28 June 2018
EMA/CHMP/239619/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Vyxeos

daunorubicin / cytarabine

On 28 June 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 Vyxeos, intended for the treatment of acute myeloid leukaemia (AML). Vyxeos was designated as an orphan medicinal product on 11 January 2012. The applicant for this medicinal product is Jazz Pharmaceuticals Ireland Limited.

Vyxeos is a liposomal formulation of a fixed combination of daunorubicin and cytarabine, antineoplastic agents that inhibit topoisomerase II activity and also cause DNA damage (ATC code: L01XY01). The product will be available as a powder for concentrate for solution for infusion. After reconstitution the solution will contain 2.2 mg/ml of daunorubicin and 5 mg/ml of cytarabine.

The benefits with Vyxeos are its ability to increase survival compared with a standard combination of cytarabine and daunorubicin in patients with high-risk AML. The most common side effects are hypersensitivity including rash, febrile neutropenia, oedema, diarrhoea/colitis, mucositis, fatigue, musculoskeletal pain, abdominal pain, decreased appetite, cough, headache, chills, arrhythmia, pyrexia, sleep disorders and hypotension.

The full indication is: “Vyxeos is indicated for the treatment of adults with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).”

It is proposed that Vyxeos treatment should be initiated and monitored under the supervision of a physician experienced in the use of chemotherapeutic medicinal products.

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