Tagrisso Receives Full FDA Approval for Treatment of T790M-positive NSCLC

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AstraZeneca has announced that Tagrisso (osimertinib), a medication that's been in development for the treatment of non-small cell lung cancer (NSCLC), recently received full approval from the U.S. Food and Drug Administration (FDA).

The approval is for patients with metastatic NSCLC who tested positive for the T790M mutation in the EGFR gene, and progressed following first generation tyrosine kinase inhibitors (TKI). It follows an accelerated approval granted for this indication in 2015, based on tumor response rate and duration of response.

"By following the science, we aim to turn lung cancer into a chronic, manageable disease for patients and this milestone brings us one step closer to that ambition," Sean Bohen, executive vice president, Global Medicines Development and chief medical officer at AstraZeneca, said in a press release.

"The FDA's full approval reinforces the potential of Tagrisso to become the standard of care for patients with metastatic EGFR T790M mutation-positive non-small cell lung cancer whose disease has progressed on or after first-generation EGFR-TKI therapy," he said.

Lung cancer is the leading cause of cancer-related death in both men and women. From 10 to 15 percent of patients with NSCLC in the U.S. and Europe, and 30 to 40 percent in Asia, have a particular mutation in the EGFR gene known as T790M. Although tumor cells with this particular mutation are particularly sensitive to current treatment with EGFR tyrosine kinase inhibitors (TKI), which can block cell signaling and tumor growth, many patients end up developing resistance to treatment.

Tagrisso, an 80 mg once-daily tablet, is designed to treat patients with metastatic EGFR T790M-positive NSCLC, who have seen their disease progress despite treatment with EGFR-TKI therapy. The medication is designed to inhibit EGFR sensitizing and resistance in patients with and without metastasis in the central nervous system (CNS).

Full FDA approval for Tagrisso was based largely on encouraging data from the company's Phase 3 AURA3 trial (NCT02151981) which demonstrated significantly improved progression-free survival (PFS), compared to platinum-based chemotherapy (10.1 months vs. 4.4 months). The results of the AURA3 trial were published in *The New England Journal of Medicine*

Patients treated with Tagrisso also developed fewer serious adverse reactions than patients receiving chemotherapy alone — 18 percent compared to 26 percent in the chemotherapy group.

The most common adverse reactions reported in patients treated with Tagrisso were diarrhea, rash, dry sin, nail toxicity, and fatigue. The most frequent significant adverse reactions that led to decreased dosing of Tagrisso included abnormal ECGs, decreased number of a type of blood cells called neutrophils, and diarrhea.

The FDA had previously granted Tagrisso fast track, breakthrough therapy, and priority review designations in 2015.