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CHUGAI
Roche Group

Translation

Anti-Cancer Agent "Avastin®," Application for Approval of Additional Indication of Ovarian Cancer

October 5, 2012 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, Chugai)] announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare (hereafter, MHLW) for the approval of an additional indication of ovarian cancer (including primary peritoneal cancer and fallopian tube cancer) for the anti-cancer agent/ anti-VEGF humanized monoclonal antibody, "AVASTIN I.V. Infusion 100mg/4mL and 400mg/16mL" [generic name: bevacizumab (recombinant) for Infusion] (hereafter, Avastin®).

On December 13, 2010, Chugai received a request from the MHLW to develop "Avastin®" for the treatment of ovarian cancer, as a result of the evaluation by the "Review Committee on Unapproved Drugs and Indications with High Medical Needs," and has been preparing to file for the addition of this indication.

The application was filed based on phase III studies (GOG-0218 study conducted in the US and other countries and ICON7 study conducted in EU and other countries), both in first line therapy for the patients with ovarian cancer. Both studies evaluated the usefulness of "Avastin®" when administered in combination with carboplatin/paclitaxel, a standard chemotherapy, and then continued "Avastin®" alone as a maintenance therapy. Both studies demonstrated that the progression free survival, defined as the primary endpoint, was significantly prolonged in patients with ovarian cancer who received "Avastin®" as compared with those who received the standard chemotherapy. Avastin® was well tolerated and its safety profile was consistent with the previously reported data of "Avastin®."

The GOG-Japan, a member of the Japanese Gynecologic Oncology Group (JGOG; President: Kazunori Ochiai, Professor, Jikei University), participated to the GOG-0218 study which was an investigator-led clinical study starting in the US, and Japanese patients were also enrolled to the study. The application was filed based on the results of the Japanese patients in this investigator-led clinical study.

The number of patients newly diagnosed as ovarian cancer in Japan continues to rise each year and is estimated to approximately 8,500 annual average in 2010-2014[1)].

"Avastin®" is approved for ovarian cancer (first line therapy) in more than 47 countries worldwide.

Chugai will work closely with related parties who were involved in the investigators GOG-0218 study in order to receive approval for "Avastin®" as soon as possible in Japan.

1. T. Sobue, et al., Cancer White Paper 2012, Shinoharashinsha Inc.

About "Avastin®"

"Avastin®" is an antibody drug that binds specifically to VEGF, which plays an important role in the vascularization needed for the growth and metastatis of tumors, and impedes its activity. "Avastin®" received approval for the treatment of metastatic colorectal cancer in the U.S. in February 2004 and is recommended as one of the standard treatments in several guidelines. In Japan, it received approval for "unresectable advanced or recurrent colorectal cancer" in April 2007, "unresectable advanced or recurrent non-squamous non-small cell lung cancer" in November 2009 and "inoperable or recurrent breast cancer" in September 2011.

About the "Review Committee on Unapproved Drugs and Indications with High Medical Needs"

The "Review Committee on Unapproved Drugs and Indications with High Medical Needs" was established for the purpose of "enhancing development by the pharmaceutical companies of drugs and indications that have been approved for use in western countries but not yet approved in Japan, through activities such as evaluating medical needs and confirming the applicability of "application based on evidence in the public domain" and investigating the need for studies that should be additionally conducted."