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Durvalumab is Clinically Active and Well-Tolerated in Heavily-Pretreated Metastatic Patients with NSCLC

Vienna, Austria—December 7, 2016—Dr. Marina Garassino, of the Fondazione IRCCS Istituto Nazionale dei Tumori in Milan, today presented data from a single-arm Phase II global trial that showed durvalumab was clinically active and well-tolerated when given to heavily-pretreated metastatic patients with non-small cell lung cancer (NSCLC). The data were presented at the **IASLC 17th World Conference on Lung Cancer (WCLC)** in Vienna, Austria.

Durvalumab is a monoclonal antibody that targets programmed death ligand 1 (PD-L1) and is currently being tested as both monotherapy and in combination with tremelimumab (CTLA-4 mAb) in NSCLC. Treatment with anti-PD-1/PD-L1 antibodies has demonstrated meaningful clinical benefit in patients with advanced NSCLC. However, patients that progress after two lines of chemotherapy have few treatment options and poor outcomes.

Dr. Marina Garassino and her colleagues presented data from a global trial that enrolled three groups of patients with locally-advanced unresectable or metastatic NSCLC in the Phase II ATLANTIC trial.

The trial includes three cohorts of patients all of which have EGFR/ALK wild-type or unknown status and previously received at least 2 lines of chemotherapy; the data presented at WCLC focus on results from Cohort 2 [divided into PD-L1 low (<25% tumour cells) and PD-L1 high (≥25% tumour cells)] and Cohort 3 [PD-L1 high (≥90% tumour cells)]. 60% of patients in cohort 2 and 40% of patients in cohort 3 received durvalumab as 4th line therapy or beyond.

Dr. Garassino reported that objective response rate (ORR) was higher in patients whose tumours were PD-L1 high (≥25% tumour cells), with observed rates of 30.9% (95% CI, 20.2–43.3) in Cohort 3 and rates of 16.4% (95% CI, 10.8–23.5) in PD-L1 high and 7.5% (95% CI, 3.1–14.5) in PD-L1 low from Cohort 2. Additionally, responses to durvalumab appeared durable, with one-year overall survival (OS) rates of 50.8% (95% CI, 36.9–63.2) in Cohort 3 and 47.7% (95% CI, 39.3–55.5) and 34.5% (95% CI, 25.0–44.1) in Cohort 2, PD-L1 high and low, respectively.

Durvalumab showed a manageable safety and tolerability profile; most adverse events (AEs) were low grade and resolved with treatment delay and/or immunosuppressive interventions. Grade ≥3 treatment-related AEs occurred in 8.3% and 17.6% of Cohort 2 and Cohort 3 patients, respectively.

“Results from this trial with durvalumab in a heavily pre-treated population, many of whom have had three or more prior regimens, are encouraging and consistent with efficacy observed with other IO medicines in metastatic, relapsed NSCLC” said Dr. Garassino.

About the WCLC:

The WCLC is the world’s largest meeting dedicated to lung cancer and other thoracic malignancies, attracting more than 6,000 researchers, physicians, and specialists from more than 100 countries. The goal is to increase awareness, collaboration, and understanding of lung cancer, and to help participants implement the latest developments across the globe. Organized under the theme of “Together Against Lung Cancer,” the conference will cover a wide range of disciplines and unveil several research studies and clinical trial results. For more information, visit <http://wclc2016.iaslc.org/>.

About the IASLC:

The International Association for the Study of Lung Cancer (IASLC) is the only global organization dedicated to the study of lung cancer. Founded in 1974, the association's membership includes more than 5,000 lung cancer specialists in over 100 countries. Visit www.iaslc.org for more information.

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