

For Immediate Release

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Plexxikon Reports Positive Data from Phase 3 and Phase 2 Trials of Vemurafenib (PLX4032)

*Vemurafenib Phase 3 Data Presentation Featured in Plenary Session at
American Society of Clinical Oncology Annual Meeting*

Tokyo, Japan (June 6, 2011)-Attached is the press release from Plexxikon which was issued on June 5, 2011. Plexxikon is a member of the Daiichi Sankyo Group.

Plexxikon Reports Positive Data from Phase 3 and Phase 2 Trials of Vemurafenib (PLX4032)

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Berkeley, CA and Chicago, IL — June 5, 2011

Plexxikon Inc., a member of the Daiichi Sankyo Group, today announced efficacy and safety data from the BRIM3 trial, a large, randomized, multi-center Phase 3 clinical study of vemurafenib in patients with previously untreated metastatic melanoma with the BRAF^{V600} mutation. The BRIM3 study met the pre-specified criteria for co-primary endpoints of overall survival (OS) and progression-free survival (PFS). For patients treated with vemurafenib compared to those treated with chemotherapy, the risk of death was significantly reduced, by 63 percent, as reflected by the hazard ratio of 0.37, and a p value of less than 0.0001. In addition, vemurafenib treatment significantly reduced the risk of disease progression, by 74 percent (hazard ratio=0.26; p<0.0001). Vemurafenib is an oral, novel drug that targets an oncogenic BRAF mutation, present in about half of all melanomas.

BRIM3 data also will be presented today by Paul Chapman, M.D., a medical oncologist and attending physician in the Melanoma and Sarcoma Service at Memorial Sloan Kettering Cancer Center and principal investigator of BRIM3, in a plenary session at the 2011 Annual Meeting of the American Society for Clinical Oncology (ASCO) meeting in Chicago (Abstract #LBA4, June 5, 2011 3:15 – 3:30 pm CDT, Hall B1).

Key data from the 675-patient BRIM3 trial, based on the analysis as of December 30, 2010, showed:

- Six months after randomization to treatment, 84 percent of vemurafenib-treated patients were alive, compared to 64 percent of patients randomized to chemotherapy.
- More patients treated with vemurafenib experienced tumor shrinkage (48.4 percent) than patients treated with chemotherapy (5.5 percent).
- Median OS could not be reliably estimated at the time of this analysis since the median time for patients receiving treatment was only 3.75 months (median follow up). However, at that time, the estimated median OS in the vemurafenib treatment arm was 9.23 months compared to 7.75 months in the chemotherapy arm. As of an updated analysis on March 1, 2011, the estimated median OS was 10.51 months for the vemurafenib treatment arm, while the chemotherapy arm remained unchanged at 7.75 months.
- Median progression-free survival (PFS) was 5.3 months compared to 1.6 months in the chemotherapy arm.

- All subgroups of patients in the vemurafenib arm showed consistent benefit in terms of OS, PFS and tumor shrinkage, regardless of disease staging, age, gender or performance status.

In January 2011, the data safety monitoring board for BRIM 3 recommended termination of the study due to compelling efficacy data, and further recommended that study patients receiving chemotherapy have the option to crossover to the vemurafenib treatment arm.

Updated results from BRIM2 as of January 31, 2011, also were presented at ASCO by Antoni Ribas, M.D., a medical oncologist, UCLA Jonsson Comprehensive Cancer Center. BRIM2 met its primary endpoint, and these data were consistent with earlier BRIM2 data reported at the Society for Melanoma Research in November 2010. This study enrolled 132 previously treated melanoma patients with the BRAF^{V600} mutation, and updated results showed:

- Tumor shrinkage with a confirmed response rate of 53 percent.
- 29 percent of patients showed stable disease.
- Median progression-free survival was 6.7 months.
- Median duration of response also was 6.7 months.
- Median OS had not been reached; however, at 12 months, 58 percent of patients treated with vemurafenib were alive. Median follow up was 10 months.

