CHUGAI PHARMACEUTICAL CO., LTD.
Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome,
Chuo-ku Tokyo, 103-8324 Japan
TEL:+81-(0)3-3273-0881
FAX:+81-(0)3-3281-6607
E-mail:pr@chugai-pharm.co.jp
URL:http://www.chugai-pharm.co.jp

Translation

Launch of the Anti-Cancer Agent / BRAF Inhibitor "Zelboraf®"
- Contribution to the Treatment of Melanoma by Personalized Healthcare -

February 25, 2015 (Tokyo) - Chugai Pharmaceutical Co., Ltd. [Main Office: Chuo-ku, Tokyo. Chairman & CEO: Osamu Nagayama (hereafter, "Chugai")] announced today that it will launch the BRAF inhibitor "Zelboraf® Tablet 240mg" [generic name: vemurafenib] (hereafter, Zelboraf®) for the indication of "unresectable melanoma with *BRAF* mutation" on February 26, 2015. Zelboraf® received a manufacturing and marketing approval on December 26, 2014 and was listed on the National Health Insurance (NHI) reimbursement price list on February 24, 2015.

Prior to administration of Zelboraf® for patients with "unresectable melanoma with *BRAF* mutation," it is essential to detect the *BRAF* mutation with the cobas® 4800 BRAF V600 Mutation Test, launched by Roche Diagnostics K.K. [Main Office: Minato-ku, Tokyo. President & CEO: Makoto Ogasawara]. Thus, Zelboraf® matches with the personalized healthcare strategy that selects an appropriate drug for patients expected to obtain the therapeutic effect by using biomarkers and/or diagnostic tools. It will enable to select the appropriate treatment for each patient before drug administration by personalized healthcare. This kit has been covered by insurance since February 1, 2015.

Zelboraf®, created by Plexxikon, a member of the Daiichi Sankyo Group, is an oral, small molecule BRAF kinase inhibitor that is designed to selectively inhibit a cancer-driving mutated form of the BRAF protein. Zelboraf® was approved for the treatment of adult patients with unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation in the U.S. in 2011 and in Europe in 2012.

It is reported that each year 1,300 to 1,400 patients (Globocan 2012) are newly diagnosed with melanoma (all stages) in Japan, and the number has been growing. Of these patients, approximately 30 to 40% have the *BRAF* gene mutation[1, 2].

As the top pharmaceutical company in the field of oncology in Japan, Chugai will promote appropriate use of Zelboraf® in order to contribute optimally to the treatment of patients with "unresectable melanoma with *BRAF* mutation," a disease with poor prognosis and with high unmet medical need, by providing a new therapeutic option.

1. Ashida A., et al.: J Dermatol Sci. 2012 Jun; 66 (3): 240-242.
2. Yamazaki N., et al.: Melanoma Res. 2015 Feb; 25 (1): 9-14.

Drug Information

Brand name:	Zelboraf® Tablet 240mg	
Generic name:	Vemurafenib	
Indications:	Unresectable melanoma with *BRAF* mutation	
Dosage and administration:	The usual adult dosage is 960mg vemurafenib administered orally twice daily.	
Date of approval:	December 26, 2014	
Date of listing in the NHI reimbursement price:	February 24, 2015	
Date of launch:	February 26, 2015	
Shelf life:	Zelboraf® Tablet 240mg	2 years
Drug price:	Zelboraf® Tablet 240mg/tablet	4,935.50 yen

About conditions for approval of Zelboraf®

1. A drug risk management plan should be prepared and appropriately implemented.
2. Because the number of patients in Japanese clinical trials is very limited, postmarketing drug use surveillance of all patients receiving Zelboraf® should be conducted until data for a set number of patients are collected in order to identify the background characteristics of patients using Zelboraf®, collect early data on the safety and efficacy of Zelboraf®, and take necessary measures for appropriate use of Zelboraf®.

About the drug use surveillance of Zelboraf® (All-case registration surveillance)

For the first 500 patients who receive Zelboraf® treatment, data will be collected, analyzed and reported to the health authority. After collecting data for 500 cases, a review and decision will be made to determine whether a new surveillance or further safety measures should be considered. Results of this surveillance shall be reported to the public in future scientific meetings, as well as to the regulatory authorities.

Package photo