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Eisai Co., Ltd.

EISAI ANNOUNCES RESULTS OF PHASE III STUDY OF ANTICANCER AGENT FARLETUZUMAB IN PATIENTS WITH RELAPSED PLATINUM-SENSITIVE OVARIAN CANCER

Eisai Co., Ltd. (Headquarters: Tokyo, President & CEO: Haruo Naito, "Eisai") announced today the preliminary results of its global Phase III study (Study FAR 131, MORAb-003-004) of farletuzumab (MORAb-003), an investigational compound under development at its U.S. subsidiary, Morphotek, Inc., in patients with platinum-sensitive epithelial ovarian cancer in first relapse.

The study was a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparative study of 1,100 patients with platinum-sensitive epithelial ovarian cancer in first relapse. The patients received standard-of-care therapy (carboplatin and a taxane) in combination with doses of either 1.25 mg/kg of farletuzumab, 2.5 mg/kg of farletuzumab, or placebo.

Preliminary results showed that the trial did not meet the pre-specified statistical criteria for significant progression-free survival (PFS), the study's primary endpoint. The post hoc exploratory analysis showed, however, a trend toward improved PFS in some patient subsets and further analysis is ongoing. The preliminary safety analysis indicated that the most commonly reported adverse events were those known to be associated with the study chemotherapy agents. Additionally, some immune-mediated events were observed with farletuzumab. After further analysis of these clinical results, the company will determine a new development strategy based on discussion with external experts and the relevant health authorities.

Eisai remains committed to understanding the potential clinical benefits of farletuzumab in order to further contribute to patients with cancer, including patients with recurrent ovarian cancer, and their families.

[Please refer to the following notes for further information on farletuzumab, Study FAR 131, ovarian cancer and Eisai's commitment to oncology.]

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[Notes to editors]

1. About farletuzumab

Farletuzumab is a humanized, IgG_1 monoclonal antibody that binds to the folate receptor-alpha (FRA), a folate-binding protein that is expressed on ovarian and several other epithelial cancer cells. Monoclonal antibodies are a type of immunotherapy used to treat cancer that are manmade versions of immune system proteins and can be designed to attack a specific part of a cancer cell. Immunotherapy drugs offer a method of treatment separate from chemotherapy.

2. Study FAR 131 Design Summary

This Phase III trial was a multicenter, randomized, double-blind, placebo-controlled, parallel-group comparative study of 1,100 patients with platinum-sensitive epithelial ovarian cancer in first relapse enrolled in 274 medical centers. The study assessed the efficacy and safety of farletuzumab in combination with standard-of-care carboplatin and taxane (either a paclitaxel or docetaxel) chemotherapy. The primary endpoint was progression-free survival (PFS) as assessed by the Response Evaluation Criteria in Solid Tumors (RECIST).

Patients were randomized into three parallel groups to receive either a 1.25 mg/kg of farletuzumab, 2.5 mg/kg of farletuzumab or placebo, with all patients receiving standard-of-care therapy every three weeks and farletuzumab or placebo weekly for six cycles. After these six cycles, patients continued to receive their maintenance of placebo or farletuzumab until disease progression was observed.

Eligible patients must have been treated initially with surgery, had a response to first-line platinum- and taxane-based therapy, and have relapsed as defined by the presence of measurable disease. Patients must have also relapsed between 6 and 24 months from the time of completion of their first-line platinum and taxane therapy and been eligible for carboplatin and taxane treatment.

3. About Ovarian Cancer

Globally, an estimated 225,000 patients are diagnosed with ovarian cancer each year, with an estimated 140,000 deaths due to this disease annually. Approximately 90% of ovarian cancer tumors are epithelial (carcinomas) and often not diagnosed until the advanced stages of the disease. Although clinical complete remissions are obtained in the majority of patients through a combination of cytoreductive surgery and chemotherapy, relapse remains common.

4. Eisai's Commitment to Oncology

Eisai's commitment to meaningful progress in oncology research, built on scientific expertise, is supported by a global capability to conduct discovery and preclinical research, and develop small molecules, biologics, chemotherapies and supportive care agents for cancer across multiple indications. Along with its continued endeavors in obtaining further indication expansion for Halaven®, Eisai plans to enhance its portfolio of products in the field of oncology with other agents such as its monoclonal antibody farletuzumab and lenvatinib, a VEGF (vascular endothelial growth factor) receptor tyrosine kinase inhibitor and multikinase inhibitor.