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“Atezolizumab” plus “Avastin” Significantly Improves Progression Free Survival Compared with Sunitinib in PD-L1 Positive Patients for the First-line Treatment of Advanced Renal Cell Carcinoma in the IMmotion151 Study

TOKYO, December 11, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that the phase III IMmotion151 study met its co-primary endpoint of investigator-assessed progression free survival (PFS), and demonstrated that the combination of atezolizumab and Avastin® showed statistically significant improvement in PFS compared with sunitinib in patients whose disease expressed PD-L1 (programmed death-ligand 1: Expression ≧1%) for the first-line treatment of locally advanced or metastatic renal cell carcinoma (RCC).

Observations of as pre-specified subgroup analysis of the atezolizumab and Avastin combination indicated that, in people whose disease expressed PD-L1, a numerical difference favoring atezolizumab and Avastin group was seen across all patient risk factor groups (favorable, intermediate and poor) compared to sunitinib; however, due to the study design these data could not be assessed for statistical significance and are descriptive only. As data is not fully matured, analysis for another co-primary endpoint of overall survival (OS) as well as the assessment of secondary endpoints is ongoing. Safety for the atezolizumab and Avastin combination appeared consistent with the known safety profile of the individual medicines and what was previously reported in the Phase II IMmotion150 study. No new safety signals were identified with the combination. The data of the IMmotion151 study will be presented at an upcoming oncology conference in 2018.

“Avastin is currently approved overseas for the treatment of RCC in combination with interferon. We are pleased that this study in which Japanese patients are participating showed that combination of atezolizumab and Avastin demonstrated an improvement in PFS,” said Dr. Yasushi Ito, Senior Vice President and Head of Project & Lifecycle Management Unit. “We are committed to prepare the filing for approval in order to deliver both drugs to patients as a new treatment option as soon as possible.”

About the IMmotion151 Study

A global phase III, multi-center, open label, randomized study designed to evaluate the efficacy and safety of atezolizumab plus Avastin compared to sunitinib in previously untreated patients with locally advanced or metastatic RCC.

- The study’s co-primary endpoints include PFS in people whose tumors expressed PD-L1 (PD-L1 expression ≧1%) on immune cells (IC) and OS in intent to treat (ITT) population. PD-L1 expression was assessed using an immunohistochemistry (IHC) test, SP142 developed by Roche.

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- Depending on the presence of one or several of five risk factors, patients are classified in one of the three risk groups: “Favorable” with 0 risk factors, “Intermediate” with 1-2 risk factors and “Poor” with 3 or more factors.
- Study design
  915 patients were randomized into atezolizumab plus Avastin or sunitinib arm in a 1:1 ratio to receive treatment according to each group’s treatment regimen.

In Japan, Avastin is not approved for the treatment of RCC.

About atezolizumab

Atezolizumab is a monoclonal antibody designed to target a protein called PD-L1 (programmed death ligand-1), which is expressed on tumor cells and tumor-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 an anti-PD-L1 immune checkpoint inhibitor. In US, atezolizumab was granted accelerated approval for the second line treatment of locally advanced or metastatic urothelial 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 non-small cell lung cancer (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.

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