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Chugai Provides Update on the Phase III IMagyn050 study of Tecentriq in Combination with Chemotherapy and Avastin as a Treatment of Newly-Diagnosed Ovarian Cancer

TOKYO, July 13, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the Phase III IMagyn050 study, evaluating Tecentriq® in combination with paclitaxel, carboplatin, and Avastin® as a treatment for newly-diagnosed stage III or stage IV ovarian cancer (including fallopian tube and primary peritoneal cancer) did not meet its co-primary endpoint of progression-free survival (PFS).

The combination of Tecentriq, paclitaxel, carboplatin, and Avastin did not show a statistically meaningful improvement in PFS, a co-primary endpoint of the study, compared with placebo, paclitaxel, carboplatin, and Avastin. Data for the overall survival (OS), the other co-primary endpoint are currently immature and follow-up will continue until the next planned analysis.

Topline safety data indicate that safety for Tecentriq in combination with Avastin, paclitaxel and carboplatin was consistent with the known safety profile of the combination. Data from the IMagyn050 study will be presented at an upcoming medical meeting.

“It is very regrettable that Tecentriq in combination with paclitaxel, carboplatin, and Avastin did not improve PFS, although we aimed at offering a new treatment option for newly-diagnosed stage III or stage IV ovarian cancer,” said Dr. Osamu Okuda, Chugai’s President and COO. “We will analyze the data in detail to obtain new insights for future development programs.”

About the IMagyn050 study

The IMagyn050 study is a Phase III, multicenter, randomized study evaluating the efficacy and safety of Tecentriq in combination with paclitaxel, carboplatin, and Avastin in comparison to placebo plus paclitaxel, carboplatin, and Avastin, in people with newly-diagnosed stage III or stage IV ovarian, fallopian tube, or primary peritoneal cancer. The study enrolled 1,301 people who were randomized in a 1:1 ratio to either arm. The primary endpoints are PFS in the ITT population and PD-L1-positive population, and OS in the ITT population and PD-L1-positive population.

About ovarian cancer

The annual incidence of ovarian cancer in Japanese women is 10,900 (2019 predicted value), and the number of deaths is 4,800 in Japan (2019 predicted value).[1)] The most common type of ovarian cancer is a surface epithelial-stromal tumor originating primarily in the ovary. Primary peritoneal cancer and fallopian tube cancer occur in the pelvic cavity and abdominal cavity like ovarian cancer. Also, their origin is considered to be the Muellerian duct as in the case of ovarian cancer[2)] and the general clinical and biological behavior is similar to ovarian cancer. Since there are many cases that most of the patients with ovarian cancer are already in an advanced state with disseminated lesions at the time of initial diagnosis,

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the possibility of cure is considered to be low in this situation. Five-year survival rate at the advanced stage III and stage IV ovarian cancer are 49.6% and 31.8%, respectively.[3)]

Sources

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2: David W. Kindelberger, et al. Intraepithelial Carcinoma of the Fimbria and Pelvic Serous Carcinoma: Evidence for a Causal Relationship. Am J Surg Pathol 2007;31:161–169
3: Japan Society of Obstetrics and Gynecology Treatment Annual Report for 2012 [Internet; cited July, 2020] Available from: http://fa.kyorin.co.jp/jsog/readPDF.php?file=71/5/071050725.pdf

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