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CHMP recommends marketing authorization for AZ's Osimertinib

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AstraZeneca announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion, recommending the marketing authorisation of osimertinib 80mg once-daily tablets for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) T790M mutation-positive non-small cell lung cancer (NSCLC).

This indication includes NSCLC patients whose disease has progressed on or after treatment with an EGFR tyrosine kinase inhibitor (TKI) and patients with a T790M mutation who have not been treated with an EGFR-TKI.

Dr Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The CHMP's recommendation for osimertinib to receive marketing approval is a positive step for patients in Europe. This follows the recent US accelerated approval of osimertinib and its adoption in the UK under the

"Early Access to Medicines Scheme to meet urgent unmet need. Building on the breakthrough clinical evidence, we're investigating osimertinib's full potential as a monotherapy and in novel combinations with other precision medicines and immunotherapies from our comprehensive oncology pipeline."

AURA study clinical investigator Professor Jean-Charles Soria, Head of Drug Development Department, Gustave Roussy Cancer Center, Paris, France, added; "In Europe, lung cancer kills over 260,000 people every year, so there is an urgent need for new treatments. As a treating physician, it is very gratifying to see the progression of osimertinib towards use in clinical practice for patients living with EGFRm T790M non-small cell lung cancer."

Osimertinib is an EGFR-TKI designed to inhibit both the activating, sensitising mutation (EGFRm), and T790M, a genetic mutation responsible for EGFR-TKI treatment resistance.

Nearly two-thirds of patients with EGFRm NSCLC whose disease progresses after EGFR-TKI treatment develop the T790M resistance mutation, for which treatment options are limited.

The CHMP recommendation for osimertinib is based on data from two Phase II studies (AURA extension and AURA2) and the AURA Phase I expansion study, which demonstrated efficacy in 474 EGFRm T790M NSCLC patients who had progressed on or after an EGFR-TKI.

In the combined Phase II studies, the objective response rate (ORR, a measurement of tumor shrinkage) was 66%, and in the Phase I study it was 62%.

Progression-free survival (PFS) was 9.7 months in the combined Phase II studies and 11 months in the Phase I trial. Median duration of response (DOR) in the Phase I study was 9.7 months and in the combined Phase II studies, median duration of response was not reached.

The most common adverse events based on data from the two AURA Phase II studies were generally mild to moderate and included diarrhoea (42% all grades; 1.0% Grade 3/4), rash (41% all grades; 0.5% Grade 3/4), dry skin (31% all grades; 0% Grade 3/4), and nail toxicity (25% all grades; 0% Grade 3/4).

Warnings and precautions include interstitial lung disease, QT interval prolongation and embryofoetal toxicity.

The positive CHMP recommendation has been received through the EMA's Accelerated Assessment and follows the recent US Accelerated Approval of osimertinib by the Food and Drug Administration (FDA).

In Japan, osimertinib was granted Priority Review by the Pharmaceuticals and Medical Devices Agency (PMDA). Interactions with regulatory authorities in the rest of the world are ongoing.