News Release

Chugai Obtains Regulatory Approval for Tecentriq for the Additional Indication of Alveolar Soft Part Sarcoma, an Ultra-rare Disease

- Tecentriq is the first immune checkpoint inhibitor in Japan for unresectable alveolar soft part sarcoma, a disease with no standard treatment established
- Approval for unresectable alveolar soft part sarcoma in adults and children over 2 years, which is a type of alveolar soft part sarcoma of high incidence in the AYA (Adolescent and Young Adult) generation
- The approval is based on the results from an investigator-initiated Japanese phase II clinical study and a U.S. NCI-initiated overseas phase II clinical study

TOKYO, February 20, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained regulatory approval today from the Ministry of Health, Labour and Welfare 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 alveolar soft part sarcoma. Tecentriq is the first immune checkpoint inhibitor in Japan for the treatment of this disease.

“We are very pleased that we can offer Tecentriq as a new treatment for unresectable alveolar soft part sarcoma in adults and children over 2 years. This very rare disease, which occurs most often in the adolescents and young adults (AYA) generation, is known to have a poor prognosis with no standard treatment if it becomes unresectable. We will continue our efforts to provide information on the proper use of Tecentriq in order to contribute to the patients with unresectable alveolar soft part sarcoma,” said Chugai’s President and CEO, Dr. Osamu Okuda.

This approval is based on the results from a phase II ALBERT study initiated by investigators in Japan including National Cancer Center Hospital and an overseas phase II clinical study conducted by the National Cancer Institute (NCI), which evaluated the efficacy and safety of Tecentriq in patients with unresectable alveolar soft part sarcoma.

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1 Nihonbashi-Muromachi 2-chome, Chuo-ku, Tokyo 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

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 *Newly added description
Indications: unresectable alveolar soft part sarcoma
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 usual dose for children over 2 years old is 15 mg/kg (weight) (max 1200 mg) atezolizumab (genetical recombination) administered 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 the ALBERT study[1]
The ALBERT study is a domestic Phase II, multicenter, open-label, single-arm study led by physicians including National Cancer Center Hospital in Japan to evaluate the efficacy and safety of Tecentriq in patients aged 16 years and older with unresectable alveolar soft part sarcoma. The study enrolled 20 patients to investigate safety and efficacy.

The ALBERT study is being conducted as a substudy of the MASTER KEY project, which promotes the development of treatments for rare cancers through industry-academia collaboration with the National Cancer Center Hospital.

About alveolar soft part sarcoma[2, 3]
Alveolar soft part sarcoma is one of the ultra-rare cancers accounting for less than 1% of soft tissue sarcomas. It is estimated to occur in 15-40 Japanese people annually. It most commonly affects the limbs, mainly the thighs, and is more common among adolescents and young adults (15-35 years old, AYA (Adolescent and Young Adult) generation). Unresectable alveolar soft part sarcoma has a poor prognosis, and no standard treatment has been established.

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 4 indications

(extensive-stage small cell lung cancer, non-small cell lung cancer, breast cancer, and hepatocellular carcinoma).

Sources

1. An investigator-initiated clinical study conducting in patients with alveolar soft part sarcoma aged 16 years or older, with the aim of obtaining regulatory approval for the first immune checkpoint inhibitor for sarcoma and accelerating the development of new treatments for rare cancers and generation AYA patients (Press release by National Cancer Center Hospital in Japan on November 5, 2020). https://www.ncc.go.jp/jp/information/pr_release/2020/1104/index.html (accessed in January 2025) (Japanese only)
2. The Japanese Orthopaedic Association. Clinical Practice Guideline for Soft Tissue Tumor 2020 Revised Version 3. Nankodo
3. Paoluzzi L, Maki RG. Diagnosis, Prognosis, and Treatment of Alveolar Soft-Part Sarcoma: A Review. JAMA Oncol. 2019;5(2):254-260.

###