Media Release

Basel, 16 December 2011

Roche's personalized medicine Zelboraf receives positive opinion from European authority for the treatment of people with BRAF mutation-positive metastatic melanoma

Roche (SIX: RO, ROG; OTCQX: RHHBY), today announced that the Committee for Medicinal Products for Human Use (CHMP) has recommended that Zelboraf be granted full marketing authorization as a monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.

"The CHMP recommendation to approve Zelboraf represents an important milestone for people with metastatic melanoma who until recently had limited treatment options," said Hal Barron, M.D., chief medical officer and head, Global Product Development. "We are working closely with health authorities worldwide to bring Zelboraf to people with this deadly disease as soon as possible."

Metastatic melanoma is the deadliest and most aggressive form of skin cancer with less than one in four people expected to be alive 12 months after their diagnosis.[i] Earlier this year, Zelboraf became the first and only US FDA and Swissmedic approved personalised medicine for people with BRAF V600 mutation-positive inoperable or metastatic melanoma that is shown to improve survival. The cobas 4800 BRAF V600 Mutation Test, co-developed by Roche, was approved simultaneously with Zelboraf in the US and CE-marked in the EU where it is commercially available. Zelboraf is designed to target and inhibit mutated forms of the BRAF protein found in about half of all cases of melanoma.

The corresponding European Commission decision on the Marketing Authorization of Zelboraf is expected in February 2012.

Marketing authorization submissions for Zelboraf are currently under review by health authorities in Australia, New Zealand, Brazil, India, Mexico, Canada and other countries worldwide. While Roche seeks regulatory approval of Zelboraf in other countries, a global safety study is providing access to Zelboraf for people with previously treated or untreated BRAF V600 mutation-positive metastatic melanoma.

F. Hoffmann-La Roche Ltd
4070 Basel
Switzerland

Group Communications
Roche Group Media Relations

Tel. +41 61 688 88 88
Fax +41 61 688 27 75
www.roche.com

About Metastatic Melanoma and BRAF

When melanoma is diagnosed early, it is generally a curable disease. However, when it spreads to other parts of the body, it is the deadliest and most aggressive form of skin cancer. A person with metastatic melanoma typically has on average a short life expectancy that is measured in months. In 2008, there were approximately 200,000 new cases worldwide[ii] compared with 160,000 in 2002.[iii] Fewer than one in four people with metastatic melanoma are expected to be alive one year after their diagnosis[iv], and every year there are an estimated 40,000 deaths worldwide from the disease.[v]

The BRAF protein is a key component of the RAS-RAF pathway involved in normal cell growth and survival. Mutations that keep the BRAF protein in an active state may cause excessive signalling in the pathway, leading to uncontrolled cell growth and survival. These mutations of the BRAF protein are thought to occur in an estimated half of all melanomas and eight percent of solid tumours.

About BRAF V600 Mutation Testing

The cobas 4800 BRAF V600 Mutation Test is a polymerase chain reaction-based diagnostic test developed by Roche. This FDA-approved, CE-marked test was clinically validated in the BRIM2 and BRIM3 studies to identify tumours that carry the BRAF V600E mutation. The test has several advantages compared to Sanger sequencing, a commonly used method, including greater sensitivity and reliability for detecting mutations and quicker results, allowing doctors to know whether a person with metastatic melanoma is eligible for treatment with Zelboraf.

About Zelboraf

Zelboraf is an oral, small molecule, kinase inhibitor indicated for the treatment of patients with inoperable or metastatic melanoma with BRAF V600 mutations. Zelboraf is not recommended for use in melanoma patients with wild-type BRAF. Zelboraf is being co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon, a member of the Daiichi Sankyo Group.

Roche and Genentech are conducting a broad development program with Zelboraf that includes testing combinations with other medicines (both approved and investigational, from Roche/Genentech and other companies), as well as studies in other tumour types. While Roche seeks world-wide approval, Zelboraf is available to eligible patients with BRAF V600 mutation-positive metastatic melanoma through a global safety study. More information about this program or other Zelboraf studies is available at the Roche Clinical Trials Registry at www.roche-trials.com (in the EU) or www.clinicaltrials.gov (in the United States).

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80'000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

Additional information

- Roche in Oncology: www.roche.com/media/media_backgrounder/media_oncology.htm
- Cancer: www.health-kiosk.ch/start_krebs.htm
- World Health Organization: www.who.int

Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com

- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky
- Claudia Schmitt

---

[i] Korn EL, *et al.* Meta-analysis of phase II cooperative group trials in metastatic stage IV melanoma to determine progression-free and overall survival benchmarks for future phase II trials. *J Clin Oncol* 2008;26(4):527-34.

[ii] Ferlay J, Shin HR, Bray F, Forman D, Mathers C and Parkin DM.
GLOBOCAN 2008 v1.2, Cancer Incidence and Mortality Worldwide: IARC CancerBase No. 10 [Internet].
Lyon, France: International Agency for Research on Cancer; 2010. Available from: http://globocan.iarc.fr, accessed on day/month/year.

[iii] Parkin DM, *et al.* Global cancer statistics, 2002. *CA Cancer J Clin* 2005;55(2):74-108.

[iv] Korn EL, *et al.* Meta-analysis of phase II cooperative group trials in metastatic stage IV melanoma to determine progression-free and overall survival benchmarks for future phase II trials. *J Clin Oncol* 2008;26(4):527-34.

[v] Chapman PB, *et al.* Improved survival with vemurafenib in melanoma with BRAF V600E mutation. *N Engl J Med* 2011;Epub ahead of print, June 5 2011.