

AstraZeneca

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Imfinzi recommended for approval in the EU by CHMP for less-frequent, fixed-dose use in unresectable non-small cell lung cancer

Option would extend dosing from two to four weeks, reducing medical visits and improving patient convenience

AstraZeneca's *Imfinzi* (durvalumab) has been recommended for marketing authorisation in the European Union (EU) for an additional dosing option, 1,500mg fixed dose every four weeks, in the approved indication of locally advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose

tumours express PD-L1 on at least 1% of tumour cells and whose disease has not progressed following platinum-based chemoradiation therapy (CRT).

This new dosing option is consistent with the approved *Imfinzi* dosing in extensive-stage small cell lung cancer (ES-SCLC) and once approved, will be available to patients with locally advanced, unresectable NSCLC weighing more than 30kg.

Following review of the application under its accelerated assessment procedure, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency based its positive opinion on data from several *Imfinzi* clinical trials, including the PACIFIC Phase III trial which supported the two-week, weight-based dosing of 10mg/kg every two weeks already approved in locally advanced, unresectable NSCLC, and the CASPIAN Phase III trial which used fixed dosing every four weeks during maintenance treatment in ES-SCLC.

José Baselga, Executive Vice President, Oncology R&D, said: “The four-week dosing regimen will decrease the risk of exposure to infection in the healthcare setting, furthering our efforts to ensure continuity of care for cancer patients at high risk of complications during the pandemic. We look forward to offering non-small cell lung cancer patients in Europe an option that would reduce medical visits by extending dosing from two to four weeks.”

Imfinzi was recently [approved in the US](#) for this dosing regimen. *Imfinzi* is approved in the curative-intent setting of unresectable, Stage III (locally advanced) NSCLC after CRT in the EU, US, Japan, China and many other countries, based on the PACIFIC Phase III trial. Additionally, it is approved in the EU, US, Japan and many other countries around the world for the treatment of ES-SCLC based on the CASPIAN Phase III trial.

Stage III NSCLC

Stage III (locally advanced) NSCLC is commonly divided into three subcategories (IIIA, IIIB and IIIC), defined by how much the cancer has spread locally and the possibility of surgery.¹ Stage III disease is different from Stage IV disease, when the cancer has spread (metastasised), as the majority of Stage III patients are currently treated with curative intent.^{1,2}

Stage III NSCLC represents approximately one third of NSCLC incidence and in 2015 was estimated to affect nearly 200,000 patients in the following eight large countries: China, France, Germany, Italy, Japan, Spain, UK, and the US, with approximately 43,000 cases in the US alone.^{3,4} The majority of Stage III NSCLC patients are diagnosed with unresectable tumours.⁵ Prior to approval of *Imfinzi* in this setting, no new treatments beyond CRT had been available to patients for decades.⁶⁻⁸

Small cell lung cancer

SCLC is a highly aggressive, fast-growing form of lung cancer that typically recurs and progresses rapidly, despite initial response to chemotherapy.^{9,10} About two thirds of SCLC patients are diagnosed with extensive-stage disease, in which the cancer has spread widely through the lung or to other parts of the body.¹¹ Prognosis is particularly poor, as only 6% of all SCLC patients will be alive five years after diagnosis.¹¹

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.

Imfinzi is also approved for previously treated patients with advanced bladder cancer in the US and several other countries.

As part of a broad development programme, *Imfinzi* is also being tested as a monotherapy and in combinations including with tremelimumab, an anti-CTLA4 monoclonal antibody and potential new medicine, as a treatment for patients with NSCLC, SCLC, bladder cancer, head and neck cancer, liver cancer, biliary tract cancer, oesophageal cancer, gastric cancer, cervical cancer and other solid tumours.

AstraZeneca in lung cancer

AstraZeneca has a comprehensive portfolio of approved and potential new medicines in late-stage development for the treatment of different forms of

lung cancer spanning different histologies, several stages of disease, lines of therapy and modes of action.

An extensive Immuno-Oncology (IO) development programme focuses on lung cancer patients without a targetable genetic mutation which represents up to three-quarters of all patients with lung cancer.¹² *Imfinzi*, an anti-PDL1 antibody, is in development for patients with advanced disease (POSEIDON and PEARL Phase III trials) and for patients in earlier stages of disease including potentially-curative settings (MERMAID-1, MERMAID-2, AEGEAN, ADJUVANT BR.31, PACIFIC-2, PACIFIC-4, PACIFIC-5, and ADRIATIC Phase III trials) both as monotherapy and in combination with tremelimumab and/or chemotherapy.

Imfinzi is also in development in the NeoCOAST, COAST and HUDSON Phase II trials in combination with potential new medicines from the early-stage pipeline including *Enhertu* (trastuzumab deruxtecan).

AstraZeneca's approach to IO

IO is a therapeutic approach designed to stimulate the body's immune system to attack tumours. The Company's IO portfolio is anchored by 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 monotherapy and in combination with tremelimumab in multiple tumour types, stages of disease, and lines of therapy, 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 has a deep-rooted heritage in oncology and offers a quickly growing portfolio of new medicines that has the potential to transform patients' lives and the Company's future. With seven new medicines launched

between 2014 and 2020, and a broad pipeline of small molecules and biologics in development, the Company is committed to advance oncology as a key growth driver for AstraZeneca focused on lung, ovarian, breast and blood cancers.

By harnessing the power of six scientific platforms – Immuno-Oncology, Tumour Drivers and Resistance, DNA Damage Response, Antibody Drug Conjugates, Epigenetics, and Cell Therapies – and by championing the development of personalised combinations, AstraZeneca has the vision to redefine cancer treatment 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, primarily for the treatment of diseases in three therapy areas - Oncology, 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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