

# ASTRAZENECA PROVIDES UPDATE ON MYSTIC TRIAL TIMELINE

12 March 2018 07:00 GMT

AstraZeneca and MedImmune, its global biologics research and development arm, today announced an updated timeline for the final analysis of the Phase III MYSTIC trial of *Imfinzi* (durvalumab) as monotherapy and in combination with tremelimumab, versus platinum-based standard-of-care (SoC) chemotherapy in previously-untreated patients with metastatic (Stage IV) 1st-line non-small cell lung cancer (NSCLC).

MYSTIC is an event-driven clinical trial and continues per protocol. Based on current predictions, the final analysis of overall survival (OS) is now expected in the second half of 2018 (previously anticipated in the first half).

## About MYSTIC

The MYSTIC trial is a randomised, open-label, multi-centre, global Phase III trial of *Imfinzi* monotherapy or *Imfinzi* in combination with tremelimumab versus SoC in treatment of patients with epidermal growth factor receptor (EGFR) and anaplastic lymphoma kinase (ALK) wild-type locally-advanced or metastatic (Stage IV) 1st-line NSCLC.

The trial is being conducted in 167 centres across 17 countries, including the US, Canada, Europe, Russia, Australia and parts of Asia including Japan, Korea, Thailand, Taiwan and Vietnam. Primary endpoints include progression-free survival (in combination), which read out in July 2017, and OS in monotherapy and in combination.

## About *Imfinzi*

*Imfinzi* 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 February 2018, *Imfinzi* received US FDA approval for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent platinum-based chemotherapy and radiation therapy. *Imfinzi* has also received accelerated approval in the US for the treatment of patients with locally advanced or metastatic urothelial carcinoma, who have disease progression during or following platinum-containing chemotherapy, or whose disease has progressed within 12 months of receiving platinum-containing chemotherapy before (neoadjuvant) or after (adjuvant) surgery.

As part of a broad development programme, *Imfinzi* is also being investigated as a monotherapy and/or in combination with tremelimumab, an anti-CTLA-4 monoclonal antibody and potential new medicine, as a first 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 tremelimumab

Tremelimumab is an investigational human monoclonal antibody that targets the activity of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4). Tremelimumab blocks the activity of CTLA-4, contributing to T cell activation and boosting the immune response to cancer. Tremelimumab is being investigated in an extensive clinical trial programme in combination with *Imfinzi*, in NSCLC, locally-advanced or metastatic urothelial carcinoma, head and neck cancer, liver cancer and blood cancers.

## About AstraZeneca in NSCLC

Lung cancer is the leading cause of cancer death among both men and women, accounting for about one-third of all cancer deaths and more than breast, prostate and colorectal cancers combined.

AstraZeneca has a comprehensive portfolio of approved and potential new medicines in late-stage clinical development for the treatment of NSCLC across all stages of disease and lines of therapy. We aim to address 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 and ADAURA trials. Our extensive late-stage immuno-oncology programme focuses on 75-80% of patients with NSCLC without a known genetic mutation. Our portfolio includes *Imfinzi*, an anti-PDL1 antibody, which is in development as monotherapy (ADJUVANT, PACIFIC, MYSTIC, PEARL and ARCTIC trials) and in combination with tremelimumab (MYSTIC, NEPTUNE and POSEIDON trials).

## About AstraZeneca's Approach to Immuno-Oncology

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-PD-L1) as monotherapy and in combination with tremelimumab (anti-CTLA-4) 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 advance Oncology as a growth platform 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 & Metabolic Diseases; and Infection and Vaccines. The MedImmune headquarters is located in Gaithersburg, US., one of AstraZeneca's three global R&D centres, with additional sites in Cambridge, UK, and Mountain View, US. 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. The Company is also selectively active in the areas of autoimmunity, neuroscience and infection. 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.

#### **Media Relations**

Esra Erkal-Paler	UK/Global	+44 203 749 5638
Karen Birmingham	UK/Global	+44 203 749 5634
Rob Skelding	UK/Global	+44 203 749 5821
Matt Kent	UK/Global	+44 203 749 5906
Gonzalo Viña	UK/Global	+44 203 749 5916
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

#### **Investor Relations**

Thomas Kudsk Larsen		+44 203 749 5712
Craig Marks	Finance; Fixed Income; M&A	+44 7881 615 764
Henry Wheeler	Oncology	+44 203 749 5797
Mitchell Chan	Oncology; Other	+1 240 477 3771
Christer Gruvis	<i>Bilinta</i> ; Diabetes	+44 203 749 5711
Nick Stone	Respiratory; Renal	+44 203 749 5716
US toll free		+1 866 381 7277

#### **Adrian Kemp**

#### **Company Secretary, AstraZeneca PLC**

This information is provided by RNS  
The company news service from the London Stock Exchange

END