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Chugai Obtains Approval for Tecentriq as a Monotherapy for Chemotherapy-Naïve PD-L1-Positive Unresectable Advanced or Recurrent Non-Small Cell Lung Cancer (NSCLC)

- The 4th* new therapy for chemotherapy-naïve unresectable advanced or recurrent NSCLC
- Approval based on the results from phase III IMpower110 study showing Tecentriq demonstrated a significant overall survival in patients with advanced NSCLC with high PD-L1 expression compared with chemotherapy

TOKYO, December 25, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it has obtained regulatory approval for its humanized anti-PD-L1 monoclonal antibody, Tecentriq® Intravenous Infusion 1200 mg [generic name: atezolizumab (genetical recombination)] from the Ministry of Health, Labour and Welfare (MHLW) for additional dosing for the treatment of chemotherapy-naïve PD-L1-positive unresectable advanced or recurrent non-small cell lung cancer (NSCLC).

VENTANA OptiView PD-L1 (SP142), a pathological testing kit marketed by Roche Diagnostics K.K., should be used to detect PD-L1 expression. Expanded use of VENTANA OptiView PD-L1 (SP142) as a companion diagnostic of Tecentriq was approved on December 15, 2020 to allow physicians to identify patients with PD-L1-positive NSCLC who could benefit from Tecentriq.

“We are very pleased with this additional approval for Tecenctriq monotherapy, which demonstrated a significant prolongation of overall survival in patients with chemotherapy-naïve PD-L1-positive NSCLC,” said Dr. Osamu Okuda, Chugai’s President & COO. “Tecentriq is approved for five different therapies in NSCLC, including a monotherapy in patients previously treated with chemotherapy, three combination therapies in chemotherapy-naïve patients, and a newly approved monotherapy. We are committed to making our contribution to patients through these different therapies.”

This approval is based on the results from the phase III IMpower110 study. The study met its primary endpoint in an interim analysis showing that Tecentriq monotherapy improved overall survival (OS) by 7.1 months compared with chemotherapy alone in patients with high PD-L1 expression (TC3/IC3-WT) (median OS = 20.2 versus 13.1 months; hazard ratio = 0.595, 95%CI: 0.398 – 0.890; p = 0.0106 [stratified log-rank test]; two-sided significance level: 0.0413). The most common adverse events (≥5%) were fatigue, asthenia, nausea, decreased appetite, hypothyroidism, rash, increased ALT, and diarrhea.

As a leading company in the field of oncology in Japan, Chugai will continue to promote the proper use of Tecentriq so that it can contribute to the treatment of unresectable advanced or recurrent NSCLC as a new therapeutic option.

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*Tecentriq is approved in patients with chemotherapy-naïve unresectable advanced or recurrent NSCLC for three combination therapies with other anti-neoplastic drugs, including 1) carboplatin + paclitaxel + bevacizumab, 2) carboplatin or cisplatin + pemetrexed, and 3) carboplatin + paclitaxel (albumin-bound), in addition to a newly approved monotherapy.

<Reference>
Roche's Tecentriq improves overall survival as a first-line monotherapy in certain people with advanced non-small cell lung cancer (Press release issued by Roche on September 27, 2019)
https://www.roche.com/media/releases/med-cor-2019-09-27b.htm

Prescribing Information *In case of non-small cell lung cancer. The underlined parts were newly added.

Indications	Unresectable, advanced or recurrent non-small cell lung cancer
Dosage and administration	・ For patients with chemotherapy-naïve unresectable advanced or recurrent non-squamous non-small cell lung cancer The usual adult dosage is 1200 mg of atezolizumab (genetical recombination) in combination with other anti-neoplastic drugs 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. ・ For patients with chemotherapy-naïve PD-L1 positve unresectable advanced or recurrent non-small cell lung cancer The usual adult dosage is 1200 mg of atezolizumab (genetical recombination) 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. ・ For patients with unresectable advanced or recurrent non-small cell lung cancer previously treated with chemotherapy The usual adult dosage is 1200 mg of atezolizumab (genetical recombination) 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.

About non-small cell lung cancer (NSCLC)
In Japan, 125,100 people (84,500 men and 40,600 women; 2018 predicted values) are estimated to be afflicted with lung cancer each year. 77,500 people in Japan (55,100 men and 22,400 women; 2018 predicted values) die as a result of the disease. Lung cancer is the leading cause of cancer death. Lung cancer can be broadly divided into small cell lung cancer and NSCLC according to the tissue type. NSCLC has the largest number of patients, accounting for about 85% of all lung cancer cases.

About approval status of Tecentriq in Japan
Tecentriq was launched in April 2018 with an indication of unresectable, advanced or recurrent non-small cell lung cancer (NSCLC), followed by an approval for the additional dosing for the treatment of untreated unresectable, advanced or recurrent NSCLC in December 2018. In addition, an approval of extensive-stage small cell lung cancer has been obtained in August 2019, an approval of PD-L1 positive hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer has been obtained in September 2019, and an approval for the additional dosing for the treatment of chemotherapy-naïve unresectable advanced

or recurrent non-squamous NSCLC has been obtained in November 2019. In September 2020, Tecentriq was approved for the treatment of unresectable hepatocellular carcinoma.

Sources

1. Cancer Registry and Statistics. Cancer Information Service, National Cancer Center Japan from: https://ganjoho.jp/en/professional/statistics/table_download.html. Accessed December 2020
2. American Cancer Society: What Is Lung Cancer? https://www.cancer.org/cancer/lung-cancer/about/what-is.html. Accessed December 2020

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