

## CHMP recommends Imfinzi for Stage III nsclC

This announcement contains inside information

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### ***Imfinzi receives positive EU CHMP opinion for locally-advanced, unresectable non-small cell lung cancer***

***Recommended marketing authorisation for patients whose tumours express PD-L1 on  $\geq 1\%$  of tumour cells***

***Imfinzi is the first immunotherapy recommended for approval  
for the treatment of locally-advanced, unresectable NSCLC***

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency has adopted a positive opinion, recommending a marketing authorisation of *Imfinzi* (durvalumab) for the treatment of locally-advanced, unresectable non-small cell lung cancer (NSCLC) in adults whose tumours express PD-L1 on  $\geq 1\%$  of tumour cells and whose disease has not progressed following platinum-based chemotherapy and radiation therapy (CRT). The recommendation is based on the progression-free survival (PFS) and overall survival (OS) primary endpoints of the Phase III PACIFIC trial, and post-hoc subgroup analyses by PD-L1 expression requested by the CHMP.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "The CHMP positive opinion brings European patients closer to having a treatment following chemoradiation therapy. There have been no new treatments in this setting for decades. With approximately a third of European non-small cell lung cancer patients presenting with this stage of disease, we are excited by this potential new standard of care in this curative-intent setting."

In the PACIFIC trial, *Imfinzi* demonstrated a statistically-significant and clinically-meaningful improvement in PFS and OS in "all-comer" patients. The recommended label reflects most of the patients in the trial with a known PD-L1 status.

Overall survival results from the PACIFIC trial will be presented at a forthcoming medical meeting.

The positive opinion from the CHMP will now be reviewed by the European Commission, which has the authority to approve medicines for the 28 European Union member countries plus Iceland, Norway and Liechtenstein. Earlier this year, *Imfinzi* was approved for unresectable, Stage III NSCLC in the US, Canada, Switzerland, India, Japan and Brazil based on the Phase III PACIFIC trial. In addition to the EU, other global health authority reviews and submissions are ongoing.

#### **About Stage III NSCLC**

Stage III (locally advanced) NSCLC is commonly divided into three sub-categories (IIIA, IIIB and IIIC), defined by how much the cancer has spread locally and the possibility of surgery. Stage III disease is different from Stage IV disease, when the cancer has spread (metastasised) to distant organs, as Stage III is currently treated with curative intent.

Stage III NSCLC represents approximately one-third of NSCLC incidence and was estimated to affect around 105,000 patients in the top-eight countries (China, France, Germany, Italy, Japan, Spain, UK, US) in 2017. The majority of Stage III NSCLC patients are diagnosed with unresectable tumours. No new treatments beyond chemoradiation therapy, followed by active surveillance to monitor for progression, have been available to patients for decades.

#### **About PACIFIC**

The PACIFIC trial is a randomised, double-blinded, placebo-controlled, multi-centre trial of *Imfinzi* as treatment in 'all-comer' patients (i.e. regardless of PD-L1 status) with unresectable, Stage III NSCLC whose disease has not progressed following platinum-based chemotherapy and radiation therapy (CRT).

The trial is being conducted in 235 centres across 26 countries involving 713 patients. The primary endpoints of the trial are PFS and OS, and secondary endpoints include landmark PFS and OS, objective response rate, and duration of response.

#### **About 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 approved for unresectable, Stage III NSCLC in the US, Canada, Switzerland, India, and Japan based on the Phase III PACIFIC trial.

As part of a broad development programme, *Imfinzi* is also being tested as a monotherapy and in combination with chemotherapy, radiation therapy, small molecules, and tremelimumab, an anti-CTLA4 monoclonal antibody, as a first or second-line treatment for patients with NSCLC, small cell lung cancer, locally-advanced or metastatic urothelial carcinoma, head and neck cancer and other solid tumours.

#### **About AstraZeneca in Lung Cancer**

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths.

AstraZeneca has a comprehensive portfolio of approved and potential new medicines in late-stage clinical development for the treatment of different forms of lung cancer across all stages of disease and lines of therapy. We aim to address the unmet needs of patients with EGFR-mutated tumours as a genetic driver of disease, which occur in 10-15% of NSCLC patients in the US and EU and 30-40% of NSCLC patients in Asia, with our approved medicines *Iressa* and *Tagrisso* and ongoing FLAURA, ADAURA and LAURA Phase III trials. Our extensive late-stage immuno-oncology programme focuses on 75-80% of patients with lung cancer without a known genetic mutation. The portfolio includes *Imfinzi*, an anti-PDL1 antibody, which is in development as monotherapy (ADJUVANT BR.31, PACIFIC2, MYSTIC and PEARL Phase III trials) and in combination with tremelimumab and/or chemotherapy (MYSTIC, NEPTUNE, POSEIDON and CASPIAN Phase III trials).

### About AstraZeneca's Approach to Immuno-Oncology (IO)

Immuno-Oncology (IO) is a therapeutic approach designed to stimulate the body's immune system to attack tumours. At AstraZeneca and MedImmune, our biologics research and development arm, our IO portfolio is anchored by immunotherapies that have been designed to overcome anti-tumour immune suppression. We believe that IO-based therapies will offer the potential for life-changing cancer treatments for the clear majority of patients.

We are pursuing a comprehensive clinical trial programme that includes *Imfinzi* (anti-PDL1) as monotherapy and in combination with tremelimumab (anti-CTLA4) in multiple tumour types, stages of disease, and lines of therapy, 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 our IO portfolio with small, targeted molecules from across our Oncology pipeline, and with those of our research partners, may provide new treatment options across a broad range of tumours.

### About 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 at least six new medicines to be launched between 2014 and 2020, and a broad pipeline of small molecules and biologics in development, we are committed to advancing Oncology as a growth driver for AstraZeneca, focused on lung, ovarian, breast and blood cancers. In addition to our core capabilities, we actively pursue innovative partnerships and investments that accelerate the delivery of our strategy as illustrated by our investment in Acerta Pharma in haematology.

By harnessing the power of four scientific platforms - Immuno-Oncology, Tumour Drivers and Resistance, DNA Damage Response and Antibody Drug Conjugates - 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.

### About MedImmune

MedImmune is the global biologics research and development arm of AstraZeneca, a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of small-molecule and biologic prescription medicines. MedImmune is pioneering innovative research and exploring novel pathways across Oncology; Respiratory; Cardiovascular, Renal & Metabolic Diseases; and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, MD, one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK, and Mountain View, CA. For more information, please visit [www.medimmune.com](http://www.medimmune.com).

### About AstraZeneca

AstraZeneca 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. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide.

For more information, please visit [www.astrazeneca.com](http://www.astrazeneca.com) and follow us on Twitter @AstraZeneca.

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