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Imfinzi plus _Imdelltra_ demonstrated a statistically significant and highly clinically meaningful improvement in overall survival and progression-free survival in 1st-line extensive-stage small cell lung cancer

Imfinzi is the first and only immunotherapy in combination with a bispecific T-cell engager to show survival benefit in this setting

DeLLphi-305 Phase III trial results reinforce Imfinzi as the backbone immunotherapy for small cell lung cancer across stages of disease

Positive high-level results from a planned interim analysis of the DeLLphi-305 Phase III trial showed *Imfinzi* (durvalumab) plus Amgen's *Imdelltra*® (tarlatamab) demonstrated a statistically significant and highly clinically meaningful improvement in overall survival (OS) versus *Imfinzi* alone as a 1st-line maintenance treatment. The trial included patients with extensive-stage small cell lung cancer (ES-SCLC) who had not progressed following standard induction treatment with *Imfinzi* in combination with platinum chemotherapy (investigator's choice of carboplatin or cisplatin) and etoposide.

Imfinzi plus tarlatamab also demonstrated a statistically significant and clinically meaningful improvement in the secondary endpoints of progression-free survival (PFS) and objective response rate.

In 2026, an estimated 195,000 people globally will be treated for ES-SCLC, a highly aggressive, fast-growing form of lung cancer characterised by rapid tumour progression and metastatic spread to organs such as the brain and liver.[1,2] Immune checkpoint inhibitors such as *Imfinzi* have led to significant improvements in OS in ES-SCLC, establishing a 1st-line standard of care. However, many patients still experience disease progression due to the aggressive nature of the disease and median OS with the current standard of care is approximately one year.[3]

Susan Galbraith, Executive Vice President, Oncology Haematology R&D, AstraZeneca, said: "These results show that *Imfinzi*-based induction therapy followed by maintenance treatment with *Imfinzi* plus tarlatamab demonstrates an unprecedented improvement in overall survival for patients with this highly aggressive form of lung cancer. *Imfinzi* continues to reshape how lung cancer is treated, establishing new standards of care across multiple settings, and these new findings further underscore its role as the backbone immunotherapy of choice for small cell lung cancer."

Jacob Sands, MD, Associate Chief of the Lowe Center for Thoracic Oncology at Dana-Farber Cancer Institute, said: "Given the aggressive nature of small cell lung cancer, many patients quickly relapse on current therapy and never reach second-line treatment. These patients do not have time to wait, making substantial progress in the first-line setting critically important. In my career treating people with extensive-stage small cell lung cancer, these are among the most compelling survival results I have seen, indicating the potential to reshape the natural history of small cell lung cancer. DeLLphi-305 represents an unprecedented milestone and suggests we may be entering a new era where meaningfully longer survival is possible for more patients."

Overall, the safety and tolerability profile of *Imfinzi* plus tarlatamab was consistent with the known safety profiles of the individual treatments, with no new safety signals identified. These data will be presented at a forthcoming medical meeting and shared with global regulatory authorities.

Imfinzi is approved in the US, EU, Japan, China and many other countries around the world as the standard-of-care treatment for ES-SCLC and limited-stage SCLC (LS-SCLC) based on the CASPIAN and ADRIATIC Phase III trials, respectively.

Notes

Small cell lung cancer

Lung cancer is the leading cause of cancer death globally, accounting for almost one in five (19%) cancer deaths.[4,5] Lung cancer is broadly split into non-small cell lung cancer (NSCLC) and SCLC, with about 15% classified as SCLC.[6] About two-thirds of SCLC patients are diagnosed with ES-SCLC, in which the cancer has spread widely through the lung or to other parts of the body.[3] While survival rates have improved in recent years following the introduction of immune checkpoint inhibitors, prognosis is still poor, with only 18.1% of LS-SCLC patients and 3.6% of ES-SCLC patients alive five years after diagnosis.[2]

DeLLphi-305

The DeLLphi-305 trial is sponsored by Amgen, with partial funding and *Imfinzi* provided by AstraZeneca. It is a global Phase III, randomised, open-label clinical trial evaluating the efficacy and safety of *Imfinzi* in combination with tarlatamab compared to *Imfinzi* alone as 1st-line maintenance treatment for patients with ES-SCLC who have not progressed following induction treatment with *Imfinzi* in combination with platinum chemotherapy and etoposide.

