



Translation

Chugai Pharmaceutical Co., Ltd.
Roche Diagnostics K.K.

Contribution to the Personalized Healthcare for Melanoma Approval for BRAF inhibitor, “Zelboraf®” and its Companion Diagnostic, “cobas® 4800 BRAF V600 Mutation Test.”

December 26, 2014 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, “Chugai”)] announced today that it obtained approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) on December 26, 2014, for “unresectable melanoma with BRAF mutation,” for an anti-cancer agent, BRAF inhibitor, vemurafenib tablets (brand name: Zelboraf® Tablet 240mg (hereafter, “Zelboraf®”).

Also, Roche Diagnostics K.K. [Main Office: Minato-ku, Tokyo. President & CEO: Makoto Ogasawara (hereafter, “Roche Diagnostics”)] obtained approval from the MHLW for *in vitro* diagnostics to detect the BRAF mutation, “cobas® 4800 BRAF V600 Mutation Test,” as a companion diagnostics for Zelboraf® on December 2, 2014.

It is necessary to detect *BRAF* mutation with cobas® 4800 BRAF V600 Mutation Test before use of Zelboraf for patients with unresectable melanoma with *BRAF* mutation. As just described, medical approach to select an appropriate therapy for each patient before administration of a drug is called personalized healthcare. It enables to avoid a treatment unlikely to show efficacy. Furthermore, since a treatment unlikely to be effective is not given, personalized healthcare increase the benefit in terms of medical economics.

It is reported that each year 1,300 to 1,400 patients (Globocan 2012) in Japan are newly diagnosed as malignant melanoma (all stages), and the number has been growing. Of these patients, 26.7 to 41.8% have the BRAF gene mutation^{1, 2)}.

Chugai and Roche Diagnostics, members of the Roche Group and pioneers in personalized healthcare, are sure that Zelboraf® and cobas® 4800 BRAF V600 Mutation Test can contribute to the treatment of “unresectable melanoma with *BRAF* mutation,” a disease with poor prognosis and with high unmet medical needs. We will continue to dedicate ourselves to providing treatment options to suit individual patients.

1. Uhara H., et al.: Journal of Dermatological Science 66: 240-242, 2012
2. Yamazaki N., et al.: ESMO poster presentation: Presented at the 17th ECCO - 38th ESMO - 32nd ESTRO European Cancer Congress; Amsterdam, the Netherlands, September 27- October 1, 2013

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the "oncology" area.

In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and Ukima is conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research was established in Singapore in January 2012 for conducting research focusing on the generation of new antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.

The consolidated revenue in 2013 of Chugai totaled 423.7 billion yen and the operating income was 79.9 billion yen in IFRS core basis. We are aiming at the consolidated revenue of 451.0 billion yen and operating profit of 71.0 billion yen in IFRS core basis, in 2014.

Additional information is available on the Internet at <http://www.chugai-pharm.co.jp/english/>

About Roche Diagnostics K.K.

Roche Diagnostics K.K. is the Japanese affiliate of the Diagnostics Division of F. Hoffmann-La Roche, one of the world's leading healthcare companies, based on Basel, Switzerland. As of February 2014, with 783 employees and sales branches in 9 cities across Japan as well as a logistics center, Roche Diagnostics K.K. provides innovative diagnostic solutions for customers ranging from research, clinical diagnostics to patient self-monitoring in Diabetes Care. Our aim is to continuously provide tests with increased medical value and to improve testing efficiency that ultimately empower healthcare professionals to make better and timely clinical decisions for the people in Japan.

Additional information is available on the Internet at <http://www.roche-diagnostics.jp>. (Japanese only)

Zelboraf® and cobas® are registered trademarks of F. Hoffmann-La Roche, Ltd. (Switzerland).

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