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Anti-Cancer Agent “Avastin®,” Application for Approval of Additional Indication of Recurrent/Advanced Cervical Cancer

TOKYO, September 17, 2015 -- Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama] (Chugai) (TOKYO: 4519) announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare (MHLW) for the approval of an additional indication of recurrent/advanced cervical 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] (Avastin).

The application was filed based on overseas phase III studies (The GOG-0240 study) and Japanese phase II study (The JO29569 study) for the patients with cervical cancer.

The GOG-0240 study# evaluated the efficacy and safety profile of standard chemotherapies (paclitaxel and cisplatin or paclitaxel and topotecan) with or without Avastin in 452 patients with persistent, recurrent or metastatic cervical cancer.

- The study met its primary endpoint of improving overall survival (OS) with a statistically significant 26 percent reduction in the risk of death, representing a median gain in survival of 3.9 months, compared with those who received chemotherapy alone [16.8 months vs. 12.9 months; HR=0.74, stratified log-rank test, p=0.0132].
- The study showed that patients who received Avastin plus chemotherapy had a significantly improvement of progression free survilval (PFS) compared with those who received chemotherapy alone［8.3 months vs. 6.0 months; HR=0.66, stratified log-rank test, p<0.0001］.
- The study showed that patients who received Avastin plus chemotherapy had a significantly higher rate of tumor shrinkage (objective response rate, ORR) compared with those who received chemotherapy alone [45.4% (95% CI: 38.8-52.1%) vs. 33.8% (95% CI 27.6-40.4%); Chi-squared test, p=0.0117].
- The safety profile in the study was consistent with previous reports of Avastin, except for an increase in gastrointestinal-vaginal fistulas observed in patients who received Avastin plus chemotherapy compared to those who received chemotherapy alone (8.3% vs. 0.9% respectively). All patients with gastrointestinal-vaginal fistulas had a history of prior pelvic radiation.

The JO29569 study evaluated the tolerability, safety and efficacy of Avastin plus paclitaxel and cisplatin. Within eight Japanese patients with advanced or recurrent cervical cancer enrolled in the study, seven patients were evaluated, and one patient was excluded before the start of the study. As a result, the tolerability of Avastin and chemotherapy was confirmed, and the harmful phenomenon to become the problem was not accepted, and no new safety finding were observed.

Avastin is approved for cervical cancer more than 40 countries worldwide including the US (August 2014) and EU (March 2015).

The number of patients newly diagnosed as cervical cancer in Japan continues to rise each year and is estimated to approximately 10,600 annual average in 2015-2019.*

As the top pharmaceutical company in the field of oncology in Japan, Chugai will work for the early approval to provide Avastin as a new treatment option for patients with recurrent/advanced cervical cancer and medical professionals.

A 2 x 2 factorial design to compare four groups was employed in the GOG-0240 study. In addition to confirm the effectiveness of Avastin, the primary endpoints also included confirmation of effectiveness for chemotherapy without platinum agent (in combination with or without Avastin) against chemotherapy with platinum agent (in combination with or without Avastin).

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

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