EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 July 2018
EMA/CHMP/420258/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Verzenios

abemaciclib

On 26 July 2018, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Verzenios, intended for the treatment of locally advanced or metastatic breast cancer. The applicant for this medicinal product is Eli Lilly Nederland B.V.

Verzenios will be available as film-coated tablets (50 mg, 100 mg and 150 mg). The active substance of Verzenios is abemaciclib, a protein kinases inhibitor (ATC code: L01XE50) that potently and selectively inhibits cyclin-dependent kinases 4 and 6 (CDK4 and CDK6), leading to suppression of tumour growth.

The benefit with Verzenios is its ability to significantly improve progression-free survival in combination with an aromatase inhibitor or fulvestrant. The most common side effects are diarrhoea, infections, neutropenia, anaemia, fatigue, nausea, vomiting and decreased appetite.

The full indication is:

> "Verzenios is indicated for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.
>
> In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist."

It is proposed that Verzenios be prescribed by physicians 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.

[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

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5520
Send a question via our website www.ema.europa.eu/contact