EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 June 2019
EMA/CHMP/332005/2019
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Azacitidine Celgene

azacitidine

On 27 June 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 Celgene, intended for the treatment of myelodysplastic syndromes, chronic myelomonocytic leukaemia and acute myeloid leukemia. The applicant for this medicinal product is Celgene Europe BV.

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

The benefits with Azacitidine Celgene are its effect on overall survival. The most common side effects are haematological reactions including thrombocytopenia, neutropenia and leukopenia, gastrointestinal events including nausea, vomiting or injection site reactions.

The application for Azacitidine Celgene was an informed consent application. In an informed consent application, reference is made to an authorised medicine where the marketing authorisation holder of the reference medicine has given consent to the use of their dossier in the application procedure. The reference product for Azacitidine Celgene is Vidaza.

The full indication is:

> "Azacitidine Celgene 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,

[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

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- AML with >30% marrow blasts according to the WHO classification."

It is proposed that Azacitidine Celgene 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 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.