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Update on Phase III study of Immune Checkpoint Inhibitor “Atezolizumab” in Patients with Locally Advanced or Metastatic Urotherial Carcinoma

-- IMvigor211 study did not meet its primary endpoint of overall survival with atezolizumab monotherapy compared to chemotherapy --

TOKYO, May 10, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that atezolizumab did not meet its primary endpoint of statistically meaningful improvement in overall survival (OS) compared to chemotherapy in the phase III IMvigor211 study in patients with locally advanced or metastatic urotherial carcinoma (mUC) whose disease progressed during or following a platinum-containing chemotherapy. The safety profile of atezolizumab in this study was consistent with those observed in previous studies, with no new or unexpected adverse events. The results observed in people treated with atezolizumab in IMvigor 211 were generally consistent with those observed in a similar group of people in the Phase II IMvigor 210 study. However, the chemotherapy arm results were better than study design assumptions. The data of the study will be presented in the future.

"The previous studies showed atezolizumab helped people with locally advanced or mUC. We were hopeful that we could show a similar result in this study," said Dr. Yasushi Ito, Senior Vice President and Head of the Project Life Cycle Management Unit. "We will be working together with Roche to better understand the results and determine the next steps."

About the IMvigor211 Study

The global phase III, multi-centre, open label, randomized controlled study designed to evaluate the safety and the efficacy of atezolizumab compared to chemotherapy* (vinflunine, paclitaxel or docetaxel) in patients with locally advanced or mUC whose disease progressed during or following platinum-containing regimen.

- The primary endpoint of this study is OS.
- Secondary endpoints include safety, overall response rate, progression free survival, and duration of response.

931 patients were randomized into groups with a one to one ratio to receive either one of the chemotherapies vinflunine (320 mg/m^2) / paclitaxel (175 mg/m^2) / docetaxel (75 mg/m^2) or atezolizumab (1,200 mg) by intravenous injection once every three weeks. Treatment with atezolizumab was continued as long as the principal investigator determined that the patient was receiving a clinical benefit or until an unacceptable adverse event was confirmed.

* As paclitaxel and docetaxel are not approved for the indication of UC in Japan, reimbursement of the use of two drugs for the treatment of UC is officially allowed by the Ministry of Health, Labour, and Welfare. Vinflunine is not approved in Japan.

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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 releases the suppression of T cells and promotes T cells to attack tumour cells.

Atezolizumab (overseas brand name: Tecentriq®) is the anti-PD-L1 immune checkpoint inhibitor and was granted accelerated approval for the second line treatment of locally advanced or mUC by the FDA in May, 2016. The FDA also granted accelerated approval for atezolizumab as the treatment of metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy in October, 2016 and as the first line treatment of locally advanced or mUC who are ineligible for cisplatin chemotherapy in April, 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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