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Chugai Files for Additional Indication of Tecentriq for the Treatment of Alveolar Soft Part Sarcoma, an Ultra-rare Disease

- The filing 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 in patients with unresectable alveolar soft part sarcoma, an extremely rare disease
- If approved, Tecentriq is expected to be the first immune checkpoint inhibitor in Japan for alveolar soft part sarcoma, a disease with a high incidence in the AYA generation for which no standard treatment has been established.

TOKYO, March 14, 2024 -- 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 an additional indication of alveolar soft part sarcoma.

"Alveolar soft part sarcoma, which is very common and most common in the adolescents and young adults (AYA) generation and very rare, is known to have a poor prognosis with no standard treatment if it becomes unresectable. We are working to obtain approval so that Tecentriq, a cancer immunotherapy that demonstrated favorable efficacy, can be delivered to patients as soon as possible as a new therapeutic option for alveolar soft part sarcoma," said Chugai's President and CEO, Dr. Osamu Okuda.

This filing 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, a leading company in the oncology field, remains committed to addressing unmet medical need in cancer treatment with innovative medicines for patients and healthcare professionals.

About ALBERT study[1]

ALBERT study is a Phase II, multicenter, open-label, single-arm study led by physicians including National Cancer Center Hospital to evaluate the efficacy and safety of Tecentriq in patients with unresectable alveolar soft part sarcoma. The study enrolled 20 patients to investigate safety and efficacy. The primary endpoint is overall response rate. Major secondary endpoints include progression-free survival, overall survival, and safety.

ALBERT study is being conducted as a substudy of the MASTER KEY project, which promotes the

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

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 an ultra-rare cancer 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 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 March 2024)
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.

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