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advanced NSCLC

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PHASE 2, OPEN-LABEL, INTERNATIONAL, NON-COMPARATIVE STUDY OF MEDI4736 IN PATIENTS WITH LOCALLY ADVANCED OR METASTATIC, PD-L1 + , STAGE 3B–4 NSCLC WHO HAVE RECEIVED ≥2 PRIOR SYSTEMIC TREATMENT REGIMENS (ATLANTIC)

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Background: The inhibitory programmed cell death-1 (PD-1)/programmed cell death ligand-1 (PD-L1) pathway plays a major role in controlling T-cell activation. Many cancers appear to exploit this pathway to evade antitumour responses. Encouraging clinical activity against several tumour types has been seen for anti-PD-L1 mAbs. 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 seen in a Phase 1 study, with initial data indicating that PD-L1 expression is associated with a higher objective response rate (ORR). An accelerated clinical development programme for MEDI4736 in NSCLC is underway. Here we describe the ATLANTIC (NCT02087423) study that is assessing the efficacy and safety of MEDI4736 in patients (pts) with locally advanced or metastatic NSCLC.

Trial design: In this Phase 2, open-label, international, non-comparative study, the efficacy and safety of MEDI4736 (10 mg/kg IV every 2 weeks for up to 12 months) is being assessed in pts with PD-L1$^+$ locally advanced or metastatic NSCLC (Stage 3B–4). Pts were initially included regardless of PD-L1 status, but once a diagnostic became available, this was amended to PD-L1$^+$ tumours only. Eligible pts must have a WHO Performance Status of 0 or 1, and received ≥2 prior systemic treatment regimens, including 1 platinum-based chemotherapy. Around 188 PD-L1$^+$ pts (Cohort 1: ~50% epidermal growth factor receptor [EGFR] or anaplastic lymphoma kinase [ALK] positive; Cohort 2: ~50% EGFR and ALK-negative), will be treated at ~100 sites across North America, Asia, and Europe. In Cohort 1, prior therapy must include the appropriate tyrosine kinase inhibitor. The primary outcome measure is ORR according to RECIST v1.1 based on independent central review. Secondary outcome measures