The safety profile demonstrated in both BRIM3 and BRIM2 trials was consistent with previous vemurafenib data. The most frequent Grade 3 adverse event observed in these studies was cutaneous squamous cell carcinoma, a common skin cancer treated by local excision (minor surgery done in a physician's office), with continuation of treatment. The most common adverse events were rash, increased sun sensitivity, joint pain, hair loss and fatigue. Adverse events also were generally reversible with dose modification or interruption. Possible serious side effects of vemurafenib include liver problems, changes in heartbeat or very fast or abnormal heartbeats and allergic reactions.

"We are very enthusiastic about the potential benefits seen with vemurafenib treatment in BRAF mutation-positive melanoma patients," said K. Peter Hirth, chief executive officer of Plexxikon. "The consistency and statistical significance of the data generated to date from BRIM3, BRIM2 and even seen early on in the Phase 1 trial, underscores the power of a personalized medicine approach for patients. Not only have we been able to detect an efficacy signal early on in the clinic, but we have been able to accelerate development of this molecularly targeted treatment, in combination with a companion diagnostic, ultimately for the benefit of patients."

"The data presented from studies conducted with vemurafenib treatment provide new hope to patients who currently have limited treatment options. We remain committed to bringing innovative solutions, like vemurafenib, to patients by combining potent therapies with

diagnostic tools to provide better outcomes," said Glenn Gormley, chief science officer, Daiichi Sankyo.

Additional clinical trials will further evaluate vemurafenib in combination with other approved drugs and investigational agents targeting melanoma, and will also evaluate vemurafenib as a single agent in thyroid patients with the BRAF mutation. Moreover, a trial in BRAF mutation-positive patients with brain metastases is also ongoing.

Applications for market approval of vemurafenib (PLX4032/RG7204) for the treatment of melanoma have been submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). During the marketing application review period, vemurafenib is available to eligible patients with BRAF V600 mutation-positive melanoma through a global patient access program. More information about this program or other vemurafenib studies is available at www.clinicaltrials.gov (in the U.S.), www.clinicaltrialsregister.eu (in the EU) or on the Roche Clinical Trials Registry at www.roche-trials.com. Genentech can also be contacted by calling the company's clinical trial call center at 888-662-6728 or emailing genentech@druginfo.com.

About BRIM3

BRIM3, a global, randomized, open-label, multicenter Phase 3 study, is evaluating vemurafenib compared to intravenous dacarbazine (the current chemotherapy standard of care) in patients with previously untreated mutation-positive metastatic melanoma. Study participants were randomized to receive either: vemurafenib 960 mg orally twice daily, or dacarbazine 1000 mg/m² intravenously every three weeks. Patients continue dosing until their disease progresses or there is unacceptable toxicity. Co-primary endpoints were overall survival and progression-free survival. There were 675 patients enrolled in this study. BRIM3 was initiated in December 2009 and includes over 100 sites worldwide.

About BRIM2

BRIM2, a Phase 2 trial, is a single-arm study of previously treated metastatic melanoma patients with the BRAF V600 mutation. The primary endpoint for this study was best overall response rate assessed by an independent review committee (IRC) using RECIST criteria, and secondary endpoints were best overall response rate assessed by clinical investigators, duration of response, progression-free survival, overall survival and safety. The open-label, multi-center study enrolled 132 patients.

About Melanoma

Melanoma is the most serious type of skin cancer and is growing at a rate of about five to six percent annually. More than 68,000 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.

About Vemurafenib (PLX4032)

Vemurafenib is a novel, oral small molecule being developed for the treatment of melanoma and other cancers harboring the oncogenic BRAF mutation. Plexxikon utilized its structure-guided chemistry platform to discover vemurafenib, and initiated clinical development in 2006. A DNA-based companion diagnostic to identify patients whose tumors carry the BRAF mutation is being co-developed by Plexxikon and Roche in parallel with the therapeutic development of vemurafenib.

About Plexxikon

Plexxikon, a member of the 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 compound, vemurafenib (PLX4032), is in late-stage clinical trials for the treatment of melanoma and the subject of pending applications for marketing approval in the U.S. and Europe. PLX3397, the company's next oncology candidate, has advanced to Phase 2 testing. 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 proprietary Scaffold-Based Drug Discovery™ 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. For more information, please visit www.plexxikon.com.

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