



Chugai Obtains Approval of Humanized Anti-PD-L1 Monoclonal Antibody, “TECENTRIQ® Intravenous Infusion 1200mg” for the Treatment of Unresectable, Advanced or Recurrent Non-small Cell Lung Cancer

TOKYO, January 19, 2018 -- [Chugai Pharmaceutical Co., Ltd.](http://www.chugai-pharm.co.jp) (TOKYO: 4519) announced today that it has obtained approval of its humanized anti-PD-L1 (Programmed Death Ligand-1) monoclonal antibody, “TECENTRIQ® Intravenous Infusion 1200mg” (generic name: atezolizumab [recombinant]) from the Ministry of Health, Labour and Welfare (MHLW) for the treatment of “unresectable advanced or recurrent non-small cell lung cancer (NSCLC).”

“This is the first approval for TECENTRIQ in Japan, and it also represents the first step for Chugai to provide cancer immunotherapy,” said Chugai’s President & COO, Tatsuro Kosaka. “We have been preparing for the new launch to provide TECENTRIQ for all patients as early as possible, and will take every measures to deliver the information needed to promote its appropriate use.”

TECENTRIQ is a PD-L1 targeting monoclonal antibody created by Genentech, a member of the Roche Group. PD-L1 is a protein expressed on tumor and tumor-infiltrating immune cells that blocks T cell activity by binding with PD-1 and B7.1 receptors on T cell surface. By inhibiting PD-L1, TECENTRIQ may enable the activation of T cells and boost immune response against cancer cells.

TECENTRIQ is already approved in the European Union, United States and more than 50 countries for people with previously treated metastatic NSCLC and for people with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin chemotherapy, or who have had disease progression during or following platinum-containing therapy. In Japan, Chugai has been conducting seven clinical studies in the NSCLC setting to evaluate TECENTRIQ alone or in combination with other drugs. In addition to NSCLC studies, several phase III studies are ongoing for small-cell lung cancer, urothelial carcinoma, breast cancer, renal cell carcinoma, ovarian cancer and prostate cancer.

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

As a top pharmaceutical company in the field of oncology in Japan, Chugai is committed to contribute to patients with lung cancers and medical professionals by offering TECENTRIQ as a new treatment option.

About conditions for approval of TECENTRIQ

A drug use surveillance of all patients who receive TECENTRIQ must be conducted until the data on a given number of patients is accumulated.

About the drug use surveillance of TECENTRIQ (All-case registration surveillance)

The all-case registration surveillance is scheduled to collect the data of 1,000 patients who receive TECENTRIQ treatment. Once data for the first 1,000 cases is accumulated, the data will be reviewed to determine whether a new surveillance or further safety measures should be conducted. Results of the surveillance will be reported to the regulatory authorities, and the data shall be announced at future scientific meetings.

Note: The description of INDICATIONS in the Japanese package insert

The following description is noted as <Precautions related to INDICATIONS> in the INDICATIONS:

1. Efficacy and safety of TECENTRIQ in chemotherapy-naïve patients have not been established.
2. Efficacy and safety have not been established for postoperative adjuvant chemotherapy with TECENTRIQ.
3. Eligible patients should be selected after closely reading the CLINICAL STUDIES section, which provides information such as the prior treatment history of patients in the clinical studies, in order to gain a thorough understanding of the efficacy and safety of TECENTRIQ.

Trademarks used or mentioned in this release are protected by law.

* Center for Cancer Control and Information Services. Projected Cancer Statistics, 2015:
<http://ganjoho.jp/en/> (as of January 18, 2018.)

###