28 January 2021
EMA/CHMP/593869/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Sogroya

somapacitan

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Sogroya[2], intended for the treatment of growth hormone deficiency in adults. The applicant for this medicinal product is Novo Nordisk A/S.

Sogroya will be available as 10 mg/1.5 ml solution for injection. The active substance of Sogroya is somapacitan, a somatropin agonist (ATC code: H01AC07) that acts directly via the growth hormone-receptor and/or indirectly via insulin-like growth factor-I produced in tissues.

The benefits with Sogroya in adults deficient in growth hormone are its ability to normalise body composition (i.e. decreased body fat mass, increased lean body mass) and metabolism. The most common side effects are headache, peripheral oedema and adrenocortical insufficiency.

The full indication is:

> Sogroya is indicated for the replacement of endogenous growth hormone (GH) in adults with growth hormone deficiency (AGHD).

Sogroya should be prescribed by physicians experienced in the diagnosis and treatment of adult patients with growth hormone deficiency (e.g. endocrinologists).

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 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] 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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