22 April 2021
EMA/CHMP/211128/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Onureg

azacitidine

On 22 April 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Onureg, intended for the maintenance treatment of patients with acute myeloid leukemia.

The applicant for this medicinal product is Bristol-Myers Squibb Pharma EEIG.

Onureg will be available as 200 mg and 300 mg film-coated tablets. The active substance of Onureg is azacitidine, an antineoplastic agent (ATC code: L01BC07). Azacitidine is similar to cytidine, a building block of the genetic material (DNA and RNA) of cells. It exerts its antineoplastic effects by multiple mechanisms, including cytotoxicity on cells in the bone marrow and hypomethylation of DNA.

The benefit of Onureg is its ability to improve the overall survival. The most common side effects are nausea, vomiting, diarrhoea and haematological sides effects (neutropenia and thrombocytopenia).

The full indication is:

> 'Onureg is indicated as maintenance therapy in adult patients with acute myeloid leukaemia (AML) who achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy with or without consolidation treatment and who are not candidates for, including those who choose not to proceed to, hematopoietic stem cell transplantation (HSCT).'

Onureg should be prescribed by physicians 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

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