NSCLC, metastatic

**A PHASE 2, NON-COMPARATIVE, OPEN-LABEL, MULTICENTER, INTERNATIONAL STUDY OF MEDI4736 IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC PD-L1-POSITIVE NSCLC (STAGE IIIB-IV) WHO HAVE RECEIVED ≥ 2 PRIOR SYSTEMIC TREATMENT REGIMENS, INCLUDING A PLATINUM-BASED CHEMOTHERAPY (ATLANTIC)**

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**Background:** Programmed cell death-ligand 1 (PD-L1) is a cell surface protein that delivers inhibitory signals to T cells through interaction with the programmed cell death-1 (PD-1) receptor and the CD80 receptor. Numerous cancers appear to exploit this PD-L1/PD-1 pathway and evade the immune system via upregulation and cell surface expression of PD-L1. Anti-PD-L1 monoclonal antibodies (mAbs) have shown encouraging preclinical and clinical activity against a number of tumor types. MEDI4736 is a human IgG1 mAb that blocks PD-L1 binding to PD-1 and CD-80 and is associated with a low frequency of anti-drug antibodies. Evidence of clinical activity for MEDI4736 in NSCLC has been observed in a Phase 1 study. The current Phase 2 study assesses the efficacy and safety of MEDI4736 treatment in patients with locally advanced or metastatic NSCLC.

**Trial design:** ATLANTIC (NCT02087423) is a Phase 2, non-comparative, multicenter, international, open-label study, evaluating the efficacy and safety of MEDI4736 (administered IV every 2 weeks for up to 12 months) in patients with PD-L1-positive locally advanced or metastatic NSCLC (stage IIIB - IV). Eligible patients (age ≥18 years) will have a WHO Performance Status of 0 or 1 and must have received at least 2 prior systemic treatment regimens, including a platinum-based chemotherapy regimen. Approximately 188 PD-L1-positive patients (∼50% known EGFR or ALK positive [Cohort 1] and ∼50% EGFR and ALK-negative [Cohort 2]), will be treated at ∼100 sites across North America, Asia, and Europe. Prior therapy for Cohort 1 patients must include appropriate tyrosine kinase inhibitor. The primary outcome measure is objective response rate according to RECIST 1.1. Secondary outcome measures will further assess efficacy (including disease control rate, duration of response, deep sustained response, progression-free survival and overall survival), safety, tolerability, pharmacokinetics, and immunogenicity of MEDI4736. Recruitment is ongoing.

**Disclosure:** N. Rizvi: I receive consulting income from Medimmune, Roche, Merck and BMS; J. Gray: MedImmune considers the research funding received for the conduct of a MedImmune-sponsored study as conflict of interest; M. Ballas: Employee of AstraZeneca and owns stock/stock options in AstraZeneca; D. Jayawardene: Employee of AstraZeneca and owns stock/stock options in AstraZeneca; P. Stockman: Employee of AstraZeneca and owns stock/stock options in AstraZeneca; J.D. Powderly: Speaker Bureaus BMS: Ipilimumab & ImmunoOncology; Dendreon: Sipuleucel T. Genentech: Bevacizumab. Research Funding: BMS, Genentech/Roche, AstraZeneca/ MedImmune, Merck/EMD Serono, AmgenMune, Celldex, ABBVie, Lilly/Imclone. Stock Ownership: BioCytics

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