19 January 2012
EMA/34679/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Signifor

pasireotide

On 19 January 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Signifor, 0.3 mg, 0.6 mg, 0.9 mg, solution for injection, intended for the treatment of Cushing's disease. Signifor was designated as an orphan medicinal product on 08 October 2009. 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 substance of Signifor is pasireotide (as diaspartate), a novel somatostatin analogue (H01CB05), exerting its pharmacological activity through binding to somatostatin receptors.

The benefits with Signifor are due to its different binding pattern to the somatostatin receptors compared to the currently available somatostatin analogues, and its ability to reduce Urinary free cortisol (UFC) and even normalise UFC in a relevant proportion of patients suffering from Cushing's disease. Effects have also been observed on other biological parameters considered as markers of the disease and its evolution, and it seems effective in improving signs and symptoms and Quality of Life in some patients.

The most common side effects are hyperglycaemia including the development of diabetes mellitus, diarrhoea, nausea, abdominal pain, cholelithiasis, injection site reactions, fatigue, QT prolongation as well as hepatobiliary disorders that should be monitored appropriately.

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

The approved indication is: "Signifor is indicated for the treatment of adult patients with Cushing's disease for whom surgery is not an option or for whom surgery has failed."

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

[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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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 Signifor and therefore recommends the granting of the marketing authorisation.