EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 November 2021
EMA/CHMP/629422/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Regkirona

regdanvimab

On 11 November 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 Regkirona, intended for the treatment of adults with coronavirus disease 2019 (COVID 19) who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19. The applicant for this medicinal product is Celltrion Healthcare Hungary Kft.

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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