

Chugai seeks approval for anti-cancer agent Avastin in Japan

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Singapore: Japan's Chugai Pharmaceutical filed an application with the Japanese Ministry of Health, Labour and Welfare, seeking approval of an additional indication of recurrent glioblastoma for the anti-cancer agent/ anti-VEGF humanized monoclonal antibody, AVASTIN Infusion 100mg/4mL and 400mg/16mL (generic name: bevacizumab recombinant for Infusion).

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.

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 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 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.