25 April 2024
EMA/151857/2024
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Truqap

capivasertib

On 25 April 2024, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Truqap, intended for the treatment of locally advanced or metastatic breast cancer with one or more *PIK3CA/AKT1/PTEN* alterations.

The applicant for this medicinal product is AstraZeneca AB.

Truqap will be available as 160 and 200 mg film-coated tablets. The active substance of Truqap is capivasertib, an antineoplastic agent and other protein kinase inhibitor (ATC code: L01EX27). The serine/threonine kinase AKT is a pivotal node in the phosphatidylinositol 3-kinase (PI3K) signaling cascade regulating multiple cellular processes including cellular survival, proliferation, cell cycle, metabolism, gene transcription and cell migration. Capivasertib selectively inhibits all isoforms of AKT (AKT1, AKT2 and AKT3) hampering downstream proliferation signalling and thereby reducing the growth of tumour cells.

The benefit of Truqap in combination with fulvestrant is an improved progression-free survival (PFS) in patients with ER-positive, HER2-negative advanced breast cancer with one or more PIK3CA/AKT1/PTEN alterations following recurrence or progression on or after an endocrine-based therapy, when compared to fulvestrant and placebo. The most common side effects of Truqap are diarrhoea, rash, nausea, fatigue, vomiting, stomatitis, hyperglycaemia, headache and decreased appetite.

The full indication is:

> TRUQAP is indicated in combination with fulvestrant for the treatment of adult patients with oestrogen receptor (ER)-positive, HER2-negative locally advanced or metastatic breast cancer with one or more *PIK3CA/AKT1/PTEN*-alterations following recurrence or progression on or after an endocrine-based regimen (see section 5.1).

[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

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In pre- or perimenopausal women, TRUQAP plus fulvestrant should be combined with a luteinising hormone releasing hormone (LHRH) agonist.

For men, administration of LHRH agonist according to current clinical practice standards should be considered.

Truqap should be prescribed and supervised by physicians experienced in the use of cancer treatments.

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.