Vemurafenib New Drug Application Submitted to FDA for Melanoma

Bio-Medicine.Org

PARSIPPANY, N.J. and TOKYO, May 11, 2011 /PRNewswire/ -- 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 and 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 followe
'/>"/>

SOURCE [1]

Source URL (retrieved on *05/25/2013 - 5:23am*):
http://www.mdtmag.com/news/2011/05/vemurafenib-new-drug-application-submitted-fda-melanoma

Links:

[1] http://www.bio-medicine.org/medicine-technology-1/Vemurafenib-New-Drug-Application-Submitted-to-FDA-for-Melanoma-17163-1/