22 February 2018
EMA/CHMP/97060/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Alpivab

peramivir

On 22 February 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Alpivab, intended for the treatment of uncomplicated influenza. The applicant for this medicinal product is Biocryst UK Limited.

Alpivab will be available as concentrate for solution for infusion (200 mg). The active substance of Alpivab is peramivir, an inhibitor of influenza virus neuraminidase (ATC code: J05AH), an enzyme important for viral entry into uninfected cells and release and spread of new virus once cells have been infected.

The benefits with Alpivab are its ability to speed alleviation of symptoms and recovery of normal temperature in patients with uncomplicated influenza. The most common side effects are gastro-intestinal disorders, such as diarrhoea and vomiting.

The full indication is:

“Alpivab is indicated for the treatment of uncomplicated influenza in adults and children from the age of 2 years (see sections 4.4 and 5.1).”

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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact