

For Immediate Release

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**Plexxikon Announces European Approval of Zelboraf® for the Treatment of Patients with
BRAF Mutation-Positive Metastatic Melanoma**

Tokyo, Japan (February 20, 2012)-Attached is the press release from Plexxikon which was issued on February 19, 2012. Plexxikon is a member of the Daiichi Sankyo Group.



Plexxikon

Plexxikon Announces European Approval of Zelboraf® for the Treatment of Patients with BRAF Mutation-Positive Metastatic Melanoma

Berkeley, CA – February 19, 2012 – Plexxikon Inc., a member of Daiichi Sankyo Group, today announced that the European Commission has approved Zelboraf® (vemurafenib) for the monotherapy treatment of adult patients with BRAF^{V600} mutation-positive unresectable or metastatic melanoma. The cobas 4800 BRAF V600 Mutation Test, a companion diagnostic used to identify patients with the BRAF mutation, is CE marked and commercially available in Europe. Zelboraf is designed to selectively inhibit the BRAF mutation that occurs in about half of all cases of melanoma.

Zelboraf and its companion diagnostic have already been approved in the United States, Switzerland, Israel, Brazil, New Zealand and Canada. In the United States, Zelboraf is being co-promoted by Daiichi Sankyo, Inc. and Genentech, a member of the Roche Group. Roche promotes Zelboraf outside of the United States.

“The approval of Zelboraf by the European Commission marks a significant advancement for European patients with metastatic melanoma who historically have had very limited treatment options,” said K. Peter Hirth, Ph.D., chief executive officer of Plexxikon. “We are very pleased that our strategy to co-develop Zelboraf along with a companion diagnostic helped accelerate the availability of this personalized medicine for these patients.”

BRIM3

BRIM3, a global, randomized, open-label, controlled, multicenter, Phase 3 study, compared Zelboraf to dacarbazine (chemotherapy), in 675 patients with previously untreated BRAF^{V600E} mutation-positive, unresectable (inoperable) or metastatic melanoma. The endpoints for BRIM3 were overall survival (OS) and investigator-assessed progression-free survival (PFS). Other endpoints included confirmed investigator-assessed overall response rate.

In January 2011, the data safety monitoring board for BRIM3 recommended termination of the BRIM3 study due to compelling efficacy data, and further recommended that study patients receiving chemotherapy have the option to cross over to the vemurafenib treatment arm.

- The pre-specified interim analysis of BRIM3 showed the risk of death was reduced by 63 percent for patients who received Zelboraf compared to those who received standard first-line treatment (hazard ratio [HR]=0.37, p<0.0001).
- In a post-hoc analysis of BRIM3 data with a longer follow up compared to previous analyses, including cross-over of patients from the chemotherapy treatment arm to the Zelboraf treatment arm, Zelboraf significantly improved survival by providing a median overall survival of 13.2 months compared to 9.6 months for those who received chemotherapy. Historically, patients with metastatic melanoma have had a median survival of six to 10 months. This analysis

showed the risk of death was reduced by 38 percent for patients who received Zelboraf compared to those who received chemotherapy (hazard ratio [HR]=0.62, p<0.0001).

- At 12 months, 55% of patients who received Zelboraf were alive, as compared to 43% of patients who received chemotherapy.

In the single arm BRIM2 study of previously treated patients, Zelboraf treatment also showed a survival benefit compared to historical control data. These data are expected to publish shortly.

Marketing authorization submissions for Zelboraf are currently under review by health authorities in Australia, India, Mexico and other countries worldwide.

Important Safety Information about Zelboraf (vemurafenib)

This information does not take the place of the patient talking to his or her doctor about their medical condition or their treatment with Zelboraf.

Zelboraf is a prescription medicine used to treat a type of skin cancer called melanoma that has spread to other parts of the body or cannot be removed by surgery, and has a certain type of abnormal “BRAF” gene.

Zelboraf may cause a type of skin cancer called cutaneous squamous cell carcinoma (cuSCC), that usually does not spread to other parts of the body. Patients should check their skin and tell their doctor about skin changes including a new wart, a skin sore or reddish bump that bleeds or does not heal, or a mole that changes size or color.

