

Innovation all for the patients



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Tecentriq, an Anti-PD-L1 Antibody, Receives Approval for Additional Indication of Extensive-Stage Small Cell Lung Cancer

- Tecentriq is the first approved cancer immunotherapy for extensive-stage small cell lung cancer in Japan
- A new treatment option becomes available for patients with extensive-stage small cell lung cancer in 17 years

TOKYO, August 22, 2019 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it has obtained regulatory approval for its humanized anti-PD-L1 monoclonal antibody, “Tecentriq® Intravenous Infusion 1200 mg” [generic name: atezolizumab (genetical recombination)] from the Ministry of Health, Labour and Welfare (MHLW) for an additional indication of “extensive-stage small cell lung cancer.”

“Tecentriq is the first cancer immunotherapy for the treatment of aggressive and difficult-to-treat extensive-stage small cell lung cancer,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “We are very pleased that we can deliver Tecentriq as a potential new standard of care for the treatment of extensive-stage small cell lung cancer which has had limited therapeutic options for a long period of time.”

This approval is based on the results from the phase I/III IMpower133 study. Tecentriq in combination with chemotherapy met the primary endpoint of overall survival (OS) as compared with chemotherapy alone in the intent to treat (ITT) analysis (median OS, 12.3 vs 10.3 months; hazard ratio=0.70, 95% confidence interval, 0.54-0.91; p=0.0069). The study also met co-primary endpoint of progression-free survival (PFS) (median PFS, 5.2 vs 4.3 months; hazard ratio=0.77, 95% confidence interval, 0.62-0.96; p=0.017). The safety profile of Tecentriq in combination with chemotherapy was consistent with the known safety profiles of the individual medicines, and no new safety signals were identified.

<Reference>

Roche’s Tecentriq in combination with chemotherapy helped people live significantly longer as an initial treatment for people with extensive-stage small cell lung cancer (Press release issued by Roche on September 25, 2018)

<https://www.roche.com/media/releases/med-cor-2018-09-25.htm>

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.

Prescribing Information *The underlined parts were newly added.

[Indications]

- Unresectable, advanced or recurrent non-small cell lung cancer
- Extensive-stage small cell lung cancer

[Dosage and administration]

- In case of patients with untreated unresectable, advanced or recurrent non squamous non-small cell lung cancer.
The usual adult dosage is 1200 mg atezolizumab (genetical recombination) in combination with carboplatin, paclitaxel and bevacizumab (genetical recombination) by intravenous infusion over 60 minutes once every 3 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes.
- In case of patients with unresectable, advanced or recurrent non squamous non-small cell lung cancer who has undergone chemotherapy.
The usual adult dosage is 1200 mg atezolizumab (genetical recombination) administered by intravenous infusion over 60 minutes once every 3 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes.
- In case of patients with 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 over 60 minutes once every 3 weeks. If the initial infusion is well tolerated, subsequent infusions can be delivered over 30 minutes.

About small cell lung cancer

In Japan, 125,100 people (84,500 men and 40,600 women; 2018 predicted values) are estimated to be afflicted with lung cancer each year. 77,500 people in Japan (55,100 men and 22,400 women; 2018 predicted values) die as a result of the disease. Lung cancer is the leading cause of cancer death. Lung cancer can be broadly divided into small cell lung cancer (SCLC) and non-small cell lung cancer according to the tissue type, with SCLC accounting for approximately 10 to 15% of all lung cancer cases. SCLC has a high tumor-proliferative capacity, and characteristically causes a wide range of metastases rapidly after tumor diagnosis.

About application status of Tecentriq in Japan

Tecentriq was launched in April 2018 with an indication of “unresectable, advanced or recurrent non-small cell lung cancer,” followed by an approval for the additional dosing for the treatment of “untreated unresectable, advanced or recurrent non squamous non-small cell lung cancer” in December 2018. In addition, a supplementary application for breast cancer has been submitted to the MHLW in December 2018.

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Sources

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- Eilas DA. Small cell lung cancer: state-of-the-art therapy in 1996. *Chest.* 1997 Oct; 112: 251S-258S

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