News Release

Chugai Files for Additional Indication of Tecentriq for the Treatment of Adjuvant Therapy for MRD-Positive Bladder Cancer

- The filing is based on the results from the global Phase III clinical study (IMvigor011), which compared Tecentriq monotherapy or placebo, as adjuvant therapy for ctDNA MRD-positive patients with bladder cancer
- If approved, Tecentriq aims to advance personalized medicine with a new therapeutic option for high-risk, MRD-positive muscle-invasive bladder cancer

TOKYO, January 28, 2026 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed a regulatory application with the Ministry of Health, Labour and Welfare (MHLW) for the anti-cancer agent/humanized anti-PD-L1 monoclonal antibody Tecentriq® 840mg Intravenous Infusion [generic name: atezolizumab (genetical recombination)] for an additional indication of adjuvant therapy for MRD*-positive bladder cancer (MIBC).

* Minimal Residual Disease

“Muscle-invasive bladder cancer has a high recurrence rate after surgery, underscoring the need to optimize adjuvant treatment based on each patient’s individual risk. Tecentriq offers a new adjuvant treatment option for patients identified as having a high risk of recurrence through the detection of circulating tumor DNA (ctDNA) in blood tests. By advancing the personalization of cancer care, we remain committed to securing approval so that every patient can receive the most appropriate treatment for their condition,” said Chugai's President and CEO, Dr. Osamu Okuda.

** circulating tumor DNA

This filing is based on the results from a global phase III IMvigor011 study, which evaluated the efficacy and safety of Tecentriq monotherapy or placebo, as adjuvant therapy in patients with ctDNA MRD-positive MIBC. In this study, both the primary endpoint, disease-free survival (DFS), and the main secondary endpoint, overall survival (OS), showed statistically significant and clinically meaningful improvements. The safety profile observed in this study was consistent with the well-established safety profile of Tecentriq in previous studies.

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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.

About IMvigor011 study

The IMvigor011 study is a global Phase III clinical trial evaluating the efficacy and safety of Tecentriq monotherapy or placebo as adjuvant therapy in patients with ctDNA MRD positive muscle-invasive bladder cancer (MIBC). The primary endpoint was disease-free survival, and the secondary endpoints included overall survival and safety.

About muscle-invasive bladder cancer (MIBC)

Muscle-invasive bladder cancer (MIBC) is a type of bladder cancer, and about 25% of bladder cancers are MIBC.[1)] The annual incidence of MIBC in Japan is estimated to be approximately 6,000 cases as of 2021.[2)] MIBC has a high risk of recurrence after radical cystectomy and remains an area of unmet medical need, amid concerns about unnecessary treatment. More personalized development of new therapeutic options is desired.

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 7 tumour types (extensive-stage small cell lung cancer, non-small cell lung cancer, breast cancer, hepatocellular carcinoma, alveolar soft part sarcoma, extranodal natural killer/T-cell lymphoma nasal type, and thymic carcinoma).

Sources

1. Bladder Cancer Clinical Guidelines, 2019 Revised Edition
2. Bladder: National Cancer Center, Cancer Statistics – Cancer Information Service (Section 5: Annual Trends) [Internet; cited January 2026]. Available from: https://ganjoho.jp/reg_stat/statistics/stat/cancer/21_bladder.html#:~:text=%EF%BC%95%EF%BC%8E%E5%B9%B4%E6%AC%A1%E6%8E%A8%E7%A7%BB

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