24 July 2014
EMA/CHMP/338526/2014
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Zydelig

idelalisib

On 24 July 2014, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Zydelig, 100 mg and 150 mg, film-coated tablet indicated, in combination, for the treatment of patients with chronic lymphocytic leukaemia (CLL) and for the treatment of patients with refractory follicular lymphoma (FL).

The applicant for this medicinal product is Gilead Sciences International Ltd. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Zydelig is idelalisib, an antineoplastic agent (ATC Code: L01XX47) which inhibits phosphatidylinositol 3 kinase p110δ (PI3Kδ), which is hyperactive in B cell malignancies and is central to multiple signalling pathways that drive proliferation, survival, homing, and retention of malignant cells in lymphoid tissues and bone marrow.

The benefits in CLL of Zydelig in combination with rituximab are in terms of improved progression free survival (PFS) as shown in a randomised controlled trial against placebo in combination with rituximab. The benefits in FL of Zydelig in monotherapy are in terms of overall response rate and duration of response as shown in a single-arm study. The most common side effects are infections, neutropenia, increased transaminase, increased triglycerides, diarrhoea/colitis, rash and pyrexia.

A pharmacovigilance plan for Zydelig will be implemented as part of the marketing authorisation.

The approved indication is: " Zydelig is indicated in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukaemia (CLL):

- who have received at least one prior therapy, or
- as first line treatment in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.

[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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7<sector fax>
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Zydelig is indicated as monotherapy for the treatment of adult patients with follicular lymphoma (FL) that is refractory to two prior lines of treatment."

It is proposed that treatment with Zydelig should be conducted by a physician experienced in the use of anticancer therapies.

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.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Zydelig and therefore recommends the granting of the marketing authorisation.