EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2013
EMA/CHMP/160010/2013
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Stayveer

Bosentan Monohydrate

On 21 March 2013 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Stayveer 62.5 and 125 mg film-coated tablets intended for the treatment of pulmonary arterial hypertension and digital ulcer disease. The applicant for this medicinal product is Marklas Nederland BV. 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 Stayveer is Bosentan, an anti-hypertensive drug (C02KX01) and endothelin receptor (ETa and ETb) antagonist, which decreases pulmonary vascular resistance. It works by causing expansion of the blood vessels in the lungs, thereby reducing blood pressure and reducing the symptoms of PAH.

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

The approved indication is: “pulmonary arterial hypertension (PAH) to improve exercise capacity and symptoms in patients with WHO functional class III. Efficacy has been shown in primary (idiopathic and familial) PAH, PAH secondary to scleroderma without significant interstitial pulmonary disease and PAH associated with congenital systemic-to-pulmonary shunts and Eisenmenger’s physiology. Some improvements have also been shown in patients with PAH WHO functional class II. Stayveer is also indicated to reduce the number of new digital ulcers in patients with systemic sclerosis and on-going digital ulcer disease.” It is proposed that Stayveer is prescribed by physicians experienced in the treatment of pulmonary arterial hypertension.

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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

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