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Update on LATIFY Phase III trial of ceralasertib plus *Imfinzi* in previously treated advanced non-small cell lung cancer

The LATIFY Phase III trial of ceralasertib in combination with *Imfinzi* (durvalumab) did not meet the primary endpoint of overall survival (OS) versus standard-of-care docetaxel in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC). The trial evaluated patients without actionable genomic alterations (AGAs) whose disease progressed on or after prior immunotherapy and platinum-based chemotherapy.

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "Our goal in the LATIFY trial was to reinvigorate the immune response of patients with lung cancer whose tumours stopped responding to available therapies by combining ATR inhibition with immunotherapy. While we are disappointed by this result, we remain committed to pioneering new medicines to address the urgent need to improve outcomes for patients with lung cancer through our industry-leading portfolio."

The combination of ceralasertib and *Imfinzi* was generally well tolerated, and the safety profile was consistent with the known profiles of each individual medicine, with no new safety concerns identified. These data will be presented at a forthcoming medical meeting.

Notes

NSCLC
Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-fifth of all cancer deaths.[1] Lung cancer is broadly split into small cell lung cancer (SCLC) or NSCLC, the latter accounting for about 80-85% of cases.[2-3] Patients are most commonly diagnosed with metastatic disease, when the tumour has spread outside the lung.[4] Approximately 12% of people with metastatic NSCLC will still be alive five years after diagnosis.[5]

LATIFY
LATIFY is a randomised, open-label, multi-centre, global Phase III trial of ceralasertib plus *Imfinzi* in patients with locally advanced or metastatic NSCLC without AGAs, and whose disease has progressed on or after prior anti-PD-(L)1 therapy and platinum-based chemotherapy. Patients were randomised 1:1 to receive ceralasertib 240mg twice daily oral tablets for seven days in combination with a 1,500mg fixed dose of *Imfinzi* on day eight every four weeks or docetaxel every three weeks until disease progression, unacceptable toxicity, withdrawal of consent or a discontinuation criterion was met.

The trial enrolled 594 patients across more than 20 countries. The primary endpoint is OS and secondary endpoints include progression-free survival, objective response rate, duration of response, time to response, disease control rate and patient reported outcomes.

Ceralasertib
Ceralasertib is an oral, potent and selective inhibitor of the ATR kinase, which is crucial for DNA damage responses and cell survival. Ceralasertib acts on the tumour microenvironment, moving it from a suppressed immune state into an activated state when combined with immunotherapy.

Imfinzi
Imfinzi (durvalumab) is a human monoclonal antibody that binds to the PD-L1 protein and blocks the interaction of PD-L1 with the PD-1 and CD80 proteins, countering the tumour's immune-evading tactics and releasing the inhibition of immune responses.

In lung cancer, *Imfinzi* is the global standard of care based on OS in the curative-intent setting of unresectable, Stage III NSCLC in patients whose disease has not progressed after chemoradiotherapy (CRT). Additionally, *Imfinzi* is approved as a perioperative treatment in combination with neoadjuvant chemotherapy in resectable NSCLC, and in combination with a short course of *Imjudo* (tremelimumab) and chemotherapy for the treatment of metastatic NSCLC. *Imfinzi* is also approved for limited-stage SCLC in patients whose disease has not progressed following concurrent platinum-based CRT; and in combination with chemotherapy for the treatment of extensive-stage SCLC.

In addition to its indications in lung cancers, *Imfinzi* is also approved in combination with chemotherapy in locally advanced or metastatic biliary tract cancer and in combination with *Imjudo* in unresectable hepatocellular carcinoma (HCC). *Imfinzi* is also approved as a monotherapy in unresectable HCC in Japan and the European Union (EU), and in resectable, early-stage and locally advanced gastric and gastroesophageal junction cancers in the US.

Perioperative *Imfinzi* in combination with neoadjuvant chemotherapy is approved for muscle-invasive bladder cancer. In May 2025, *Imfinzi* added to Bacillus Calmette-Guerin induction and maintenance therapy met the primary endpoint of disease-free survival for patients with high-risk non-muscle-invasive bladder cancer in the POTOMAC Phase III trial.

Imfinzi in combination with chemotherapy followed by *Imfinzi* monotherapy is approved as a 1st-line treatment for primary advanced or recurrent endometrial cancer (mismatch repair deficient disease only in the US and EU). *Imfinzi* in combination with chemotherapy followed by *Lynparza* (olaparib) and *Imfinzi* is approved for patients with mismatch repair proficient advanced or recurrent endometrial cancer in the EU and Japan.

Since the first approval in May 2017, more than 414,000 patients have been treated with *Imfinzi*. As part of a broad development programme, *Imfinzi* is being tested as a single treatment and in combinations with other anti-cancer treatments for patients with NSCLC, bladder cancer, breast cancer, ovarian cancer and several gastrointestinal cancers.

AstraZeneca in immuno-oncology (IO)
AstraZeneca is a pioneer in introducing the concept of immunotherapy into dedicated clinical areas of high unmet

AstraZeneca is a pioneer in introducing the concept of immunotherapy into dedicated clinical areas of high unmet medical need. The Company has a comprehensive and diverse IO portfolio and pipeline anchored in immunotherapies designed to overcome evasion of the anti-tumour immune response and stimulate the body's immune system to attack tumours.

AstraZeneca strives to redefine cancer care and help transform outcomes for patients with *Imfinzi* as a monotherapy and in combination with *Imjudo* as well as other novel immunotherapies and modalities. The Company is also investigating next-generation immunotherapies like bispecific antibodies and therapeutics that harness different aspects of immunity to target cancer, including cell therapy and T-cell engagers.

AstraZeneca is pursuing an innovative clinical strategy to bring IO-based therapies that deliver long-term survival to new settings across a wide range of cancer types. The Company is focused on exploring novel combination approaches to help prevent treatment resistance and drive longer immune responses. With an extensive clinical programme, the Company also champions the use of IO treatment in earlier disease stages, where there is the greatest potential for cure.

AstraZeneca in oncology
AstraZeneca is leading a revolution in oncology with the ambition to provide cures for cancer in every form, following the science to understand cancer and all its complexities to discover, develop and deliver life-changing medicines to patients.

The Company's focus is on some of the most challenging cancers. It is through persistent innovation that AstraZeneca has built one of the most diverse portfolios and pipelines in the industry, with the potential to catalyse changes in the practice of medicine and transform the patient experience.

AstraZeneca has the vision to redefine cancer care and, one day, eliminate cancer as a cause of death.

AstraZeneca
AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca's innovative medicines are sold in more than 125 countries and used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Social Media @AstraZeneca.

Contacts
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