

Put It on the Board

Tagrisso approved for adjuvant treatment of early-stage *EGFR*-mutated NSCLC

January 2021—AstraZeneca's Tagrisso (osimertinib) has been approved in the U.S. for the adjuvant treatment of adult patients with early-stage *EGFR*-mutated non-small cell lung cancer after tumor resection with curative intent.

Tagrisso is indicated for *EGFR* mutation-positive patients whose tumors have exon 19 deletions or exon 21 L858R mutations as detected by an approved test.

The approval was based on results from the ADAURA phase three trial in which Tagrisso demonstrated a statistically significant and clinically meaningful improvement in disease-free survival in the primary analysis population of patients with stage II and IIIA *EGFR*-mutated NSCLC, and also in the overall trial population of patients with stage IB-IIIa disease.

Tagrisso was granted breakthrough therapy designation in mid-2020 for patients in the early-stage disease setting. In April 2020, an independent data monitoring committee recommended that the ADAURA trial be unblinded two years early based on a determination of overwhelming efficacy. Investigators and patients continue to participate in the trial and remain blinded to treatment. The results from the ADAURA trial were presented during the American Society of Clinical Oncology ASCO20 virtual scientific program in May 2020 and were published recently (Wu YL, et al. *N Engl J Med.* 2020;383[18]:1711-1723).

FDA clears Epoc NXS Host mobile computer

Siemens Healthineers received 510(k) clearance from the Food and Drug Administration for its Epoc NXS Host mobile computer.

The Epoc Blood Analysis System with the new Epoc NXS Host offers a handheld device with intuitive software application. The Epoc NXS Host incorporates caregiver suggestions that enhance performance and streamline the testing workflow for critically ill patients, the company said.

The NXS Host received the CE mark also.

The Epoc Blood Analysis System with Epoc NXS Host is powered by Android for advanced processing power and expanded memory. It prompts caregivers through the testing procedure with audio and visual guidance. Color-coded test results are reported securely without the caregiver having to leave the patient's side.

The Epoc Blood Analysis System streamlines the blood gas testing process and inventory management with a single, room temperature stable test card. Test results are delivered to the LIS/HIS via a secure, wireless connection.

Roche launches *PIK3CA* test with CE mark

Roche launched in December its Cobas *PIK3CA* Mutation Test for patients with advanced or metastatic breast cancer. The test, previously available as research use only, is now available in countries that accept the CE mark.

The test is a real-time PCR test for the qualitative detection and identification of 17 mutations in exons 2, 5, 8, 10, and 21 in the gene encoding the catalytic subunit of *PIK3CA* in DNA isolated from formalin-fixed, paraffin-embedded tissue.[]