News Release

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

- The first approved immune-checkpoint inhibitor in Japan for relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type (ENKL) for which standard drug therapy has not been established, in adults and children 12 years and older
- Approval based on the results of an investigator-initiated Japanese Phase II clinical study
- In addition to the expanded indication for ENKL, a new 4-weekly dosing regimen has been added to existing indications for lung cancer and breast cancer, contributing to improved convenience for patients and healthcare professionals

TOKYO, September 19, 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 relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type (ENKL). Tecentriq is the first immune-checkpoint inhibitor approved in Japan for this disease.

“We are very pleased that we can offer Tecentriq as a new treatment option for ENKL in adults and children 12 years and older. ENKL is a rare type of malignant lymphoma that primarily develops in the nasal cavity. In advanced stages, approximately 60% of patients relapse after initial treatment, and there is no established standard therapy after relapse. We will continue our efforts to provide information on the proper use of Tecentriq in order to contribute to the patients with ENKL,” said Chugai's President and CEO, Dr. Osamu Okuda.

This approval is based on the results from the 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.

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In addition to the approval of this expanded indication, we have also received additional approval for a 4-weekly dosing regimen in the “dosage and administration” for existing indications in lung cancer and breast cancer. The additional options in dosing intervals will enable more flexible treatment planning. This is expected to improve convenience for patients and healthcare professionals by reducing the number of hospital visits and lessening the burden on both.

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 or revised description (underlined)

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.

Indications	Dosage and administration
Unresectable, advanced or recurrent non-small cell lung cancer	• For patients with chemotherapy-naïve unresectable advanced or recurrent non-squamous non-small cell lung cancer The usual adult dosage is 1200 mg atezolizumab (genetical recombination) administered by intravenous infusion once every 3 weeks. Subsequently, when administered as monotherapy, atezolizumab (genetical recombination) is administered as an intravenous infusion either 1200 mg once every 3 weeks or 1680 mg once every 4 weeks. • For patients with chemotherapy-naïve PD-L1 positve unresectable advanced or recurrent non-small cell lung cancer The usual adult dosage of atezolizumab (genetical recombination) is either 1200 mg once every 3 weeks or 1680 mg once every 4 weeks administered by intravenous infusion. • For patients with unresectable advanced or recurrent non-small cell lung cancer previously treated with chemotherapy The usual adult dosage of atezolizumab (genetical recombination) is either 1200 mg once every 3 weeks or 1680 mg once every 4 weeks administered by intravenous infusion.

PD-L1-positive adjuvant non-small cell lung cancer	The usual adult dosage of atezolizumab (genetical recombination) is either 1200 mg once every 3 weeks or 1680 mg once every 4 weeks administered by intravenous infusion. The dosage period is up to 12 months.
Extensive-stage small cell lung cancer	The usual adult dosage is 1200 mg atezolizumab (genetical recombination) in combination with carboplatin and etoposide by intravenous infusion once every 3 weeks for 4 doses. This is followed by atezolizumab (genetical recombination) 1200 mg administered as an intravenous infusion once every 3 weeks or 1680 mg once every 4 weeks.
Unresectable hepatocellular carcinoma	The usual adult dosage is 1200 mg atezolizumab (genetical recombination) in combination with bevacizumab administered by intravenous infusion once every 3 weeks.
PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer	The usual adult dosage of atezolizumab (genetical recombination) in combination with *nab*-paclitaxel (albumin-bound) is either 840 mg once every 2 weeks or 1680 mg once every 4 weeks administered by intravenous infusion.
Unresectable alveolar soft part sarcoma	The usual adult dosage is 1200 mg atezolizumab (genetical recombination) administered by intravenous infusion 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 once every 3 weeks.
Relapsed or refractory extranodal natural killer/T-cell lymphoma, nasal type	The usual adult dosage of 1200 mg atezolizumab (genetical recombination) administered by intravenous infusion once every 3 weeks. The usual dose for patients aged 12 to < 18 years is 15 mg/kg (body weight) atezolizumab (genetical recombination) (max 1200 mg) administered by intravenous infusion once every 3 weeks.

About the 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 the independent review committee (IRC)-assessed overall response rate. Key secondary endpoints include progression-free survival, and overall survival.

The 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 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 5 indications (non-small cell lung cancer, extensive-stage small cell lung cancer, breast cancer, hepatocellular carcinoma and alveolar soft part sarcoma).

Sources

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