25 June 2020
EMA/CHMP/311506/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Veklury

remdesivir

On 25 June 2020, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a conditional[2] marketing authorisation for the medicinal product Veklury, intended for the treatment of (SARS-CoV-2), a novel coronavirus causing a respiratory illness designated as coronavirus disease 2019, or COVID-19. The applicant for this medicinal product is Gilead Sciences Ireland UC.

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

[2] A conditional marketing authorisation is granted to a medicinal product that fulfils an unmet medical need when the benefit to public health of immediate availability outweighs the risk inherent in the fact that additional data are still required. The marketing authorisation holder is likely to provide comprehensive clinical data at a later stage.

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