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Tecentriq in combination with chemotherapy meets primary endpoint, regardless of PD-L1 status, as initial treatment for people with early triple-negative breast cancer

- IMpassion031 data will be discussed with health authorities globally, including the U.S. Food and Drug Administration and the European Medicines Agency
- Tecentriq is the only approved cancer immunotherapy for the treatment of metastatic triple-negative breast cancer (TNBC), a very aggressive and difficult-to-treat form of breast cancer

TOKYO, June 18, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the Phase III IMpassion031 study met its primary endpoint, regardless of PD-L1 status, as initial treatment for people with early triple-negative breast cancer.

IMpassion031 study is evaluating Tecentriq® in combination with chemotherapy (Abraxane®, albumin-bound paclitaxel; nab-paclitaxel; followed by doxorubicin and cyclophosphamide) in comparison to placebo plus chemotherapy. The study met its primary endpoint by demonstrating a statistically significant and clinically meaningful improvement in pathologic complete response (pCR) for the treatment of people with early triple-negative breast cancer (TNBC), regardless of PD-L1 expression. The IMpassion031 study is the second positive phase III study demonstrating the benefit of Tecentriq in TNBC, and the first Tecentriq study to demonstrate benefit in early TNBC.

Safety for the Tecentriq combination appeared consistent with the known safety profiles of the individual medicines and no new safety signals were identified. Results of the IMpassion031 study will be presented at an upcoming medical meeting and will be discussed with global health authorities including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA).

“Tecentriq is the first approved immune checkpoint inhibitor in the breast cancer field. We are pleased that Tecentriq showed positive results in the treatment of the early TNBC,” said Dr. Osamu Okuda, Chugai’s President and COO. “TNBC is an aggressive and rapidly progressing disease with limited treatment options, and there are high unmet medical needs. We will be working together with Roche to provide patients with this new treatment option as early as possible.”

About the IMpassion031 study

The IMpassion031 study is a Phase III, multicenter, randomized, double-blind study evaluating the efficacy and safety of Tecentriq in combination with chemotherapy (Abraxane®, albumin-bound paclitaxel; nab-paclitaxel; followed by doxorubicin and cyclophosphamide) in comparison to placebo plus chemotherapy, in people with previously untreated, early TNBC. The study enrolled 333 people who were

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

randomized in a 1:1 ratio to receive Tecentriq or placebo plus chemotherapy in the neoadjuvant (before surgery) setting. The primary endpoint is pCR using the American Joint Committee on Cancer (AJCC) staging system in the ITT population and in the PD-L1-positive population.

About Triple-Negative Breast Cancer (TNBC)

In Japan, 92,200 women (2019 predicted value) are estimated to be afflicted with breast cancer each year. 15,100 women in Japan (2019 predicted value) die as a result of the disease. [1)] TNBC 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)] TNBC 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, TNBC has a high tumor-proliferative capacity and shorter overall survival, compared with other forms of breast cancer. [3, 5)]

Sources

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