Tarlatamab is a first-in-class targeted immunotherapy that binds to both DLL3 on tumour cells and CD3 on T cells, thereby activating T cells to kill DLL3-expressing SCLC cells. DLL3 is a protein that is expressed on the surface of SCLC cells in ~85-96% of patients with SCLC, but is minimally expressed on healthy cells.

In the trial, 563 patients who completed *Imfinzi*-based induction treatment were randomised 1:1 to receive either *Imfinzi* in combination with tarlatamab or *Imfinzi* alone until progression or unacceptable toxicity. Following tarlatamab infusion on Cycle 1 Day 1 and Cycle 1 Day 8, patients were monitored in a healthcare setting for 1 to 2 hours (6 to 8 hours in certain regions including Europe). The trial included patients with both treated and untreated asymptomatic brain metastases at baseline.

The primary endpoint is OS for *Imfinzi* plus tarlatamab versus *Imfinzi* alone. PFS is a key secondary endpoint.

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 addition to its indications in SCLC, *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 in combination with chemotherapy in locally advanced or metastatic biliary tract cancer and in combination with *Imjudo* in unresectable hepatocellular carcinoma (HCC). It is also approved as a monotherapy in unresectable HCC in Japan, China and the EU, and in resectable, early-stage and locally advanced gastric and gastroesophageal junction cancers in the US and the EU. Additionally, in April 2026, *Imfinzi* in combination with *Imjudo*, lenvatinib and transarterial chemoembolisation (TACE) demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of PFS versus TACE alone for patients with unresectable HCC eligible for embolisation in the EMERALD-3 Phase III trial.

Perioperative *Imfinzi* in combination with neoadjuvant chemotherapy is approved for cisplatin-eligible muscle-invasive bladder cancer (MIBC). *Imfinzi* in combination with Bacillus Calmette-Guérin (BCG) induction and maintenance therapy is approved in the US and other countries for patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer. In May 2026, positive high-level results from the VOLGA Phase III trial showed that perioperative treatment with *Imfinzi* in combination with neoadjuvant enfortumab vedotin (EV) demonstrated statistically significant and clinically meaningful improvements in event-free survival (EFS) and OS in patients with MIBC who were ineligible for or had declined cisplatin-based chemotherapy. In addition, perioperative *Imfinzi* plus *Imjudo* in combination with neoadjuvant EV demonstrated a statistically significant and clinically meaningful improvement in EFS and a favourable trend for OS; however, the OS data were not statistically significant at this planned interim analysis and will be formally reassessed at a subsequent analysis. In July 2026, positive high-

level results from the NILE Phase III trial showed *Imfinzi* plus chemotherapy demonstrated a statistically significant and clinically meaningful improvement in OS versus chemotherapy as 1st-line treatment for patients with PD-L1 high unresectable, locally advanced or metastatic urothelial cancer.

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 US, EU and China). *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 EU and Japan.

Since the first approval in May 2017, more than 470,000 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 lung cancer

AstraZeneca is working to bring patients with lung cancer closer to cure through the detection and treatment of early-stage disease, while also pushing the boundaries of science to improve outcomes in the resistant and advanced settings. By defining new therapeutic targets and investigating innovative approaches, the Company aims to match medicines to the patients who can benefit most.

The Company's comprehensive portfolio includes leading lung cancer medicines and the next wave of innovations, including *Tagrisso* (osimertinib) and *Iressa* (gefitinib); *Imfinzi* and *Imjudo*; *Enhertu* (trastuzumab deruxtecan) and *Datroway* (datopotamab deruxtecan) in collaboration with Daiichi Sankyo; *Orpathys* (savolitinib) in collaboration with HUTCHMED; as well as a pipeline of potential new medicines and combinations across diverse mechanisms of action.

AstraZeneca is a founding member of the Lung Ambition Alliance, a global coalition working to accelerate innovation and deliver meaningful improvements for people with lung cancer, including and beyond treatment.

AstraZeneca in immuno-oncology (IO)

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/NYSE: 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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