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CHUGAI
Roche Group

Translation

Anti-Malignancy Agent Avastin®
Obtained Approval for Additional Indication of Non-Small Cell Lung Cancer

November 9, 2009 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. President: Osamu Nagayama (hereafter "Chugai")] announced today that it obtained approval by the Ministry of Health, Labour and Welfare (MHLW) on 6 November for the additional indication of "Unresectable advanced or recurrent non-squamous non-small cell lung cancer" of its anti-VEGF human monoclonal antibody bevacizumab (genetic recombination) [Product name: "Avastin® Injection 100 mg/4 mL and 400 mg/16 mL" (hereafter, "Avastin®")].

Avastin® was approved for unresectable advanced or recurrent non-squamous non-small cell lung cancer (NSCLC) in the US in October 2006 and in Europe in August 2007. Since then, it has become one of the standard treatments outside Japan recommended by treatment guidelines, used in combination with chemotherapy. With this approval in Japan, Avastin® is now available for patients with non-squamous NSCLC or colorectal cancer in Japan as well as US and Europe.

In November 2008, Chugai filed an application for approval with the MHLW with results from overseas studies (phase II and phase III) and a domestic phase II study. In two comparative trials conducted overseas in patients with previously untreated advanced or recurrent non-squamous NSCLC, 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. The domestic phase II study also reported comparable results with overseas studies, showing a significant prolongation of progression-free survival in patients who received Avastin® in combination with standard chemotherapy (carboplatin and paclitaxel), showing efficacy of the drug in Japanese patients.

In domestic and overseas trials of Avastin® in non-squamous NSCLC, a higher incidence of pulmonary hemorrhage (hemoptysis) was reported in patients who received Avastin®, compared to the reported incidences in colorectal cancer indication which has already been approved in Japan. To provide further safety information and promote appropriate use of the product, Chugai plans to implement measures including a six-month post-marketing survey following launch in non-squamous NSCLC to ensure appropriate use and monitor adverse events, and a special drug-use survey to investigate risk profiles for pulmonary hemorrhage (hemoptysis) in non-squamous NSCLC.

Chugai positions oncology as one of its key therapeutic areas. Through development of new treatment options, Chugai will continue its effort to contribute to cancer treatment.

[Reference]

* The underlined descriptions are newly added.

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

Generic name: Bevacizumab (genetic recombination)

Indications, and 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.

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