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Chugai's Tecentriq Obtains Regulatory Approval as the First Immunotherapy in Japan for Adjuvant Treatment of Non-small Cell Lung Cancer

- Anti-PD-L1 antibody Tecentriq received regulatory approval for an additional indication of adjuvant treatment for PD-L1-positive non-small cell lung cancer (NSCLC)
- Tecentriq is the first cancer immunotherapy which showed efficacy as an adjuvant treatment for NSCLC in a global phase III study
- The approval makes cancer immunotherapy available as one of treatment options for early-stage NSCLC

TOKYO, May 26, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained regulatory approval for an additional indication of the anti-cancer agent/humanized anti-PD-L1 monoclonal antibody Tecentriq® Intravenous Infusion 1200 mg [generic name: atezolizumab (genetical recombination)] for the adjuvant treatment of PD-L1-positive non-small cell lung cancer (NSCLC) from the Ministry of Health, Labour and Welfare.

VENTANA OptiView PD-L1 (SP263), a pathological testing kit marketed by Roche Diagnostics K.K., should be used to detect PD-L1 expression. An expanded use of this test kit as a companion diagnostic for Tecentriq was approved on May 23, 2022 to allow physicians to identify patients with PD-L1-positive NSCLC who could benefit from Tecentriq.

"I am very pleased that we can offer Tecentriq as the first cancer immunotherapy for adjuvant treatment of NSCLC. This makes cancer immunotherapy available for certain patients with early-stage NSCLC," said Chugai's President and CEO, Dr. Osamu Okuda. "In early-stage cancer, it is critical to prevent recurrence and increase the chance of cure, the ultimate goal of treatment. Tecentriq is the first cancer immunotherapy to demonstrate a reduction in the risk of recurrence or death in early-stage lung cancer, for which there has been no significant progress in treatment over the past decade. We will continue our efforts to provide information on the proper use of Tecentriq in order to contribute to postoperative adjuvant treatment of non-small cell lung cancer."

This approval is based on the results from phase III IMpower010 study examining Tecentriq as an adjuvant treatment in NSCLC. The study showed that treatment with Tecentriq following surgery and chemotherapy reduced the risk of disease recurrence or death (disease-free survival; DFS) by 34% (hazard ratio [HR]=0.66, 95% CI: 0.50–0.88) in people with Stage II-IIIA NSCLC, whose tumors express PD-L1≥1%, compared with best supportive care (BSC). The most frequent adverse reactions (5% or more) included hypothyroidism, pruritus, rash, increased AST, increased ALT, hyperthyroidism, pyrexia, and arthralgia.

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Approval Information *Newly added description

Indications:

Adjuvant treatment of PD-L1-positive non-small cell lung cancer

Dosage and administrations:

The usual adult dosage is 1200 mg atezolizumab (genetical recombination) administered by intravenous infusion over 60 minutes once every 3 weeks. The dosage period is up to 12 months. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes.

<References>

Chugai Files for Additional Indication of Tecentriq for the Adjuvant Treatment of Non-small Cell Lung Cancer (July 7, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210707170000_839.html

Pivotal Phase III data at ASCO show Roche's Tecentriq helps certain people with early lung cancer live significantly longer without their disease returning (Press release by Roche issued on May 20, 2021)
https://www.roche.com/media/releases/med-cor-2021-05-20

About IMpower010 study

IMpower010 is a Phase III, global, multicenter, open-label, randomized study evaluating the efficacy and safety of Tecentriq compared with BSC, in participants with Stage IB-IIIA NSCLC (UICC 7th edition), following surgical resection and up to 4 cycles of adjuvant cisplatin-based chemotherapy. The study randomized 1,005 people with a ratio of 1:1 to receive either at most 16 cycles of Tecentriq or BSC. The primary endpoint is investigator-determined DFS in the PD-L1-positive Stage II-IIIA, all randomized Stage II-IIIA and ITT Stage IB-IIIA populations. Key secondary endpoints include OS in the overall study population, ITT Stage IB-IIIA NSCLC.

About non-small cell lung cancer (NSCLC)

In Japan, 122,825 people (82,046 men and 40,777 women; 2018) reportedly become afflicted with lung cancer each year. 75,585 people in Japan (53,247 men and 22,338 women; 2020) reportedly die as a result of the disease. Lung cancer is the leading cause of cancer death.[1)] 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.[2)]

About approval status of Tecentriq in Japan

Tecentriq was launched in Japan in April 2018 for 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 2019, the drug obtained regulatory approval for additional indications of extensive-stage small cell lung cancer in August, PD-L1-positive hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer in September, and for an additional dosing for the treatment of chemotherapy-naïve unresectable advanced or recurrent non-squamous NSCLC in November. In 2020, Tecentriq was approved for the treatment of unresectable hepatocellular carcinoma in September, followed by an approval for the additional dosing for the treatment

of untreated PD-L1-positive, unresectable, advanced or recurrent NSCLC in December.

Sources

1. Cancer Registry and Statistics. Cancer Information Service, National Cancer Center Japan from: https://ganjoho.jp/reg_stat/statistics/data/dl/en.html. Accessed May 2022
2. American Cancer Society: What Is Lung Cancer? https://www.cancer.org/cancer/lung-cancer/about/what-is.html. Accessed May 2022

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