EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/CHMP/595680/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Azacitidine Accord

azacitidine

On 12 December 2019, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Azacitidine Accord, intended for the treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia. The applicant for this medicinal product is Accord Healthcare S.L.U.

Azacitidine Accord will be available as a 25 mg/ml powder for suspension for injection. The active substance of Azacitidine Accord is azacitidine, a pyrimidine analogue (ATC code: L01BC07) which exerts its antineoplastic effects by multiple mechanisms, including cytotoxicity on cells in the bone marrow and hypomethylation of DNA.

Azacitidine Accord is a generic of Vidaza, which has been authorised in the EU since 17 December 2008. Studies have demonstrated the satisfactory quality of Azacitidine Accord. Since Azacitidine Accord is administered intravenously and is 100% bioavailable, a bioequivalence study versus the reference product Vidaza was not required. A question and answer document on generic medicines can be found here.

The full indication is:

"Azacitidine Accord is indicated for the treatment of adult patients who are not eligible for haematopoietic stem cell transplantation (HSCT) with:

- Intermediate 2 and high-risk myelodysplastic syndromes (MDS) according to the International Prognostic Scoring System (IPSS),
- chronic myelomonocytic leukaemia (CMML) with 10 29 % marrow blasts without myeloproliferative disorder,
- acute myeloid leukaemia (AML) with 20 30 % blasts and multi-lineage dysplasia, according to World Health Organisation (WHO) classification,
- AML with >30% marrow blasts according to the WHO classification."

It is proposed that Azacitidine Accord be prescribed by physicians experienced in the use of

[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

chemotherapeutic agents.

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.