25 January 2024
EMA/CHMP/31327/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Ryzneuta

efbemalenograstim alfa

On 25 January 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Ryzneuta, intended to reduce the duration of neutropenia and the incidence of febrile neutropenia due to chemotherapy. The applicant for this medicinal product is Evive Biotechnology Ireland Limited.

Ryzneuta will be available as a 20 mg solution for injection. The active substance of Ryzneuta is efbemalenograstim alfa, an immunostimulant/colony stimulating factor (ATC code: L03AA18) that belongs to the class of haematopoietic growth factors (granulocyte-colony stimulating factor; G-CSF) which increase the production and differentiation of mature and functionally active neutrophils from bone marrow precursor cells.

The benefit of Ryzneuta is the reduction in the duration of severe neutropenia during the first cycle of chemotherapy compared to placebo and, to a similar extent, pegfilgrastim (a pegylated G-CSF). The most common side effects concern musculoskeletal pain, such as bone and back pain, arthralgia and pain in extremities.

The full indication is:

> Ryzneuta is indicated for the reduction in the duration of neutropenia and the incidence of febrile neutropenia in adult patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes).

Ryzneuta should be initiated and supervised by physicians experienced in oncology and/or haematology.

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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union