



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 December 2020
EMA/CHMP/646289/2020
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

Tukysa

tucatinib

On 10 December 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 Tukysa, intended for the treatment of HER2-positive locally advanced or metastatic breast cancer. The applicant for this medicinal product is Seagen B.V.

Tukysa will be available as 50 and 150 mg film-coated tablets. The active substance of Tukysa is tucatinib, an antineoplastic protein kinase inhibitor (ATC code: L01EH03) which inhibits HER2 kinase. This leads to inhibition of downstream cell signalling and cell proliferation and induces death in HER2-driven tumour cells.

The benefits with Tukysa are its ability to increase progression free survival and overall survival including in patients with metastases. The most common side effects are diarrhoea and increased liver enzymes (ALT and AST).

The full indication is:

TUKYSA is indicated in combination with trastuzumab and capecitabine for the treatment of adult patients with HER2-positive locally advanced or metastatic breast cancer who have received at least 2 prior anti-HER2 treatment regimens.

Tukysa should be prescribed by physicians experienced in the administration of anti-cancer 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

