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Chugai Files for Additional Indication of Tecentriq for the Treatment of Extranodal Natural Killer/T-cell Lymphoma, Nasal Type, a Rare Disease

- The filing is based on the results from an investigator-initiated Japanese phase II clinical study in patients with relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type (R/R ENKL)
- If approved, Tecentriq is expected to be the first immune checkpoint inhibitor in Japan for R/R ENKL, a disease with poor prognosis for which no standard treatment has been established.

TOKYO, October 31, 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 [generic name: atezolizumab (genetical recombination)] for an additional indication of relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type (R/R ENKL).

“ENKL is a rare type of malignant lymphoma that primarily develops in the nose. It is known to have a poor prognosis, with about 60% of patients in advanced stages relapsing after initial treatment, and there is no standard therapy for relapsed cases. 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 ENKL,” said Chugai’s President and CEO, Dr. Osamu Okuda.

This filing is based on the results from a phase II ATTACK study initiated by investigators in Japan including National Cancer Center Hospital, which evaluated the efficacy and safety of Tecentriq in patients with R/R ENKL. Response was shown in 7 out of 13 cases and the study met its primary endpoint with an overall response rate of 53.8% (95% CI: 25.1-80.8%). The safety profile was consistent with that in other tumors.

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 ATTACK study[1]

ATTACK study (NCCH1903, jRCT2031190177) is a Japanese 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 relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type. The study enrolled 14 patients to investigate safety and efficacy. The primary endpoint is independent review committee (IRC)-assessed overall response rate. Key secondary endpoints include progression-free survival, overall survival, and safety.

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

ATTACK 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 extranodal natural killer/T-cell lymphoma, nasal type (ENKL)

ENKL is a form of malignant lymphoma that primarily affects the nasal cavity. It can occur in individuals of all ages, from children to adults.[2,3,4] ENKL is rare, accounting for approximately 0.68% of all malignant lymphoma cases (annual incidence: about 36,000 cases) in Japan.[5] For patients with advanced ENKL, about 60% experience relapse following initial treatment.[6,7] Relapsed or refractory ENKL has a poor prognosis, and there is currently no established standard treatment.

About Tecentriq[8]

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). Tecentriq was filed for additional indication of alveolar soft part sarcoma in March 2024.

Sources

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