15 September 2022
EMA/CHMP/722554/2022
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Veklury

remdesivir

On 15 September 2022, 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 Veklury. The marketing authorisation holder for this medicinal product is Gilead Sciences Ireland UC.

The CHMP adopted an extension to the existing indication for Veklury to include the treatment of paediatric patients from the age of 4 weeks.

For information, the full indication for Veklury will be as follows:[2]

Veklury is indicated for the treatment of coronavirus disease 2019 (COVID-19) in:

- Adults and **paediatric patients** ~~adolescents(aged 12 to less than 18 years~~ **at least 4 weeks of age** and weighing at least **3** kg) with pneumonia requiring supplemental oxygen (low- or high flow oxygen or other non-invasive ventilation at start of treatment)
- Adults **and paediatric patients (weighing at least 40kg)** who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19

(see section 5.1)

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, removed text as strikethrough

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