DURVALUMAB ATLANTIC TRIAL SUPPORTS CLINICAL ACTIVITY AND ASTRAZENECA'S OVERALL IMMUNO-ONCOLOGY STRATEGY

Durvalumab demonstrated clinical activity and durable responses in 3rd-line or later stage NSCLC patients; full data to be presented at a scientific congress in 2016

Durvalumab monotherapy and combination trials on track in multiple cancers, including 1st-line therapy for NSCLC, head & neck and bladder cancers

AstraZeneca today provided an update on preliminary findings from the ATLANTIC trial of durvalumab as 3rd-line or later stage therapy in patients with locally advanced or metastatic programmed death ligand-1 (PD-L1) positive non-small cell lung cancer (NSCLC) that lacks epidermal growth factor receptor (EGFR) or ALK alterations. An initial analysis supports durvalumab's clinical activity, with durable responses and an established safety profile in these difficult-to-treat patients.

ATLANTIC investigated the efficacy and tolerability of durvalumab in patients who received at least two prior systemic treatment regimens including platinum-based chemotherapy, and who have limited options for further therapy. A full evaluation of the data is ongoing and the results will be presented at a scientific congress in 2016.

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: "As we have seen in other studies, durvalumab has demonstrated expected clinical activity and durable response in these heavily pre-treated patients. As previously communicated, the treatment and regulatory landscape in lung cancer is evolving. We now believe it is unlikely that ATLANTIC can be used for regulatory submission as a monotherapy, but we will make that determination following a full analysis of the data. Durvalumab is a cornerstone of our immuno-oncology portfolio with a fast advancing development programme focused primarily on novel combinations."

A comprehensive durvalumab registration programme is underway across multiple tumour types, stages of disease, and lines of therapy both as monotherapy and in combination. This forms part of AstraZeneca's late-stage immuno-oncology programme and includes more than 9,000 patients in 16 clinical trials in lung, bladder, head & neck, and other cancers, summarised below.

DURVALUMAB DEVELOPMENT PROGRAMME

Status as of Year-To-Date and Q3 2015 Financial results on 5 November 2015
Next update with FY 2015 Results on 4 February 2016

LUNG CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Early disease						
Monotherapy						
ADJUVANT	III	N/A	Stage Ib-IIIa NSCLC	durvalumab vs placebo	Data expected 2020	Recruiting
PACIFIC	III	N/A	Stage III unresect-able NSCLC	durvalumab vs placebo	Data expected 2017	Recruiting
Advanced/metastatic disease						
Monotherapy						
ATLANTIC	II	3rd line	PD-L1 pos. NSCLC	durvalumab (single arm)	Full data 2016	-
Combination therapy						
ARCTIC	III	3rd line	NSCLC	durvalumab vs SoC (PD-L1 pos.) or durvalumab vs tremelimumab vs durva + treme vs SoC (PD-L1 neg.)	Data expected 2017	Recruiting
MYSTIC	III	1st line	NSCLC (PFS endpoint)	durvalumab vs durva + treme vs SoC	Data expected 2017	First patient dosed
NEPTUNE	III	1st line	NSCLC (OS endpoint)	durva + treme vs SoC	Data expected 2018	Awaiting first patient dosed
-	III	1st line	NSCLC	durvalumab + chemotherapy +/- tremelimumab		In preparation
CAURAL	III	2nd line	T790M+ NSCLC	osimertinib vs osimertinib + durvalumab	Data expected 2018	Initiated enrolment; currently on partial clinical hold to characterise incidence of interstitial lung disease

METASTATIC HEAD AND NECK CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
Monotherapy						

