25 May 2023
EMA/CHMP/221367/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Sogroya

somapacitan

On 25 May 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Sogroya. The marketing authorisation holder for this medicinal product is Novo Nordisk A/S.

The CHMP recommended the addition of a new strength of 15 mg/1.5 mL solution for injection in pre-filled pen.

The CHMP adopted an extension to an existing indication as follows:[2]

> Sogroya is indicated for the replacement of endogenous growth hormone (GH) in children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD).

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR) and will be available in all official European Union languages after a decision on this change to 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
[2] New text in bold

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