16 December 2021
EMA/CHMP/694182/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Xevudy

sotrovimab

On 16 December 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 Xevudy, intended for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with coronavirus disease 2019 (COVID-19) who do not require oxygen supplementation and who are at increased risk of progressing to severe COVID-19 (see section 5.1). The applicant for this medicinal product is GlaxoSmithKline Trading Services Limited.

Detailed recommendations for the use of this product are described in the product information (PI), which is published in English here.

The European public assessment report (EPAR) will be published after the marketing authorisation has been granted by the European Commission and will make this information available in all official European Union languages.

[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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