FDA approves new indication for Tagrisso

Dec. 23, 2020—AstraZeneca's Tagrisso (osimertinib) has been FDA approved for the adjuvant treatment of adult patients with early-stage epidermal growth factor receptor-mutated non-small cell lung cancer 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.

"Adjuvant Tagrisso has demonstrated an unprecedented disease-free survival benefit for early-stage lung cancer patients with EGFR mutations who face high rates of recurrence even after successful surgery and subsequent chemotherapy," Roy S. Herbst, MD, PhD, chief of medical oncology, Yale Cancer Center and Smilow Cancer Hospital, New Haven, Conn., and principal investigator in the ADAURA phase three trial, said in an FDA press release. "This approval reinforces how critical it is to test all lung cancer patients for EGFR mutations before deciding how to treat them and regardless of their stage at diagnosis. This will help ensure as many patients as possible can benefit from this potentially practice-changing treatment."

Approval was based on results from the ADAURA phase three trial in which adjuvant treatment with Tagrisso reduced the risk of disease recurrence or death by 83 percent in the primary endpoint of DFS in patients with stage II and IIIA disease (hazard ratio=0.17; 95 percent confidence interval, 0.12–0.23; $p<0.0001$). DFS results in the overall trial population of patients with stage IB-IIIA disease showed Tagrisso reduced the risk of disease recurrence or death by 80 percent (HR=0.20; 95 percent CI, 0.15-0.27; $p<0.0001$). At two years, 89 percent of patients treated with Tagrisso remained alive and disease free versus 52 percent on placebo after surgery.