for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone. The applicant for this medicinal product is Novartis Europharm Ltd. 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 substances of Rasilamlo (ATC code: C09XA53) are aliskiren, a renin-inhibitor, and amlodipine, a calcium antagonist. Aliskiren inhibits human renin, the enzyme responsible for the conversion of angiotensinogen to angiotensin I. Therefore the final production of the potent vasoconstrictor angiotensin II is inhibited by blocking the renin system at its very origin. Amlodipine inhibits the transmembrane entry of calcium ions into cardiac and vascular smooth muscle causing its relaxation and thus, vasodilation.

The benefits with Rasilamlo are its ability to effectively lower the blood pressure achieved by a combination of two antihypertensive agents acting on different pathways. The most common side effects are hypotension and peripheral oedema.

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

The approved indication is: "Rasilamlo is indicated for the treatment of essential hypertension in adult patients whose blood pressure is not adequately controlled with aliskiren or amlodipine used alone."

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