22 November 2016
EMA/CHMP/714398/2016
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zinplava

bezlotoxumab

On 22 November 2016, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion via written procedure, recommending the granting of a marketing authorisation for the medicinal product Zinplava, intended for the prevention of recurrence of *Clostridium difficile* infection (CDI). The applicant for this medicinal product is Merck Sharp & Dohme Limited.

Zinplava will be available as a 25 mg/ml concentrate for solution for infusion. The active substance of Zinplava is bezlotoxumab, a human monoclonal antitoxin antibody that binds with high affinity to *C. difficile* toxin B and neutralizes its activity (ATC code: J06BB21).

The benefits with Zinplava are its ability to prevent the recurrence of *C. difficile* infection diarrhoea episodes in the 12 weeks after treatment. The most common side effects following infusion are nausea, pyrexia and headache.

The full indication is:

"Zinplava is indicated for the prevention of recurrence of *Clostridium difficile* infection (CDI) in adults at high risk for recurrence of CDI (see sections 4.2, 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