Anti-malignancy agent / anti-VEGF humanised monoclonal antibody, Avastin®
Application for Approval of Additional Indication of NSCLC

November 26, 2008 (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 for the approval of an additional indication of non-small cell lung cancer (NSCLC) for the anti-malignancy agent / anti-VEGF humanised monoclonal antibody, "AVASTIN I.V. Infusion 100mg/4mL and 400mg/16mL" [generic name: bevacizumab (Recombinant) for Infusion] (hereafter, Avastin®). Avastin® has been approved in Japan for the treatment of unresectable advanced or recurrent colorectal cancer. Avastin® is a novel drug that inhibits the growth of a network of blood vessels that supply nutrients and oxygen to cancerous tissue.

In pivotal phase III clinical trials conducted overseas in patients with previously untreated advanced or recurrent non-squamous NSCLC (E4599 and AVAiL), overall and/or progression-free survival of patients who received Avastin® in combination with standard platinum-based chemotherapy were significantly prolonged compared to patients given only chemotherapy. Based on these data, the drug has been approved for the first-line treatment of patients with advanced or recurrent non-squamous NSCLC outside Japan.

In Japan, NSCLC is the most frequent cause of deaths from cancer (ranked no.1 in male, no.2 in female) and the number of patients is increasing year by year. Chugai positions Oncology as one of its key therapeutic areas, and will work for the approval to offer medical practitioners and patients a new treatment option as soon as possible.

It is estimated that there will be approximately 99,000 patients with lung cancer in Japan in 2010.

*1: Vascular Endothelial Growth Factor

About Avastin®
Avastin® received approval for the treatment of metastatic colorectal cancer in the U.S. in February 2004 and is recommended as standard treatment in guidelines. Avastin® was approved as a first-line therapy for advanced non-squamous NSCLC in the U.S. in October 2006 and in Europe in August 2007. 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.