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New Drug Application Filed for Immune Checkpoint Inhibitor, Atezolizumab

- First Application as anti PD-L1 Antibody for the Treatment of Unresectable Advanced or Recurrent Non-Small Cell Lung Cancer in Japan -

TOKYO, February 17, 2017 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has filed a new drug application to the Ministry of Health, Labour and Welfare (MHLW), for Engineered anti PD-L1 monoclonal antibody “atezolizumab (genetic recombinant)” for the treatment of “unresectable advanced or recurrent non-small cell lung cancer (NSCLC).”

“The cancer immunotherapy has set a new trend of cancer treatment worldwide,” said Dr. Yasushi Ito, Chugai’s Senior Vice President, Head of Project & Lifecycle Management Unit. ”Atezolizumab, an immune checkpoint inhibitor, is the only anti PD-L1 antibody approved in the United States for the treatment of lung cancer. We are committed to deliver atezolizumab to patients as early as possible to contribute to the development of and access to better treatments in Japan.”

Chugai filed the application with the MHLW based on the results from a global phase III clinical study (the OAK study) and several clinical studies.

The OAK study is a global, multicenter, open-label, randomized, controlled Phase III study that evaluated the efficacy and safety of atezolizumab compared with docetaxel in people with locally advanced or metastatic NSCLC whose disease had progressed following previous treatment with platinum-containing chemotherapy, with the primary analysis consisting of the first 850 randomized patients. The primary endpoint of this study was overall survival (OS).

The study showed that the median OS was 13.8 months (95% CI: 11.8-15.7 months) for the atezolizumab group and 9.6 months (95% CI: 8.6-11.2 months) for the docetaxel group. The atezolizumab arm showed a statistically significant OS extension, regardless of their levels of PD-L1 expression [HR=0.73 (95% CI: 0.62-0.87), P=0.0003 (stratified log-rank test)].

As for safety, the adverse events (AEs) expressed in both arms in the OAK study were consistent with previous reports. AEs occurring more frequently for atezolizumab arm than docetaxel arm were musculoskeletal pain (10.5% for atezolizumab vs. 4.3% for docetaxel) and pruritus (8.2% for atezolizumab vs. 3.1% for docetaxel).

Please refer to Roche’s press release on October 9, 2016 for the details of the OAK study results.
http://www.roche.com/media/store/releases/med-cor-2016-10-09.htm

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In Japan, the annual forecast of a lung cancer prevalence is estimated to be about 134,000 in 2015 (male: 91,000, female: 43,000). The annual mortality of lung cancer is about 77,000 (male: 55,000, female: 22,000, predicted figure at 2015) and lung cancer is the leading cause of cancer deaths in Japan.*

As the top pharmaceutical company in the field of oncology in Japan, Chugai will work for the early approval to provide atezolizumab as a new treatment option for patients with unresectable advanced or recurrent NSCLC and medical professionals.

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

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 enable the activation of T cells, effectively detect and attack tumour cells.

Atezolizumab (overseas brand name: Tecentriq®) is the anti-PD-L1 immune checkpoint inhibitor approved by the FDA, and is indicated for the treatment of locally advanced or metastatic urothelial carcinoma (UC) in May, 2016 and for the treatment of metastatic NSCLC who have disease progression during or following platinum-containing chemotherapy in October, 2016. The FDA granted priority review for atezolizumab for the treatment of locally advanced or metastatic UC who are ineligible for cisplatin chemotherapy.

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