EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2020
EMA/373250/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Adakveo

crizanlizumab

On 23 July 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional marketing authorisation for the medicinal product Adakveo[2], intended for the prevention of recurrent vaso-occlusive crises (VOCs) in patients with sickle cell disease. The applicant for this medicinal product is Novartis Europharm Limited.

Adakveo will be available as 10 mg/ml concentrate for solution for infusion. The active substance of Adakveo is crizanlizumab, a monoclonal antibody that binds to P-selectin with high affinity and blocks the interaction with its ligands (ATC code: B06AX01). Binding to P-selectin on activated endothelium and platelets has been shown to block interactions between endothelial cells, platelets, red blood cells and leucocytes, thereby preventing vaso-occlusion.

The benefits of Adakveo are its ability to reduce the number of VOCs and the number of days in hospital related to VOCs per year. Additionally, three times as many patients on crizanlizumab compared with placebo remained completely free of VOCs over the 1-year study period. The most common side effects are oropharyngeal pain, nausea, abdominal pain, diarrhoea, vomiting, pruritus, arthralgia, back pain, myalgia, musculoskeletal chest pain, pyrexia, and reactions at the infusion site or related to the infusion.

The full indication is:

> Adakveo is indicated for the prevention of recurrent vaso occlusive crises (VOCs) in sickle cell disease patients aged 16 years and older. It can be given as an add on therapy to hydroxyurea/hydroxycarbamide (HU/HC) or as monotherapy in patients for whom HU/HC is inappropriate or inadequate.

Adakveo should be prescribed by physicians experienced in the management of sickle cell disease.

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

[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
[2] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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