

## Translation

# Anti-Malignancy Agent/Anti-VEGF Humanized Monoclonal Antibody, Avastin<sup>®</sup> Application for Approval of Additional Indication of Breast Cancer

October 16, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, Chugai)] announced today that the company filed an application with the Japanese Ministry of Health, Labour and Welfare (hereafter, MHLW) for the approval of an additional indication of breast cancer for the anti-malignancy agent/anti-VEGF humanized monoclonal antibody, "AVASTIN I.V. Infusion 100mg/4mL and 400mg/16mL" [generic name: bevacizumab (Recombinant) for Infusion] (hereafter, Avastin<sup>®</sup>).

Based on the phase III clinical trials conducted overseas in patients with previously untreated advanced or recurrent breast cancer, those who received Avastin<sup>®</sup> in combination with chemotherapy saw a significant prolongation of progression-free survival, which was the primary endpoint. Outside Japan, after the approval of the drug in March 2007 in Europe and in February 2008 in the U.S., Avastin<sup>®</sup> has been used in combination with chemotherapy for previously untreated advanced or recurrent breast cancer.

The phase II clinical trial conducted in Japan in patients with previously untreated advanced or recurrent breast cancer confirmed that the efficacy and the tolerability of Avastin<sup>®</sup> in Japanese patients were comparable to those seen in overseas clinical trials.

The number of patients newly afflicted with breast cancer in Japan continues to rise each year. The number of such patients is estimated to reach over 45,000 in 2010\*. As the top pharmaceutical company in the field of oncology, Chugai will work for the approval to provide patients and medical practitioners with new treatment options as soon as possible.

\*A. Oshima, T. Kuroishi, K. Tajima, Cancer White Paper - Incidence / Death / Prognosis - 2004, 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 metastasis 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 guidelines. Avastin® was approved for the treatment of breast cancer in March 2007 in Europe and in February 2008 in the U.S., and has since been used as the first-line treatment for advanced or recurrent breast cancer. In Japan, it received approval for unresectable advanced or recurrent colorectal cancer in April 2007. Chugai has promoted the proper use of Avastin® since launch by conducting a special drug-use results survey. Chugai filed an application with the MHLW for the approval of an additional indication of non-squamous, non-small cell lung cancer. The review is currently under way.