HAWK	II	2nd line	PD-L1 pos. SCCHN	durvalumab (single arm)	Data expected H2 2016	Recruiting Indication granted FDA Fast Track designation
Combination therapy						
CONDOR	II	2nd line	PD-L1 neg. SCCHN	durvalumab vs tremelimumab vs durva + treme	Data expected 2017	Recruiting
EAGLE	III	2nd line	SCCHN	durvalumab vs durva + treme vs SoC	Data expected 2018	In preparation
KESTREL	III	1st line	SCCHN	durvalumab vs durva + treme vs SoC	Data expected 2018	In preparation

METASTATIC BLADDER CANCER

Name	Phase	Line of treatment	Population	Design	Timelines	Status
DANUBE	III	1st line	Cisplatin chemo-therapy-eligible/ ineligible	durvalumab vs durva + treme vs SoC	Data expected 2018	First patient dosed

OTHER TUMOUR TYPES

Name	Phase	Line of treatment	Indication	Design	Timelines	Status
-	II	2nd/ 3rd line	Metastatic gastric cancer	durvalumab vs tremelimumab vs durva + treme		In preparation
-	II	2nd line	Unresect-able liver cancer	durvalumab vs tremelimumab vs durva + treme		In preparation
ALPS	II	2nd line	Metastatic pancreatic cancer	durva + treme (single arm)		In preparation

SoC = Standard of Care, PFS = Progression Free Survival, OS = Overall Survival

About durvalumab (MEDI4736)

Durvalumab is an investigational human monoclonal antibody directed against PD-L1. Signals from PD-L1 help tumours avoid detection by the immune system. Durvalumab blocks these signals, countering the tumour's immune-evading tactics. Durvalumab is being developed, alongside other immunotherapies, to empower the patient's immune system and attack the cancer. Durvalumab is being investigated in an extensive clinical trial programme, as monotherapy or in combination with tremelimumab, in NSCLC, head and neck, gastric, pancreatic, bladder and blood cancers.

About the ATLANTIC trial
ATLANTIC is a Phase II, non-comparative, open-label, multi-centre, international trial of durvalumab in patients with locally advanced or metastatic NSCLC (Stage IIIB-IV) who have received at least two prior systemic treatment regimens including one platinum-based chemotherapy regimen.

About AstraZeneca in Oncology
Oncology is a therapy area in which AstraZeneca has deep-rooted heritage. It will be potentially transformational for the company's future, becoming the sixth growth platform. Our vision is to help patients by redefining the cancer treatment paradigm and one day eliminate cancer as a cause of death. By 2020, we are aiming to bring six new cancer medicines to patients.

Our broad pipeline of next-generation medicines is focused on four main disease areas - lung, ovarian, breast and haematological cancers. These are being targeted through four key platforms - immuno-oncology, the genetic drivers of cancer and resistance, DNA damage repair and antibody drug conjugates.

About AstraZeneca
AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three main therapy areas - respiratory, inflammation, autoimmune disease (RIA), cardiovascular and metabolic disease (CVMD) and oncology - as well as in infection and neuroscience. 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

CONTACTS

Media Enquiries

Esra Erkal-Paler	UK/Global	+44 20 7604 8030
Neil Burrows	UK/Global	+44 20 7604 8032
Vanessa Rhodes	UK/Global	+44 20 7604 8037
Karen Birmingham	UK/Global	+44 20 7604 8120
Jacob Lund	Sweden	+46 8 553 260 20
Michele Meixell	US	+1 302 885 2677

Investor Enquiries

UK

Thomas Kudsk Larsen	Oncology	+44 7818 524185
Eugenia Litz	RIA	+44 7884 735627
Nick Stone	CVMD	+44 7717 618834
Craig Marks	Finance	+44 7881 615764

Christer Gruvris	Consensus Forecasts	+44 7827 836825

US

Lindsey Trickett	Oncology, ING	+1 240 543 7970
Mitch Chan	Oncology	+1 240 477 3771
Dial / Toll-Free		+1 866 381 7277

Key: RIA - Respiratory, Inflammation and Autoimmunity, CVMD - Cardiovascular and Metabolic Disease, ING - Infection, Neuroscience and Gastrointestinal

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