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CHUGAI
Roche Group

Translation

Anti-Cancer Agent, Avastin®
Obtained Approval for Additional Indication and Dosage and Administration of "Inoperable or Recurrent Breast Cancer"

September 26, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter, "Chugai")] announced today that it obtained approval by the Japanese Ministry of Health, Labour and Welfare (MHLW) on September 26, 2011 for the additional indication of "inoperable or recurrent breast cancer" for the anti-VEGF human monoclonal antibody bevacizumab (genetic recombination) [brand name: Avastin® Injection 100 mg/4 mL and 400 mg/16 mL, hereafter, "Avastin®"]. In Japan, Avastin® is currently marketed for the indications of "unresectable advanced or recurrent colorectal cancer," and "unresectable advanced or recurrent non-squamous non-small cell lung cancer."

In October 2009, Chugai filed an application for approval with the MHLW based on the results from a domestic phase II clinical trial and overseas phase III clinical trials. In the overseas phase III clinical trials in advanced or recurrent breast cancer patients previously untreated with chemotherapy, those who received Avastin® in combination with paclitaxel saw a significant prolongation of progression-free survival, the primary endpoint, compared to those who received paclitaxel alone. The phase II clinical trial conducted in Japan in advanced or recurrent breast cancer patients previously untreated with chemotherapy confirmed the efficacy in Japanese patients, and also confirmed that the tolerability of Avastin® combined with paclitaxel in Japanese patients were comparable to those seen in overseas clinical trials. Based on these data, Avastin® obtained the approval for additional indication and dosage and administration of "inoperable or recurrent breast cancer."

Chugai strongly believes that Avastin® will make a contribution to patients as a treatment for "inoperable or recurrent breast cancer," an indication with high unmet medical needs. Through development of new treatment options, Chugai will continue its effort to contribute to the advancement of cancer therapies.

[Reference]

The underlined descriptions are newly added.

Brand name: Avastin® for intravenous infusion 100 mg/4 mL
Avastin® for intravenous infusion 400 mg/16 mL

Generic name: bevacizumab (genetic recombination)

Indications, dosage and administration:

Indications	Dosage and Administration
Unresectable advanced or recurrent colorectal cancer	The usual adult dosage of Avastin is 5 mg/kg (body weight) or 10 mg/kg (body weight) of bevacizumab per intravenous infusion in combination with other anti-cancer chemotherapy. The administration interval of Avastin should be 2 weeks or longer.
	The usual adult dosage of Avastin is 7.5 mg/kg (body weight) of bevacizumab per intravenous infusion in combination with other anti-cancer chemotherapy. The administration interval of Avastin should be 3 weeks or longer.
Unresectable advanced or recurrent non-squamous non-small cell lung cancer	The usual adult dosage of Avastin is 15 mg/kg (body weight) of bevacizumab per intravenous infusion in combination with other anti-cancer chemotherapy. The administration interval of Avastin should be 3 weeks or longer.
<u>Inoperable or recurrent breast cancer</u>	<u>The usual adult dosage of Avastin is 10 mg/kg (body weight) of bevacizumab per intravenous infusion in combination with paclitaxel. The administration interval of Avastin should be 2 weeks or longer.</u>

Drug prices: Avastin® for intravenous infusion 100 mg/4 mL, JPY 49,959/vial
Avastin® for intravenous infusion 400 mg/16 mL, JPY 190,253/vial