30 January 2020
EMA/CHMP/36892/2020 Corr.[1]
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[2] (initial authorisation)

Azacitidine Mylan

azacitidine

On 30 January 2020, 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 Mylan, intended for the treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukaemia. The applicant for this medicinal product is Mylan Ireland Limited.

Azacitidine Mylan will be available as a powder for suspension for injection (25 mg/ml). The active substance of Azacitidine Mylan 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 Mylan is a generic of Vidaza, which has been authorised in the EU since 17 December 2008. Studies have demonstrated the satisfactory quality of Azacitidine Mylan. A question and answer document on generic medicines can be found here.

The full indication is:

'Azacitidine Mylan 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% to 29% marrow blasts without myeloproliferative disorder,
- acute myeloid leukaemia (AML) with 20% to 30% blasts and multi-lineage dysplasia, according to World Health Organization (WHO) classification,
- AML with > 30% marrow blasts according to the WHO classification.'

It is proposed that Azacitidine Mylan be prescribed by physicians experienced in the use of chemotherapeutic agents.

Detailed recommendations for the use of this product will be described in the summary of product

[1] 04 February 2020
[2] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion

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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.