News Release

Chugai Files for Additional Indication of Tecentriq for the Treatment of Thymic Carcinoma

- The filing is based on the results from an investigator-initiated Japanese phase II clinical study evaluating Tecentriq in combination with carboplatin and paclitaxel, the standard chemotherapy regimen for unresectable thymic carcinoma as first-line treatment
- Designated as an orphan drug, making it eligible for priority review
- If approved, Tecentriq would become the first immune checkpoint inhibitor in Japan for thymic carcinoma

TOKYO, May 14, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed a regulatory application with the Ministry of Health, Labour and Welfare (MHLW) for the anti-cancer agent/humanized anti-PD-L1 monoclonal antibody Tecentriq® Intravenous Infusion [generic name: atezolizumab (genetical recombination)] for an additional indication of thymic carcinoma. Tecentriq received orphan drug designation for this indication from the MHLW on March 31 this year, and the applications will be reviewed under priority review.

“Thymic carcinoma is a rare cancer with poor prognosis after recurrence, and there is a need for new treatment options. We are working to obtain approval so that Tecentriq that demonstrated favorable efficacy in combination with standard chemotherapy can be delivered to patients as soon as possible as a new therapeutic option for thymic carcinoma,” said Chugai's President and CEO, Dr. Osamu Okuda.

This filing is based on the results from a phase II MARBLE study initiated by investigators, which evaluated the efficacy and safety of Tecentriq in combination with carboplatin and paclitaxel as first-line treatment for patients with unresectable thymic carcinoma. In this study, the overall response rate, which was the primary endpoint, was 56.3% (95% CI: 41.2-70.5). Common adverse reactions included peripheral sensory neuropathy, alopecia, constipation, anemia, decreased white blood cell count, nausea, maculopapular rash, neutropenia, decreased neutrophil count, decreased appetite, fatigue, and arthralgia. The safety profile observed in this study was consistent with the known safety profiles of each drug.

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Chugai Pharmaceutical, a leading company in the oncology field, remains committed to addressing unmet medical needs in cancer treatment with innovative medicines, supporting patients and healthcare professionals.

About MARBLE study[1]

MARBLE study (jRCT2031220144) is a Japanese Phase II, multicenter, open-label, single-arm study led by physicians to evaluate the efficacy and safety of Tecentriq in combination with carboplatin and paclitaxel in patients aged 20 years or older with unresectable or advanced recurrent thymic carcinoma. The study evaluated safety and efficacy in 48 patients. The primary endpoint was overall response rate, and secondary endpoints included progression-free survival, overall survival, and safety.

About thymic carcinoma

Thymic carcinoma is a type of thymic epithelial tumor that originates from the thymic epithelium, which plays an important role in T-lymphocyte maturation, and is characterized by cellular atypia. The annual incidence in Japan is estimated to be 0.29 per 100,000 people[2]. The prognosis for unresectable cases is poor, highlighting the need for new therapeutic options.

About Tecentriq

Tecentriq is a cancer immune checkpoint inhibitor targeting PD-L1, which is a protein expressed on tumor 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, Tecentriq was launched in April 2018 and has obtained approval for 5 indications (extensive-stage small cell lung cancer, non-small cell lung cancer, breast cancer, hepatocellular carcinoma, and alveolar soft part sarcoma).

Sources

1. Takehito S, et al. Activity and safety of atezolizumab plus carboplatin and paclitaxel in patients with advanced or recurrent thymic carcinoma (MARBLE): a multicentre, single-arm, phase 2 trial. Lancet Oncol. 2025 Mar;26(3):331-342.
2. Koizumi T, et al. National incidence and initial therapy for thymic carcinoma in Japan: based on analysis of hospital based cancer registry data, 2009-2015. Jpn J Clin Oncol. 2020;50(4):434 9.

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