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CHUGAI
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Translation

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

September 19, 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 recurrent glioblastoma 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 April 6, 2012, Chugai received a request from the MHLW to develop "Avastin®" for the treatment of recurrent glioblastoma, as a result of the evaluation by the "11th Review Committee on Unapproved Drugs and Indications with High Medical Needs" held on March 23, 2012, and has been preparing to file for the addition of this indication. On September 13, 2012, "Avastin®" for glioblastoma has been designated as orphan drug, as the estimated number of newly diagnosed glioblastoma patient per year is about 1,000.

The application was filed based on a US phase II study (BRAIN study), and a domestic phase II study (JO22506 study), both in patients with glioblastoma that recurred after treatment with temozolomide and radiotherapy. The BRAIN study demonstrated a progression-free survival at 6 months of 42.6% and an objective response rate of 28.2%, and the JO22506 study demonstrated a progression free survival at 6 months of 33.9% and an objective response rate of 27.6%. These efficacy data exceed those reported in the previous studies with recurrent glioblastoma patients. Avastin® was well tolerated and its safety profile was consistent with the previously reported data of "Avastin®."

"Avastin®" is approved for recurrent glioblastoma in the US and more than 35 countries worldwide, as a single agent and in some countries in combination with irinotecan. The approval in the US was granted under the Food and Drug Administration's (FDA) accelerated approval programme.

As the top pharmaceutical company in the field of oncology, Chugai will work for the early approval to provide Avastin® as a new treatment option for patients and medical professionals for the recurrent glioblastoma, a disease with extremely high-grade malignancy and with high unmet medical need.

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."