While taking Zelboraf, patients should avoid going out in the sun. When patients go outside, they should wear clothes that protect their skin, including head, face, hands, arms and legs. They should use lip balm and a broad-spectrum UVA/UVB sunscreen with SPF 30 or higher.

Possible serious side effects of Zelboraf include severe allergic reactions; severe skin reactions; changes in the electrical activity of the heart called QT prolongation, which can potentially be life-threatening; abnormal liver function tests; eye problems; or new melanoma lesions.

Common side effects of Zelboraf include joint pain, rash, hair loss, tiredness, sunburn or sun sensitivity, nausea, itching or warts.

These are not all of the possible side effects of Zelboraf. Patients must tell their doctor if they have any side effect that bothers them or does not go away. For more information about side effects, patients should ask their doctor or pharmacist.

Patients should call their doctor for medical advice about any side effects. Patients or their caregivers are encouraged to report negative side effects of prescription drugs to the FDA at 1-800-FDA-1088 or at www.fda.gov/medwatch. They may also report side effects to Genentech at 1-888-835-2555.

Patients should read the Zelboraf full Prescribing Information and Medication Guide for additional important safety information at www.zelboraf.com.

About Zelboraf (vemurafenib)

Vemurafenib is a novel, oral small molecule, which was approved by the FDA in August 2011 and is being marketed in the U.S. as Zelboraf for the treatment of patients with BRAF^{V600E} mutation-positive inoperable or metastatic melanoma as detected by an FDA-approved test. Zelboraf also has been approved by the European Commission, and in Switzerland, Israel, Brazil, New Zealand and Canada. Zelboraf is not recommended for use in melanoma patients who lack the BRAF^{V600} mutation. Plexxikon utilized its structure-guided chemistry platform to discover vemurafenib, and initiated clinical development in 2006. Shortly thereafter, Plexxikon and Roche signed a collaboration agreement to co-develop vemurafenib.

The cobas 4800 BRAF V600 Mutation Test, a DNA-based companion diagnostic used to identify patients whose tumors carry the BRAF mutation, was simultaneously approved in the U.S., and is CE marked and commercially available in Europe. Roche Molecular Diagnostics developed the cobas 4800 BRAF V600 Mutation Test following a 2005 agreement with Plexxikon.

Studies of vemurafenib in combination with other approved and investigational medicines as well as in other tumor types are being conducted. More information about ongoing vemurafenib studies is available at www.clinicaltrials.gov (in the U.S.) or www.clinicaltrialregister.eu or on the Roche Clinical Trials Registry at www.roche-trials.com (in the EU). Genentech can also be contacted by calling the company's clinical trial call center at 1-888-662-6728 or emailing Genentech@druginfo.com.

About Melanoma and BRAF mutation

Melanoma is the most serious type of skin cancer and is growing at a rate of about five to six percent annually. More than 75,000 people in the U.S. and 160,000 people worldwide are diagnosed with melanoma each year. It is one of the deadliest cancers, with a five-year survival rate of 15 to 20 percent for people with advanced (Stage IV) melanoma, according to the American Cancer Society.

Risk factors for melanoma include a positive family history of melanoma, prior melanoma, multiple clinically atypical moles or dysplastic nevi, inherited genetic mutations, fair skin and sun exposure. However, melanoma can occur in any ethnic group and also in areas of the body without substantial exposure to the sun.

The BRAF gene is a key component of a pathway involved in normal cell growth and survival. BRAF mutations may lead to uncontrolled cell growth, and are thought to occur in about half of all cases of melanoma and eight percent of all solid tumors.

About Plexxikon

Plexxikon, a member of Daiichi Sankyo Group, is a leader in the structure-guided discovery and development of novel small molecule pharmaceuticals to treat human disease. The company's lead drug Zelboraf (vemurafenib/PLX4032) was approved by the FDA in August 2011, and is being co-promoted in the U.S. by Daiichi Sankyo Inc. and Genentech. The company is developing a portfolio of clinical and preclinical stage compounds to address significant unmet medical needs in oncology, as well as in several other therapeutic indications. Plexxikon's Scaffold-Based Drug DiscoveryTM platform integrates multiple state-of-the-art technologies, including structural screening as a key component that provides a significant competitive advantage over other drug discovery approaches.

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