28 June 2018
EMA/CHMP/433871/2018
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Nerlynx

neratinib

On 28 June 2018, the Committee for Medicinal Products for Human Use (CHMP), following a re-examination procedure, adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Nerlynx, intended for the adjuvant treatment of adult patients with breast cancer. The applicant for this medicinal product is Puma Biotechnology Limited.

Nerlynx will be available as 40-mg film-coated tablets. The active substance of Nerlynx is neratinib, an irreversible pan-erythroblastic leukaemia viral oncogene homolog (ERBB) tyrosine kinase inhibitor (ATC code: L01XE45). It blocks mitogenic growth factor signal transduction through covalent, high-affinity binding to the ATP binding site of 3 epidermal growth factor receptors (EGFRs) resulting in sustained inhibition of these growth promoting pathways in breast cancers with HER2-amplified or over-expressed, or which are HER2-mutant.

The benefits with Nerlynx are its ability to reduce the risk of invasive disease recurrence after two years compared with placebo. The most common side effects are diarrhoea, nausea, fatigue, vomiting, abdominal pain, rash, decreased appetite, upper abdominal pain, stomatitis and muscle spasms.

The full indication is: "Nerlynx is indicated for the extended adjuvant treatment of adult patients with early-stage hormone receptor positive HER2-overexpressed/amplified breast cancer and who are less than one year from the completion of prior adjuvant trastuzumab based therapy". It is proposed that Nerlynx be prescribed by physicians experienced in the treatment of cancer.

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