FDA Approval of Zelboraf™ (vemurafenib) Establishes Oncology Foothold in US for Daiichi Sankyo

First-In-Class Treatment Option Soon Available to Treat Deadly Form of Skin Cancer

August 17, 2011 – Parsippany, NJ – With the US Food and Drug Administration (FDA) approval today of Zelboraf™ (vemurafenib), a first-in-class personalized treatment for patients with unresectable (inoperable) or metastatic melanoma with a $BRAF^{V600E}$ mutation as detected by an FDA-approved test, Daiichi Sankyo prepares to enter the US cancer market with its first oral, targeted anti-cancer therapy.

"The Zelboraf approval is not only a significant milestone for these metastatic melanoma patients, but also for Daiichi Sankyo, and is an excellent example of the highly personalized approach to cancer treatment that can come through exploring multiple molecular pathways, unique discovery technology and advanced genetic insights," said Glenn Gormley, MD, PhD, chief science officer and president, Daiichi Sankyo Pharma Development. "Our growing understanding of the biology of cancer will allow Daiichi Sankyo to continue developing a balanced portfolio of small molecules and antibodies through our own efforts and in collaboration with our partners."

Zelboraf should be used only in people whose metastatic melanoma carries a $BRAF^{V600E}$ mutation, as determined by an FDA-approved test. The cobas 4800 BRAF V600 Mutation Test, a DNA-based companion diagnostic to identify patients eligible for Zelboraf treatment, was co-developed by Plexxikon and Roche Molecular Systems, Inc., and has simultaneously been approved by the FDA.

Daiichi Sankyo, Inc. will co-promote Zelboraf with Genentech in the US; co-promotion rights for Zelboraf were transferred to Daiichi Sankyo when the company acquired Plexxikon, which discovered Zelboraf and co-developed this new medicine with Roche.

"Daiichi Sankyo has proven experience in building infrastructures to successfully commercialize medicines in the US and globally," said John Gargiulo, president and CEO, Daiichi Sankyo, Inc. "The new Daiichi Sankyo oncology sales team is poised and is partnering closely with Genentech to ensure that patients diagnosed with $BRAF^{V600E}$ mutation-positive metastatic melanoma, one of the world's deadliest cancers, have access to this important new treatment. We expect Zelboraf to be available within the next two weeks through specialty pharmacies."

Daiichi Sankyo Pipeline in Oncology
Today, key compounds in the Daiichi Sankyo Group pipeline target a variety of unique pathways including agents coming through the clinic from Plexxikon's Scaffold-Based Drug Discovery platform. Targeted pathways under investigation at Daiichi Sankyo include a c-MET inhibitor, a death receptor 5 (DR5) agonist, a PPARγ agonist, a selective kinase inhibitor, an anti-HER3 antibody among others.

Zelboraf Efficacy in BRAF^{V600E} Mutation-Positive Unresectable or Metastatic Melanoma
The FDA approval of Zelboraf is based on results from two clinical studies (BRIM3 and BRIM2) in patients with BRAF^{V600E} mutation-positive inoperable or metastatic melanoma as determined by the cobas BRAF Mutation Test.

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

BRIM2 is a global, single-arm, multicenter, open-label Phase II study that enrolled 132 patients with previously treated BRAF^{V600E} mutation-positive, unresectable or metastatic melanoma. The primary endpoint of BRIM2 was confirmed overall response rate as assessed by independent review.

Findings:

- In BRIM3, the risk of death was reduced by 56 percent for patients who received Zelboraf compared to those who received chemotherapy (hazard ratio [HR]=0.44, p<0.0001). At the time of the analysis, median overall survival of patients receiving Zelboraf had not been reached, and was 7.9 months for those receiving chemotherapy.
- In BRIM 3, patients who received Zelboraf also had a 74 percent reduced risk of the disease getting worse or dying (PFS) compared to those who received chemotherapy (HR=0.26, p<0.0001). Median PFS was 5.3 months for those who received Zelboraf compared to 1.6 months for those who received chemotherapy.
- In BRIM3, the confirmed, investigator-assessed response rate (those who experienced tumor shrinkage) in patients who received Zelboraf was 48.4 percent (1 percent complete responses and 47.4 percent partial responses) compared to 5.5 percent (partial responses) for those who received chemotherapy (p<0.0001).
- In BRIM2, Zelboraf shrank tumors in 52 percent of trial participants.

Important Safety Information for Zelboraf
This information does not take the place of the patient talking to their 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 protects their skin, including head, face, hands, arms and legs. They should use lip balm and a broad-spectrum 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 visit 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 BRAF Mutation-Positive Metastatic Melanoma and Zelboraf

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. The American Cancer Society estimates there will be more than 70,000 new cases of melanoma and nearly 8,800 melanoma deaths this year in the United States.

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 signaling 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 tumors.

About Zelboraf (pronounced ZEL-bor-af); vemurafenib (pronounced vem-yoo-RAF-en-ib)
Zelboraf is an oral, small molecule kinase inhibitor indicated for the treatment of patients with unresectable or metastatic melanoma with $BRAF^{V600E}$ mutation as detected by an FDA-approved test. Zelboraf is not recommended for use in melanoma patients who lack the $BRAF^{V600E}$ mutation.

Zelboraf is being co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon, a member of the Daiichi Sankyo Group. An application for market approval of vemurafenib (PLX4032) for the treatment of melanoma is also being reviewed by the European Medicines Agency (EMA).

For more information about Zelboraf distribution, doctors can contact Genentech Zelboraf Access Solutions (http://www.ZelborafAccessSolutions.com or 1-888-249-4918). Zelboraf Access Solutions also provides doctors and patients coverage and reimbursement support, patient assistance and information resources.

About Daiichi Sankyo
The Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address the diversified, unmet medical needs of patients in both mature and emerging markets. While maintaining its portfolio of marketed pharmaceuticals for hypertension, hyperlipidemia, and bacterial infections, the Daiichi Sankyo Group is engaged in the development of treatments for thrombotic disorders and focused on the discovery of novel oncology and cardiovascular-metabolic therapies. Furthermore, the Daiichi Sankyo Group has created a "Hybrid Business Model," which will respond to market and customer diversity and optimize growth opportunities across the value chain. For more information, please visit www.daiichisankyo.com.

Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. For more information on Daiichi Sankyo, Inc., please visit www.dsi.com.

Disclaimer
Except for the historical information contained herein, this release contains forward-looking statements. Words such as "expect", "estimate", "project", "budget", "forecast", "anticipate", "intend", "plan", "may", "will", "could", "should", "believes", "predicts", "potential", "continue", and similar expressions are intended to identify such forward-looking statements. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and any risk factors listed from time to time in Daiichi Sankyo's Annual Report. Actual results may differ materially from those contained in the forward-looking statements in this press release.

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