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Immune Checkpoint Inhibitor “Atezolizumab” Significantly Improves Progression Free Survival in Patients with Non-Small Cell Lung Cancer Compared with Chemotherapy in the IMpower150 Study

TOKYO, November 21, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today atezolizumab and combination of chemotherapy demonstrated a statistically significant improvement in progression free survival (PFS), one of the co-primary endpoints of the phase III IMpower150 study, compared with combination of chemotherapy in previously untreated patients with stage IV non-squamous non-small cell lung cancer (NSCLC). The IMpower150 study was designed to evaluate atezolizumab with combination of chemotherapy (atezolizumab, carboplatin, paclitaxel and bevacizumab) compared to combination of chemotherapy (carboplatin, paclitaxel and bevacizumab) in the first line treatment patients with stage IV non-squamous NSCLC. Initial observations for another co-primary endpoint of overall survival (OS) analysis are encouraging. These data are not fully mature and the next OS analysis will be expected in the first half of 2018. The safety profile of atezolizumab and bevacizumab plus chemotherapy combination appeared consistent with the known safety profile of the individual medicines, and no new safety signals were identified with the combination. The data of the IMpower150 study will be presented at the European Society for Medical Oncology (ESMO) Immuno Oncology Congress in Geneva, Switzerland in December 2017.

“Lung cancer is third most frequent cancer among Japanese[1)]. High unmet medical needs exist especially in advanced non-squamous NSCLC. We are pleased that the combination of atezolizumab and chemotherapy demonstrated an improved PFS this segment compared to chemotherapy alone,” said Dr. Yasushi Ito, Senior Vice President and Head of the Project Life Cycle Management Unit. “OS will be also investigated in future data analyses. We hope atezolizumab can further bring benefits to patients by showing improvement in OS.”

About the IMpower150 Study

The global phase III, multi-center, open label, randomized controlled study designed to evaluate the safety and the efficacy of atezolizumab in combination of chemotherapy compared to chemotherapy in previously untreated patients with stage IV non-squamous NSCLC.

- The study’s co-primary endpoints include:
  - PFS in all randomized people without an ALK or EGFR genetic mutation (intent to treat wild type, ITT-WT) and T-effector gene signature, “Teff” selected sub group people. This analysis of the study’s endpoint of PFS was only statistically powered to demonstrate a comparison between Arm B versus Arm C.
  - OS in ITT-WT population
- Study design

  1,202 patients were randomized into Arm A to C groups in a 1:1:1 ratio to receive the following treatment regimens once every three weeks. Treatment with atezolizumab was

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continued as long as the principal investigator determined that the patient was receiving a clinical benefit or until an unacceptable adverse event was confirmed.

Arm A	atezolizumab (1,200mg IV) + carboplatin (AUC 6) + paclitaxel (200 mg/m^2 IV)
Arm B	atezolizumab (1,200mg IV) + carboplatin (AUC 6) + paclitaxel (200 mg/m^2 IV) + bevacizumab (15 mg/kg IV)
Arm C	carboplatin (AUC 6) + paclitaxel (200 mg/m^2 IV) + bevacizumab (15 mg/kg IV)

About atezolizumab

Atezolizumab is a monoclonal antibody designed to target a protein called PD-L1 (programmed death ligand-1), which is expressed on tumour cells and tumour-infiltrating immune cells. PD-L1 binds to PD-1 and B7.1, both found on the surface of T cells, causing inhibition of T cells. By blocking this coupling, atezolizumab may enable to release the suppression of T cells and promotes T cells to effectively attack tumor cells.

Atezolizumab (overseas brand name: TECENTRIQ®) is the anti-PD-L1 immune checkpoint inhibitor. In US, atezolizumab was granted accelerated approval for the second line treatment of locally advanced or metastatic urotherial carcinoma (mUC) by the FDA in May, 2016. The FDA also approved atezolizumab as the treatment of metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy in October, 2016 and granted accelerated approval as the first line treatment of locally advanced or mUC who are ineligible for cisplatin chemotherapy in April, 2017. In EU, EMA approved atezolizumab for the second line treatment of locally advanced or mUC, the treatment of metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy and the first line treatment of locally advanced or mUC who are ineligible for cisplatin chemotherapy in September 2017. In Japan, the new drug application of atezolizumab for the treatment of unresectable advanced or recurrent NSCLC was filed in February, 2017.

1) Center for Cancer Control and Information Services. Projected Cancer Statistics, 2015 (http://ganjoho.jp/en/)

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