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Launch of the Anti-Cancer Agent / a Humanized Anti-PD-L1 Monoclonal Antibody “TECENTRIQ®”

TOKYO, April 18, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it has launched atezolizumab, a recombinant humanized anti-PD-L1 monoclonal antibody, (brand name, “TECENTRIQ® Intravenous Infusion 1200 mg;” hereafter, “TECENTRIQ”) for the treatment of “unresectable advanced or recurrent non-small cell lung cancer (NSCLC) today. TECENTRIQ received a manufacturing and marketing approval on January 19, 2018 and was listed on the National Health Insurance (NHI) reimbursement price list today.

“Cancer immunotherapy is expected to be a breakthrough therapy which may significantly change cancer treatment. As our mission is to deliver innovative therapeutic drugs to patients, it is a great pleasure for us to finally being able to launch TECENTRIQ,” said Chugai’s President & CEO, Tatsuro Kosaka. “We will continue our research and development activities in multiple cancer types and combination therapies to realize sustained therapeutic effects and improvement of survival rate, as well as cure in more patients with cancer.”

TECENTRIQ is an immune checkpoint inhibitor targeting PD-L1 (Programmed Death-Ligand 1) which is a protein expressed on tumor cells and tumor-infiltrating immune cells. PD-L1 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.

In Japan, the annual prevalence of lung cancer is estimated to be approximately 128,700 in 2017 (male: 86,700, female: 42,000). The annual mortality of lung cancer, the leading cause of cancer deaths (the second leading cause in women) in Japan, is approximately 78,000 (male: 55,600, female: 22,400; predicted figure for 2017).*

As a top company in the field of oncology in Japan, Chugai firmly believes that the launch of TECENTRIQ in Japan as a new therapeutic option for the treatment of “unresectable advanced or recurrent NSCLC,” will allow us to further contribute to treat patients and promote appropriate use of drugs.

* Center for Cancer Control and Information Services. Projected Cancer Statistics, 2017: (http://ganjoho.jp/en/) as of April 10, 2018.)

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Drug Information

Product name:	TECENTRIQ® Intravenous Infusion 1200 mg
Generic name:	atezolizumab (recombinant)
Indications:	Unresectable, advanced or recurrent non-small cell lung cancer <Precautions related to INDICATIONS> 1. The efficacy and safety of TECENTRIQ in chemotherapy-naive patients has not been established. 2. Efficacy and safety have not been established for postoperative adjuvant chemotherapy with TECENTRIQ. 3. Regarding the information on prior treatment history of patients participated in the clinical studies as provided in the CLINICAL STUDIES section, eligible patients should be selected after closely reading the CLINICAL STUDIES section to gain a thorough understanding of the efficacy and safety of TECENTRIQ.
Dosage and administration:	The usual adult dosage is 1200 mg atezolizumab (recombinant) administered by intravenous infusion over 60 minutes once every 3 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes.
Date of approval:	January 19, 2018
Date of NHI reimbursement price listing:	April 18, 2018
Date of launch:	April 18, 2018
Shelf life:	3 years
Drug price:	TECENTRIQ® Intravenous Infusion 1200 mg JPY 625,567/Vial