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Chugai Files for Additional Indication and Additional Formulation of Anti-PD-L1 Antibody TECENTRIQ® for Breast Cancer

TOKYO, December 21, 2018 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed an application for humanized anti-PD-L1 monoclonal antibody TECENTRIQ® [generic name: atezolizumab (genetical recombination)] to the Ministry of Health, Labour and Welfare (MHLW) for an additional indication of unresectable, locally advanced or metastatic breast cancer and a new 840 mg formulation.

This application is based on the results from a global phase III clinical study (IMpassion130 study). The IMpassion130 study is a multicenter, double-blind, randomized, placebo-controlled, global clinical study evaluating the efficacy, safety, and pharmacokinetics of TECENTRIQ in combination with nab-paclitaxel (albumin-bound) compared with nab-paclitaxel alone (albumin-bound) in patients with unresectable locally advanced or metastatic triple-negative breast cancer who have not received prior systemic therapy for metastatic breast cancer. Co-primary endpoints of this study are progression-free survival per investigator assessment and overall survival. Both primary endpoints are assessed in intent-to-treat (ITT) and PD-L1 positive population. Secondary endpoints are objective response rate, duration of response, and time to deterioration in Global Health Status/Health-Related Quality of Life.

"Triple-negative breast cancer is an aggressive disease with poor prognosis and high unmet medical needs," said Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "TECENTRIQ is the first immune checkpoint inhibitor whose efficacy against triple-negative breast cancer has been confirmed. We are committed to deliver atezolizumab to patients as early as possible, and contribute to the realization of better treatment in Japan."

[Reference information]
Roche's Tecentriq in combination with Abraxane improves outcomes as an initial treatment for people with PD-L1-positive metastatic triple-negative breast cancer (Roche media release dated October 20, 2018)
https://www.roche.com/media/releases/med-cor-2018-10-20.htm

About Triple-Negative Breast Cancer

In Japan, 86,500 women (2018 predicted value) are estimated to be afflicted with breast cancer each year. 14,285 women in Japan (2017 predicted value) die as a result of the disease. 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. 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

CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL: +81-(0)3-3273-0881 E-mail: pr@chugai-pharm.co.jp
Investor Relations Group TEL: +81-(0)3-3273-0554 E-mail: ir@chugai-pharm.co.jp

general, triple-negative breast cancer has a high tumor-proliferative capacity and shorter overall survival, compared with other forms of breast cancer.

About TECENTRIQ

In Japan, TECENTRIQ was approved for "unresectable and advanced/recurrent non-small cell lung cancer" in January, 2018 and launched in April. Applications for additional indications of first-line treatment of small cell lung cancer were filed, and first-line treatment of non-small cell lung cancer were approved in December, 2018.

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About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2017 of Chugai totalled 534.2 billion yen and the operating income was 103.2 billion yen (IFRS Core basis).

Additional information is available on the internet at https://www.chugai-pharm.co.jp/english.