

## Translation

### Chugai to In-license BRAF Inhibitor Vemurafenib

August 15, 2011 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Head Office: Chuo-ku, Tokyo; President: Osamu Nagayama (hereafter, "Chugai")] announced today that it has entered into a license agreement with F. Hoffmann-La Roche, Ltd [Head Office: Basel, Switzerland / CEO: Severin Schwan (hereafter, "Roche")] for the BRAF inhibitor vemurafenib, which has been submitted by Roche for approval in Europe and the United States for BRAF V600 mutation-positive metastatic melanoma. Under the agreement, Chugai obtains exclusive rights for the development and marketing of vemurafenib in Japan, and will make milestone payments to Roche.

Chugai plans to start a phase I clinical trial in Japan in 2012 for BRAF mutation-positive metastatic melanoma. Further development for other tumor types with BRAF mutations will be considered in accordance with the progress and results of the clinical trials conducted by Roche.

To date, Chugai has made contributions to healthcare through the launches of innovative anti-cancer treatments including Avastin<sup>®</sup>, Herceptin<sup>®</sup>, Rituxan<sup>®</sup>, Tarceva<sup>®</sup> and Xeloda<sup>®</sup>. With the addition of the BRAF inhibitor vemurafenib, a first-in-class compound, to the product portfolio, Chugai's strength as a leading pharmaceutical company in the area of oncology will be enhanced, enabling Chugai to make greater contributions to the advancement of cancer treatment.

Chugai is committed to continuing its efforts to meet unmet medical needs by effectively utilizing the research and development resources of Roche to find innovative new drugs.

## **[Reference]**

### **About vemurafenib**

Vemurafenib is an investigational, oral, small molecule that is designed to selectively inhibit a cancer-driving mutated form of the BRAF protein. Vemurafenib is being co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon, a member of the Daiichi Sankyo Group.

It is reported that each year 1,300-1,400 patients (Globocan 2008) in Japan are newly diagnosed with malignant melanoma, the deadliest and most aggressive form of skin cancer. Of these patients, approximately 30% are estimated to have mutations in the BRAF protein.

The BRAF protein is a key component of the RAS-RAF pathway involved in normal cell growth and survival. Mutations that lock the BRAF protein in an active state may cause excessive signaling in the pathway, leading to uncontrolled cell growth and survival.

A Phase III study (BRIM3) in patients with BRAF V600 mutation-positive metastatic melanoma demonstrated that vemurafenib prolonged both overall survival and progression-free survival compared with the current chemotherapy standard of care.

Vemurafenib exemplifies Roche's personalized healthcare approach using biomarkers and diagnostic tools to identify the right medicine for the right patient. Vemurafenib was co-developed with an investigational diagnostic test, the Roche cobas 4800 BRAF V600 Mutation Test, to identify patients whose tumors carry the mutated BRAF V600 gene.