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Chugai Files for Additional Indication of Tecentriq for the Adjuvant Treatment of Non-small Cell Lung Cancer

- Tecentriq is the first cancer immunotherapy which showed efficacy for the adjuvant treatment of non-small cell lung cancer (NSCLC)
- The filing is based on the results from the phase III IMpower010 study in which Tecentriq improved disease-free survival by 34% in people with PD-L1-positive resectable early-stage lung cancer, compared with best supportive care

TOKYO, July 7, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed regulatory application with the Ministry of Health, Labour and Welfare for 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 non-small cell lung cancer (NSCLC) on July 6, 2021.

“Approximately 50% of patients with early-stage lung cancer experience relapse following surgery. It is very important to prevent recurrence in order to improve the cure rate. Tecentriq is the first cancer immunotherapy which reduced the risk of disease recurrence or death in NSCLC as adjuvant therapy following surgery,” said Chugai’s President and CEO, Dr. Osamu Okuda. “We are working to obtain regulatory approval to deliver Tecentriq, which has been shown to reduce the rate of recurrence or death, to patients as soon as possible as a new adjuvant treatment for early-stage lung cancer.”

This filing is based on the results from phase III IMpower010 study examining Tecentriq as an adjuvant treatment in NSCLC. The study showed for the first time 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). VENTANA OptiView PD-L1 (SP263) Assay, a pathological testing kit marketed by Roche Diagnostics K.K., was used to detect PD-L1 expression. Safety data for Tecentriq were consistent with its known safety profile and no new safety signals were identified.

<Reference>
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.htm

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),

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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, 130,000 people (86,800 men and 43,100 women; 2020 predicted values) are estimated to be afflicted with lung cancer each year. 75,600 people in Japan (53,200 men and 22,300 women; 2020 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. Tecentriq was approved for the treatment of unresectable hepatocellular carcinoma in September 2020, followed by an approval for the additional dosing for the treatment of untreated PD-L1 positive, unresectable, advanced or recurrent NSCLC in December 2020.

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 July 2021
2. American Cancer Society: What Is Lung Cancer? https://www.cancer.org/cancer/lung-cancer/about/what-is.html. Accessed July 2021

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