News Release

Chugai Obtains Regulatory Approval for Tecentriq for the Additional Indication of Thymic Carcinoma, a Rare Disease

- The first immune-checkpoint inhibitor approved in Japan for unresectable thymic carcinoma
- The approval is based on the results of an investigator-initiated, Japanese Phase II clinical trial that evaluated Tecentriq in combination with standard chemotherapy (carboplatin and paclitaxel) as a first-line treatment

TOKYO, December 22, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained approval from 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 unresectable thymic carcinoma. Tecentriq received orphan drug designation for this indication from the MHLW on March 31, 2025. Chugai subsequently filed an application on May 14, 2025, which underwent Priority Review.

“We are very pleased to be able to deliver Tecentriq as a new treatment option for unresectable thymic carcinoma. Effective treatment options for this disease are limited, and new therapies have been highly anticipated. We will continue our efforts to provide information on the proper use of Tecentriq to contribute to the patients with thymic carcinoma.” said Chugai's President and CEO, Dr. Osamu Okuda.

This approval is based on the results from the investigator-initiated phase II MARBLE study conducted in Japan, which evaluated the efficacy and safety of Tecentriq in combination with carboplatin and paclitaxel as first-line treatment for patients with unresectable thymic carcinoma.

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.

Approval Information *Excerpt from related parts
Indication: Unresectable thymic carcinoma
Dosage and administration:
All indications: The initial dose of Tecentriq must be administered over 60 minutes. If the first infusion is tolerated, all subsequent infusions may be administered over 30 minutes.

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Unresectable thymic carcinoma: The usual adult dosage is 1200 mg atezolizumab (genetical recombination) in combination with carboplatin and paclitaxel by intravenous infusion once every 3 weeks.

[Reference]

Chugai Files for Additional Indication of Tecentriq for the Treatment of Thymic Carcinoma (Press release by Chugai issued on May 14, 2025)
https://www.chugai-pharm.co.jp/english/news/detail/20250514153000_1155.html

About MARBLE study[1]

MARBLE study (jRCT2031220144) is a Japanese Phase II, multicenter, open-label, single-arm study led by investigators 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[3]

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 the 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 6 tumor types (extensive-stage small cell lung cancer, non-small cell lung cancer, breast cancer, hepatocellular carcinoma, alveolar soft part sarcoma, and extranodal NK/T-cell lymphoma, nasal type).

Sources

1. Shukuya T, 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.

3. Tecentriq Intravenous Infusion 840 mg / 1200 mg. Electronic Package Insert Information (Revised December 2025, 12th Edition)