23 July 2020
EMA/CHMP/374568/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Calquence

acalabrutinib

On 23 July 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 Calquence,[2] intended for the treatment of chronic lymphocytic leukaemia (CLL). The applicant for this medicinal product is AstraZeneca AB.

Calquence will be available as 100 mg hard capsules. The active substance of Calquence is acalabrutinib, a protein kinase inhibitor (ATC code: L01XE51) which acts by inhibiting the Bruton tyrosine kinase (BTK), thus preventing signalling for B-cell survival and proliferation and resulting in blocking cellular adhesion, trafficking, and chemotaxis.

The benefits with Calquence are its ability to prolong progression-free survival when used on its own or in combination with obinutuzumab. The most common side effects are respiratory tract infections, headache bruising, contusion, diarrhoea, nausea, rash, musculoskeletal pain, fatigue, decreased haemoglobin and decreased platelets.

The full indication is:

> Calquence as monotherapy or in combination with obinutuzumab is indicated for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).
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> Calquence as monotherapy is indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy.

It is proposed that Calquence be prescribed by physicians experienced in the use of anticancer 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
[2] This product was designated as orphan medicine during its development. EMA will now review the information available to date to determine if the orphan designation can be maintained

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