Vemurafenib New Drug Application Submitted to FDA for Melanoma

Daiichi Sankyo US Sales Force On Board to Co-Promote, Pending Approval

Parsippany, NJ (May 11, 2011) and Tokyo, Japan (May 11, 2011) -- Daiichi Sankyo announced that applications have been submitted for market approval for vemurafenib (PLX4032/RG7204) for the treatment of metastatic melanoma to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Additionally, a pre-marketing application for approval for a companion diagnostic test has been submitted in the U.S.; the test also will be registered in Europe. Vemurafenib is an oral, novel drug that targets the oncogenic BRAF mutation present in about half of melanoma cancers and about eight percent of all solid tumors.

In April 2011, Daiichi Sankyo, Co., Ltd. acquired Plexxikon, which discovered and is co-developing vemurafenib with Roche. Daiichi Sankyo, Inc. will co-promote vemurafenib in the U.S. with Genentech under Plexxikon's co-promote agreement with Genentech, a member of the Roche Group.

"The NDA submission to FDA for vemurafenib only six years after its discovery reflects Plexxikon's highly efficient research platform to identify unique molecules as well as the team's strategic approach to early development," said Glenn Gormley, MD, PhD, chief science officer & president, Daiichi Sankyo Pharma Development. "This is the very reason Daiichi Sankyo is proud to have made Plexxikon part of the Daiichi Sankyo Group, and from now on, to jointly bring forward novel medicines for the patients who need them."

"Daiichi Sankyo has brought on board a highly experienced sales team to co-promote vemurafenib with Genentech in the U.S., pending FDA approval, and we look forward to working with our partner to bring this new personalized approach to this deadly type of cancer to patients and providers," said John Gargiulo, president and CEO, Daiichi Sankyo, Inc. "We are fortunate and excited that vemurafenib has the potential to be the first entry into the oncology market for Daiichi Sankyo, Inc., and we expect it will be followed by other promising molecules from our robust pipeline."

About the Vemurafenib Clinical Program

The submissions are based on results from two clinical studies (BRIM2 and BRIM3) that evaluated vemurafenib in people with BRAF V600 mutation-positive metastatic melanoma, as determined by the cobas 4800 $BRAF^{V600}$ Mutation Test.

Earlier this year, Plexxikon reported positive data from an interim analysis of BRIM3, which showed that the study met the pre-specified criteria for co-primary endpoints for BRIM3 for progression free survival and overall survival (OS), and that the safety profile was generally consistent with the previous vemurafenib studies. Based on these results, the data safety monitoring board for the trial recommended early termination of the trial and allowed dacarbazine-treated patients to immediately cross over to vemurafenib treatment. BRIM2 results reported earlier showed a 52 percent confirmed response rate, with tumor shrinkage in the majority of patients, consistent with results from earlier studies.

The most frequent Grade 3 adverse event observed in clinical trials of vemurafenib was cutaneous squamous cell carcinoma, a common skin cancer treated by local excision (minor

surgery done in a physician's office). The most common adverse events were rash, increased sun sensitivity, joint pain, hair loss and fatigue. Possible serious side effects of vemurafenib include liver problems, changes in heartbeat or very fast or abnormal heartbeats, and allergic reactions.

Comprehensive data from BRIM3 will be presented at a plenary session at the 47th Annual Meeting of the American Society of Clinical Oncology (ASCO) in June. Additionally, updated BRIM2 data also will be presented at ASCO.

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 70,000 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 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)—A Personalized Medicine for Cancer Treatment
Vemurafenib is a novel, oral small molecule for treating 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. Plexxikon and Roche signed a license and collaboration agreement in 2006 to co-develop vemurafenib. Under a 2005 agreement, a DNA-based companion diagnostic to identify patients whose tumors carry the BRAF mutation is being co-developed by Plexxikon and Roche Molecular Systems in parallel with the therapeutic development of vemurafenib.

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 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.

In April 2011, Daiichi Sankyo acquired Plexxikon, which will maintain its research and development operations as an independent member of the Daiichi Sankyo Group.

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.

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