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Europe approves Astrazeneca's lung cancer drug

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Singapore: European Medicines Agency (EMA) has recommended granting a conditional marketing authorisation for AstraZeneca's Tagrisso (osimertinib) for the treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with a specific mutation (T790M) of the epidermal growth factor receptor (EGFR).

Tagrisso is a tablet that should be taken orally once per day. It is intended for patients who have developed a mutation in the EGFR gene. Mutations of the EGFR gene may develop in tumours and reduce the effect of EGFR-blocking medicines. Tagrisso is intended for use in tumours with one such mutation, T790M.

The Committee for Medicinal Products for Human Use (CHMP) reviewed Tagrisso under EMA's accelerated assessment program and recommended conditional approval for the medicine. These are two of the Agency's main mechanisms to facilitate earlier access by patients to medicines that fulfill unmet medical needs.

The safety and efficacy of Tagrisso were demonstrated in two single-arm phase II trials involving a total of 411 patients with advanced EGFR T790M mutation-positive NSCLC whose disease progressed after treatment with EGFR-blocking therapies.

The most common reported side effects of Tagrisso are diarrhoea and skin and nail conditions such as dry skin, rash and acne.