



## Avastin® Received Orphan Drug Designation for the Treatment of Malignant Pleural Mesothelioma

TOKYO, December 22, 2016 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced that Avastin® received orphan drug designation by the Ministry of Health, Labour and Welfare for the treatment of malignant pleural mesothelioma.

It is estimated that there are approximately 2,000 patients with malignant pleural mesothelioma in Japan. [Patient Survey 2014 (by classification of diseases), Statistic Bureau, Ministry of Internal Affairs and Communications]. Treatment options for malignant pleural mesothelioma, which is a refractory disease, include surgery, radiotherapy, chemotherapy and symptomatic therapy, and the treatment provided is determined based on the clinical stage of the cancer and general condition of the patient. Systemic chemotherapy can be chosen even for limited-stage malignant pleural mesothelioma without metastasis, due to its clinical characteristics.

“There is high unmet medical need for patients with malignant pleural mesothelioma whose prognosis is poor,” said Chugai’s Senior Vice President, Head of Project & Lifecycle Management Unit, Dr. Yasushi Ito. “With the results of a study conducted in France and a Japanese phase II study, I have high hopes that Avastin will be newly added as a drug with an indication of malignant pleural mesothelioma in Japan. We are committed to deliver Avastin to patients as early as possible to contribute to the development of and access to better treatments.”

In Japan, the phase II study (JO39183) to evaluate the tolerance and safety of triplet combination therapy (Avastin, cisplatin and pemetrexed) in chemotherapy-naïve patients with unresectable malignant pleural mesothelioma has been conducted.

### **About malignant pleural mesothelioma**

The lungs, the heart, and abdominal organs such as the stomach, the intestines and the liver are covered by membranes called the pleura, pericardium, and peritoneum, respectively. The surface of these membranes is wrapped around by the “mesothelium” and tumours developing from this layer are called mesothelioma. Therefore, mesothelioma can be divided into pleural mesothelioma, pericardial mesothelioma, and peritoneal mesothelioma, depending on the site of onset.

Pleural mesothelioma is a malignant cancer, commonly referred to as malignant pleural mesothelioma. Malignant pleural mesothelioma develops in a localized pattern (in which a mass is formed in one specific area) or in a diffuse pattern (in which a tumour widely spreads along the pleura). While this is a rare cancer, it is known to be triggered by asbestos.

(Reference: The Rare Cancer Center, National Cancer Center)

**About orphan drug designation**

Orphan drug designation is granted in conjunction with priority review status by the Minister of Health, Labour and Welfare according to the Pharmaceuticals and Medical Devices Law. Drugs satisfying the following criteria may be designated as orphan drugs: 1) the eligible number of patients should be less than 50,000 in Japan, 2) the drugs should be indicated for the treatment of serious diseases, and they must be drugs for which there are high medical needs where there is no appropriate alternative drug or treatment, or high efficacy or safety is expected compared with existing products, 3) there should be a theoretical rationale for the use of the product for the target disease, and the development plan should be appropriate.