

AstraZeneca

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Imfinzi demonstrated unprecedented survival in unresectable, Stage III lung cancer with 43% of patients surviving five years

Long-term data from PACIFIC Phase III trial at ASCO showed 33% of patients remained progression-free at five years

Longest-ever survival reported in a Phase III immunotherapy trial in this setting

Updated results from the positive PACIFIC Phase III trial showed

AstraZeneca's *Imfinzi* (durvalumab) demonstrated a sustained, clinically meaningful overall survival (OS) and progression-free survival (PFS) benefit at five years in patients with unresectable, Stage III non-small cell lung cancer (NSCLC) who had not progressed following concurrent chemoradiation therapy (CRT).

Lung cancer is the leading cause of cancer death accounting for about one-fifth of all cancer deaths, and 80-85% of patients with lung cancer have NSCLC.¹⁻³ One in four patients with NSCLC are diagnosed at Stage III, where the majority of tumours are unresectable (cannot be removed with surgery).^{4,5} The approval of *Imfinzi* in this setting based on the results of this trial was the first new treatment to be available to these patients in decades.^{2,6,7}

Results from the updated post-hoc analyses showed an estimated five-year OS rate of 42.9% for patients treated with *Imfinzi* versus 33.4% for those on placebo after CRT. Median OS was 47.5 months for *Imfinzi* versus 29.1 for placebo. Following a maximum treatment course of one year, an estimated 33.1% of patients treated with *Imfinzi* had not progressed five years after enrolment versus 19% for placebo. These results build on the primary PFS and OS analyses published in *The New England Journal of Medicine* in [2017](#) and [2018](#), which demonstrated a sustained, significant benefit with *Imfinzi* for these primary endpoints.^{8,9}

David Spigel, MD, Chief Scientific Officer at the Sarah Cannon Research Institute, and investigator in the PACIFIC trial, said: "This trial has once again set a new precedent in the treatment of patients with unresectable, Stage III non-small cell lung cancer. Historically, only 15-30% of these patients survived five years but these results show that with up to one year of treatment with *Imfinzi*, an estimated 43% of patients are still alive at five years. Moreover, three quarters of these patients had also not progressed in that time. This is a momentous achievement at the five-year landmark in this curative-intent setting."

Dave Fredrickson, Executive Vice President, Oncology Business Unit, said: "Five-year survival is a clinically significant and emotionally meaningful milestone for people with cancer and their families, and it's incredible to see the majority of patients surviving that long have not progressed four years after completing treatment. These results – the first of their kind in Stage III unresectable lung cancer – reinforce the long-term benefit of *Imfinzi* as the established standard of care in this curative-intent setting. With trials like

PACIFIC and our comprehensive development programme in early-stage disease across cancer settings, our strategy is to improve cancer outcomes by treating patients as early as possible, aiming to deliver life-changing treatments that increase the potential for cure.”

In the primary OS analysis of the PACIFIC Phase III trial, the most common adverse events (AEs) (greater than or equal to 20%) among patients treated with *Imfinzi* versus placebo were cough (35.2% versus 25.2%), fatigue (24.0% versus 20.5%), dyspnoea (22.3% versus 23.9%) and radiation pneumonitis (20.2% versus 15.8%). A grade 3 or 4 AE was experienced by 30.5% of patients treated with *Imfinzi* versus 26.1% for placebo, and 15.4% of patients discontinued treatment due to AEs with *Imfinzi* versus 9.8% for placebo.⁹

These results were presented on 4 June during the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting.

Imfinzi is approved in the curative-intent setting of unresectable, Stage III NSCLC after CRT in the US, Japan, China, across the EU and in many other countries. Since the first approval in February 2018, more than 80,000 patients in this setting have been treated with *Imfinzi*.

