AstraZeneca

Imfinzi granted FDA Priority Review for SCLC

29 November 2019 07:00 GMT

Imfinzi granted FDA Priority Review for the treatment of patients with extensive-stage small cell lung cancer

AstraZeneca today announced that the US Food and Drug Administration (FDA) has accepted a supplemental Biologics License Application (sBLA) and granted Priority Review for *Imfinzi* (durvalumab) for the treatment of patients with previously untreated extensive-stage small cell lung cancer (SCLC).

SCLC is an aggressive, fast-growing form of lung cancer that recurs and progresses rapidly despite initial response to platinum-based chemotherapy.[1] A Prescription Drug User Fee Act date is set for the first quarter of 2020.

The sBLA was based on positive results from the Phase III CASPIAN trial published in *The Lancet*, showing *Imfinzi* in combination with standard-of-care (SoC) chemotherapy (etoposide with either cisplatin or carboplatin) demonstrated a statistically significant and clinically meaningful improvement in overall survival (OS) vs. SoC. The risk of death was reduced by 27% (equal to a hazard ratio of 0.73), with median OS of 13.0 months for *Imfinzi* plus chemotherapy vs. 10.3 months for SoC. Results showed an estimated 33.9% of patients were alive at 18 months following treatment with *Imfinzi* plus chemotherapy vs. 24.7% of patients receiving SoC.

Imfinzi is approved in the curative-intent setting of unresectable, Stage III non-small cell lung cancer (NSCLC) after chemoradiation therapy in 54 countries, including the US, Japan and the EU, based on the Phase III PACIFIC trial.

About CASPIAN

CASPIAN is a randomised, open-label, multi-centre, global, Phase III trial in the 1st-line treatment of patients with extensive-stage SCLC. The trial compared *Imfinzi* in combination with etoposide and either cisplatin or carboplatin chemotherapy, or *Imfinzi*, tremelimumab and chemotherapy vs. chemotherapy alone. In the experimental arms, patients were treated with up to four cycles of chemotherapy. In comparison, the control arm allowed up to six cycles of chemotherapy and prophylactic cranial irradiation. The trial will continue to the final analysis of OS for the combination of *Imfinzi*, tremelimumab and chemotherapy. The trial is being conducted in more than 200 centres across 23 countries, including the US, Europe, South America, Asia and the Middle East. The primary endpoint is OS.

About small cell lung cancer

Lung cancer is the leading cause of cancer death among both men and women and accounts for about one-fifth of all cancer deaths.[2] Lung cancer is broadly split into NSCLC and SCLC, with about 15% classified as SCLC.[3] About three quarters 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. Prognosis is particularly poor, as only 6% of all SCLC patients will be alive five years after diagnosis.[4]

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 also approved for previously treated patients with advanced bladder cancer in 11 countries, including the US.

As part of a broad development programme, *Imfinzi* is also being tested as a monotherapy and in combination 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, cervical cancer and other solid tumours.

About AstraZeneca in lung cancer

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 spanning several stages of disease, lines of therapy and modes of action. 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* (gefitinib) and *Tagrisso* (osimertinib), and ongoing Phase III trials ADAURA, LAURA, and FLAURA2 as well as the Phase II combination trials SAVANNAH and ORCHARD.[5-7]

Our extensive late-stage Immuno-Oncology programme focuses on lung cancer patients without a targetable genetic mutation which represents approximately three-quarters of all patients with lung cancer.[8] *Imfinzi*, an anti-PDL1 antibody, is in development for patients with advanced disease (Phase III trials POSEIDON, PEARL, and CASPIAN) and for patients in earlier stages of disease including potentially-curative settings (Phase III trials AEGEAN, ADJUVANT BR.31, PACIFIC-2, PACIFIC-4, PACIFIC-5, and ADRIATIC) both as monotherapy and in combination with tremelimumab and/or chemotherapy.

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. The Company's IO portfolio is anchored by immunotherapies that have been designed to overcome anti-tumour immune suppression. AstraZeneca believes that IO-based therapies offer the potential for life-changing cancer treatments for the majority of patients.

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, 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 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.

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, the Company is committed to advance oncology as a key growth driver for AstraZeneca focused on lung, ovarian, breast and blood cancers. In addition to AstraZeneca's main capabilities, the Company is actively pursuing innovative partnerships and investments that accelerate the delivery of our strategy, as illustrated by the 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 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 and Metabolism, and Respiratory. 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.

Media Relations

Gonzalo Viña		+44 203 749 5916
Rob Skelding	Oncology	+44 203 749 5821
Rebecca Einhorn	Oncology	+1 301 518 4122
Matt Kent	BioPharmaceuticals	+44 203 749 5906
Jennifer Hursit	Other	+44 203 749 5762
Christina Malmberg Hägerstrand	Sweden	+46 8 552 53 106
Michele Meixell	US	+1 302 885 2677

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvris	BioPharmaceuticals (CV, Metabolism)	+44 203 749 5711
Nick Stone	BioPharmaceuticals (Renal), ESG	+44 203 749 5716
Josie Afolabi	BioPharmaceuticals (Respiratory), other medicines	+44 203 749 5631
Craig Marks	Finance, fixed income	+44 7881 615 764
Jennifer Kretzmann	Corporate access, retail investors	+44 203 749 5824
US toll-free		+1 866 381 72 77

References

1. Kalemkerian GP, *et al*. Treatment Options for Relapsed Small-Cell Lung Cancer: What Progress Have We Made? *Journal of Oncology Practice*, volume 14, issue no. 6 (June 1, 2018) 369-370.
2. World Health Organization. International Agency for Research on Cancer. Available at http://globocan.iarc.fr/Pages/fact_sheets_population.aspx Accessed November 2019.
3. LUNGevity Foundation. Types of Lung Cancer. Available at https://lungevity.org/for-patients-caregivers/lung-cancer-101/types-of-lung-cancer Accessed November 2019.
4. Cancer.Net. Lung Cancer - Small Cell. Available at https://www.cancer.net/cancer-types/33776/view-all Accessed November 2019.
5. Szumera-Ciećkiewicz A, et al. EGFR Mutation Testing on Cytological and Histological Samples in Non-Small Cell Lung Cancer: a Polish, Single Institution Study and Systematic Review of European Incidence. *Int J Clin Exp Pathol*. 2013:6;2800-12.
6. Keedy VL, et al. American Society of Clinical Oncology Provisional Clinical Opinion: Epidermal Growth Factor Receptor (EGFR) Mutation Testing for Patients with Advanced Non-Small-Cell Lung Cancer Considering First-Line EGFR Tyrosine Kinase Inhibitor Therapy. *J Clin Oncol*. 2011:29;2121-27.
7. Ellison G, et al. EGFR Mutation Testing in Lung Cancer: a Review of Available Methods and Their Use for Analysis of Tumour Tissue and Cytology Samples. *J Clin Pathol*. 2013:66;79-89.
8. Pakkala, S, et al. Personalized therapy for lung cancer: striking a moving target. *JCI Insight*. 2018;3(15):e120858.

Adrian Kemp

Company Secretary
AstraZeneca PLC