25 March 2021
EMA/CHMP/84697/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Copiktra

duvelisib

On 25 March 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 Copiktra, intended for the treatment of adult patients with relapsed or refractory chronic lymphocytic leukaemia (CLL) and refractory follicular lymphoma (FL). The applicant for this medicinal product is Verastem Europe GmbH.

Copiktra will be available as 15-mg and 25-mg hard capsules. The active substance of Copiktra is duvelisib, an anti-neoplastic agent (ATC code: L01EM04) which acts by inhibiting phosphatidylinositol 3-kinase p110δ (PI3K-δ) and PI3K-γ. These enzymes are involved in the proliferation and survival of malignant B-cell lines and primary CLL tumour cells, and in immunological pathways in the tumour microenvironment of malignant B cells.

The benefits of Copiktra are that it prolongs the survival time without any progression of the disease as compared to ofatumumab in patients with CLL who have received 2 or more prior lines of treatment and induces tumour responses in patients with FL who have received 2 or more prior treatments. The most common side effects are respiratory tract infections, neutropenia, anaemia, thrombocytopenia, headache, dyspnoea, cough, decreased appetite diarrhoea/colitis, nausea, vomiting, abdominal pain, constipation, rash, musculoskeletal pain, arthralgia, pyrexia, fatigue and increased transaminases.

The full indication is the treatment of adult patents with:

- Relapsed or refractory chronic lymphocytic leukaemia (CLL) after at least two prior therapies. (see SmPC section 4.4.and 5.1).
- Follicular lymphoma (FL) that is refractory to at least two prior systemic therapies (see SmPC section 4.4.and 5.1).

Copiktra should be prescribed by physicians experienced in the treatment of cancer.

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

[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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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.