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Chugai Launches Tecentriq Intravenous Infusion 840 mg as an Optimal Formulation for the Treatment of PD-L1-Positive Inoperable or Metastatic Triple Negative Breast Cancer

- 840 mg formulation has been launched today as the first approved immune checkpoint inhibitor in Japan for the treatment of PD-L1-positive triple-negative breast cancer (TNBC)

TOKYO, November 27, 2019 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that an anticancer agent/anti-PD-L1 (Programmed Death-Ligand 1) monoclonal antibody Tecentriq® Intravenous Infusion 840 mg [generic name: atezolizumab (recombinant)] has been listed on the National Health Insurance (NHI) reimbursement price list and launched today. Tecentriq 840 mg is an optimal formulation to be dosed every two weeks for the treatment of PD-L1-positive hormone receptor-negative and HER2-negative inoperable or recurrent breast cancer. This additional indication and dosage were approved on September 20, 2019.

“Immune checkpoint inhibitor has been changing the treatment paradigm among various types of cancers in recent years. We are very pleased that we can now deliver Tecentriq to patients with PD-L1 positive TNBC as the first approved immune checkpoint inhibitor in the breast cancer field,” said Dr. Osamu Okuda, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “TNBC is an aggressive and rapidly progressing disease with limited treatment options, and there are high unmet medical needs. We would engage in providing information, aiming at contributing to patients thorough offering this cancer immunotherapy-based treatment for TNBC as a new treatment option.”

Tecentriq is an immune checkpoint inhibitor targeting PD-L1 which is a protein expressed on tumor cells 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. The efficacy and safety of Tecentriq were investigated in the phase III IMpassion130 study.

As a top pharmaceutical company in the field of oncology in Japan, Chugai is committed to contribute to patients and medical professionals by offering Tecentriq as a new treatment option and accordingly, to improve access to medications and appropriate use.

About the IMpassion130 study

The IMpassion130 study is a Phase III, multicenter, randomized, double-blind study evaluating the efficacy, safety and pharmacokinetics of Tecentriq plus *nab*-paclitaxel (albumin-bound) compared with *nab*-paclitaxel (albumin-bound) in people with unresectable locally advanced or metastatic TNBC who have not received prior systemic therapy for metastatic breast cancer. The co-primary endpoints are PFS

per investigator assessment (RECIST 1.1) and OS in the ITT population and in the PD-L1-positive population.

[Reference]

Chugai Obtains Approval for Additional Indication and Formulation for Tecentriq in PD-L1-Positive Triple Negative Breast Cancer (Press release issued on September 20, 2019)

https://www.chugai-pharm.co.jp/english/news/detail/20190920153002_648.html

Termination of free offering of Tecentriq 840 mg prior to the listing on the NHI reimbursement price list

Under the system for healthcare services combining insurance-covered and non-covered services provided by the Ministry of Health, Labour and Welfare, Chugai has been offering Tecentriq 840 mg for free to respond to requests for emergency use from patients with PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or metastatic breast cancer with very limited treatment options since its approval dated on September 20, 2019. Chugai announced the termination of free offering of Tecentriq 840 mg with the listing on the NHI reimbursement price list as of today.

Prescribing Information

Product name	Tecentriq® Intravenous Infusion 840 mg	
Generic name	atezolizumab (genetical recombination)	
Indications	Tecentriq® Intravenous Infusion 840 mg <ul style="list-style-type: none"> • PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or metastatic breast cancer 	
Dosage and administration	<ul style="list-style-type: none"> • In case of patients with PD-L1-positive, hormone receptor-negative and HER2-negative inoperable or metastatic breast cancer. The usual adult dosage is 840 mg atezolizumab (genetical recombination) in combination with <i>nab</i>-paclitaxel (albumin-bound) administered by intravenous infusion over 60 minutes once every 2 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes. 	
Drug price	Tecentriq® Intravenous Infusion 840 mg	JPY 448,853/vial
Conditions for approval	<ul style="list-style-type: none"> • A risk management plan should be created and appropriately implemented. 	

About Triple-Negative Breast Cancer

In Japan, 86,500 women (2018 predicted value) are estimated to be afflicted with breast cancer each year. 14,800 women in Japan (2018 predicted value) die as a result of the disease. ¹⁾ Triple-negative breast cancer accounts for 15% of all breast cancer cases and, is more common in women under the age of 50, compared with other forms of breast cancer. ²⁻⁴⁾ Triple-negative breast cancer is defined by the lack of expression of hormone receptors (estrogen and progesterone receptors) and the overexpression of human epidermal growth factor receptor 2 (HER2). In general, triple-negative breast cancer has a high tumor-proliferative capacity and shorter overall survival, compared with other forms of breast cancer. ^{3, 5)}

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Sources

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- 2: Yao H et al. Triple-negative breast cancer: is there a treatment on the horizon? *Oncotarget*. 2017;8(1):1913–1924.
- 3: BreastCancer.org. What is Triple-Negative Breast Cancer? [Internet; October, 2019] Available from: https://www.breastcancer.org/symptoms/diagnosis/trip_neg?what
- 4: Cancer Treatment Centers of America. Triple negative breast cancer risk factors. [Internet; cited October, 2019] <https://www.cancercenter.com/breast-cancer/risk-factors/tab/triple-negative-breast-cancer-risk-factors/>
- 5: Pal SK et al. Triple negative breast cancer: unmet medical needs. *Breast Cancer Res Treat*. 2011;125(3):627-636.

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