



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 December 2015
EMA/CHMP/848525/2015
Press Office

Press release

EMA fast-tracks new oral treatment for non-small cell lung cancer

Tagrisso recommended for conditional approval

The European Medicines Agency (EMA) has recommended granting a conditional marketing authorisation for 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).

Lung cancer is among the most common cancers in the world. In Europe, in 2012, 313,000 patients were newly diagnosed and 268,000 people died from the disease, accounting for one in five cancer deaths. Approximately 80-90% of all lung cancers are NSCLCs, which occur when cancer cells form in the tissues of the lung. EGFR is a protein involved in the growth and spread of cancer cells.

Despite progress in early detection and treatment, NSCLC is most often diagnosed at an advanced stage and the outlook for patients with the disease is poor. Once NSCLC has progressed to a locally advanced or metastatic stage, treatment is focused on extending life, delaying disease progression and improving symptoms and quality of life.

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. Conditional approval allows EMA to recommend a medicine for marketing authorisation before the availability of confirmatory clinical trial data, if the benefits of making this medicine available to patients immediately outweigh any risks related to the lack of comprehensive data.

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.



Results from these two trials showed that a high proportion of patients (around 66%) responded and their tumour shrunk. This response appeared to be long-lasting. The benefits in terms of progression free survival and/or overall survival have not yet been determined.

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

As part of the conditional marketing authorisation, the applicant for Tagrisso must provide results from an ongoing phase III study. Until availability of full data, the CHMP will review the benefits and risks of Tagrisso annually to determine whether the conditional marketing authorisation can be maintained.

The opinion adopted by the CHMP at its December 2015 meeting is an intermediary step on Tagrisso's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, each Member State will take a decision on price and reimbursement based on the potential role/use of this medicine in the context of its national health system.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Tagrisso is AstraZeneca AB.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Monika Benstetter

Tel. +44 (0)20 3660 8427

E-mail: press@ema.europa.eu

Follow us on Twitter [@EMA_News](https://twitter.com/EMA_News)