AstraZeneca has several ongoing registrational trials focused on testing *Imfinzi* in earlier stages of lung cancer, including in potentially curative settings (PACIFIC-2, 4 and 5, MERMAID-1 and 2, AEGEAN, ADJUVANT BR.31, and ADRIATIC Phase III trials). The Company is also testing novel combinations with *Imfinzi* in two Phase II platform trials in the Stage III unresectable setting (COAST) and neoadjuvant early-stage setting (NeoCOAST).

Stage III NSCLC

In 2020, an estimated 2.2 million people were diagnosed with lung cancer worldwide.¹ Lung cancer is broadly split into NSCLC and small cell lung cancer, with 80-85% classified as NSCLC.^{2,3,5} Stage III NSCLC represents approximately one quarter of NSCLC incidence.⁴

Stage III (locally advanced) NSCLC is divided into three subcategories (IIIA, IIIB and IIIC), defined by how much the cancer has spread locally. In contrast to Stage IV, when cancer has spread (metastasised), the majority of Stage III

patients are currently treated with curative intent.^{5,10}

PACIFIC

The PACIFIC trial was a Phase III, randomised, double-blinded, placebo-controlled, multi-centre trial of *Imfinzi* as treatment in ‘all-comer’ patients (regardless of PD-L1 status) with unresectable, Stage III NSCLC whose disease had not progressed following concurrent platinum-based CRT.

The trial was conducted at 235 centres across 26 countries involving 713 patients. The primary endpoints of the trial were PFS and OS, and secondary endpoints included landmark PFS and OS, objective response rate and duration of response.

Imfinzi

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

In addition to approvals in the unresectable, Stage III NSCLC setting, *Imfinzi* is approved for the treatment of extensive-stage small cell lung cancer (ES-SCLC) based on the CASPIAN Phase III trial in the EU, US, Japan and many other countries around the world. *Imfinzi* is also approved for previously treated patients with advanced bladder cancer in several countries.

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, SCLC, bladder cancer, hepatocellular carcinoma, biliary tract cancer (a form of liver cancer), oesophageal cancer, gastric and gastroesophageal cancer, cervical cancer, ovarian cancer, endometrial cancer and other solid tumours.

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 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* (durvalumab) and tremelimumab; *Enhertu* (trastuzumab deruxtecan) and datopotamab deruxtecan in collaboration with Daiichi Sankyo; and savolitinib in collaboration with HUTCHMED; as well as a pipeline of 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 immunotherapy

Immunotherapy is a therapeutic approach designed to stimulate the body's immune system to attack tumours. The Company's IO portfolio is anchored in immunotherapies that have been designed to overcome anti-tumour immune suppression. AstraZeneca is invested in using IO approaches that deliver long-term survival for new groups of patients across tumour types.

The Company is pursuing a comprehensive clinical-trial programme that includes *Imfinzi* as a single treatment and in combination with tremelimumab and other novel antibodies in multiple tumour types, stages of disease, and lines of treatment, and where relevant using the PD-L1 biomarker as a decision-making tool to define the best potential treatment path for a patient. In addition, the ability to combine the IO portfolio with radiation, chemotherapy, small, targeted molecules from across AstraZeneca's oncology pipeline, and from research partners, may provide new treatment options across a broad range of tumours.

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 and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts

For details on how to contact the Investor Relations Team, please click [here](#). For Media contacts, click [here](#).

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Om AstraZeneca

AstraZeneca är ett globalt, innovationsdrivet bioläkemedelsföretag med fokus på forskning, utveckling och marknadsföring av receptbelagda läkemedel, primärt för behandling av sjukdomar inom tre huvudsakliga terapiområden: cancer, kardiovaskulära sjukdomar, njursjukdomar och metabola sjukdomar och sjukdomar i andningsvägarna. AstraZeneca bedriver verksamhet i över 100 länder och dess innovativa läkemedel används av miljontals patienter över hela världen.

Mer information finns på: www.astrazeneca.com och www.astrazeneca.se. Du kan även följa oss på twitter <https://twitter.com/AstraZenecaSE>

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