AstraZeneca is pleased to share that the US Food and Drug Administration (FDA) has approved TAGRISSO® (osimertinib) for adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

About the FDA Decision
The results from the Phase III ADAURA trial supported the FDA approval and showed:

- TAGRISSO demonstrated a statistically significant and clinically meaningful improvement in disease-free survival (DFS) in the primary analysis population of patients with resectable Stage II and IIIA EGFRm NSCLC, and also in the overall trial population of patients with Stage IB-IIIA disease, a key secondary endpoint
- Adjuvant treatment with TAGRISSO reduced the risk of disease recurrence or death by 83% in the primary endpoint of DFS in patients with Stage II and IIIA disease (hazard ratio HR 0.17; 95% confidence interval CI:0.12-0.23; p<0.0001). DFS results in the overall trial population of patients with Stage IB-IIIA disease showed that TAGRISSO reduced the risk of disease recurrence or death by 80% (HR 0.20; 95% CI: 0.15-0.27; p<0.0001)
- The safety and tolerability of TAGRISSO in this trial were consistent with its established profile. The most common (≥20%) adverse reactions, including laboratory abnormalities, were leukopenia, lymphopenia, thrombocytopenia, diarrhea, anemia, rash, musculoskeletal pain, nail toxicity, neutropenia, dry skin, stomatitis, fatigue, and cough

In April 2020, the ADAURA data were released 2 years early, as recommended by an independent data monitoring committee due to overwhelming efficacy. Investigators and patients continue to participate in the trial and remain blinded to treatment. On July 30, 2020, TAGRISSO was granted FDA Breakthrough Therapy Designation (BTD) in the US based on the data from the Phase III ADAURA trial.

Biomarker-driven Treatment Option for Patients
The approval of TAGRISSO as an adjuvant treatment for resectable EGFRm NSCLC has potential to change how EGFRm NSCLC is treated and highlights the importance of biomarker testing in this patient population. Having EGFR mutation test results gives physicians more information to help ensure patients start on the right treatment option for their type of lung cancer.

We are pleased that this approval will allow more patients to benefit from TAGRISSO.

Below is the full US press release with more information about this exciting update.

SELECT SAFETY INFORMATION

- There are no contraindications for TAGRISSO
- TAGRISSO is associated with several serious and sometimes fatal adverse reactions, including interstitial lung disease (ILD)/pneumonitis, QTc interval prolongation, cardiomyopathy, keratitis, erythema multiforme and Stevens-Johnson syndrome, cutaneous vasculitis, and embryo-fetal toxicity
- The most common (≥20%) adverse reactions, including lab abnormalities, were leukopenia, lymphopenia, thrombocytopenia, diarrhea, anemia, rash, musculoskeletal pain, nail toxicity, neutropenia, dry skin, stomatitis, fatigue, and cough

INDICATION

- TAGRISSO is indicated as adjuvant therapy after tumor resection in adult patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

For additional information, please see the complete Prescribing Information, including Patient Information.

If you have any questions, please do not hesitate to contact me at 303-641-5889.

TAGRISSO approved in the US for the adjuvant treatment of patients with early-stage EGFR-mutated lung cancer

Approval based on unprecedented results from the ADAURA Phase III trial where* TAGRISSO *reduced the risk of disease recurrence or death by 80%

AstraZeneca's TAGRISSO® (osimertinib) has been approved in the US for the adjuvant treatment of adult patients with early-stage epidermal growth factor receptor-mutated (EGFRm) non-small cell lung cancer (NSCLC) after tumor resection with curative intent. TAGRISSO is indicated for EGFRm patients whose tumors have exon 19 deletions or exon 21 L858R mutations as detected by an approved test.

Best regards,

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