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Chugai Files for Additional Indication of Anti-PD-L1 Antibody TECENTRIQ® for Small Cell Lung Cancer

TOKYO, December 7, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that it filed an application for humanized anti-PD-L1 monoclonal antibody TECENTRIQ® Intravenous Infusion 1200 mg [generic name: atezolizumab (genetical recombination)], to the Ministry of Health, Labour and Welfare (MHLW) for an additional indication of the first line treatment of extensive-stage small cell lung cancer (ES-SCLC).

"I am very pleased that we have completed filing for the line extension of TECENTRIQ. TECENTRIQ is the first cancer immunotherapy treatment to extend overall survival and progression-free survival in the first line treatment of ES-SCLC, and has recently been designated as an orphan drug by MHLW," said Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "Chugai is committed to seek approval so that we may deliver TECENTRIQ to ES-SCLC patients who have limited treatment options as early as possible."

This application is based on the results from a global phase I/III clinical study (IMpower133 study). This study is a multicenter, double-blind, randomized, placebo-controlled, global clinical study evaluating the efficacy and safety of TECENTRIQ in combination with chemotherapy (carboplatin and etoposide) which was compared with chemotherapy alone (carboplatin and etoposide) in chemotherapy-naive ES-SCLC patients. 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). Safety of TECENTRIQ in combination with chemotherapy was consistent with the known safety profile of individual medicines, and no new safety signals were identified with the combination therapy.

[Reference information]
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 (Roche media release dated September 25, 2018)
https://www.roche.com/media/releases/med-cor-2018-09-25.htm

Chugai Receives Orphan Drug Designation for TECENTRIQ® in Small cell Lung Cancer and for Entrectinib in *NTRK* Fusion-positive Solid Tumors (press release issued on December 6, 2018).
https://www.chugai-pharm.co.jp/english/news/detail/20181206170000_567.html

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About TECENTRIQ

In Japan, TECENTRIQ was approved for “unresectable and advanced/recurrent non-small cell lung cancer” in January 2018 and launched in April. An application for additional indication, first line treatment of non-small cell lung cancer was filed in March 2018.