Pfizer And GSK To Initiate Study Of Novel Combination Therapy In Patients With Melanoma

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Phase I/II Study combines GSK's trametinib and Pfizer's palbociclib

Pfizer Inc. announced today that it has entered into an agreement with GSK to explore the anti-cancer efficacy and the safety of GSK's trametinib (GSK1120212) combined with Pfizer's palbociclib (PD-0332991) in a Phase I/II study (Study 200344) in patients with advanced/metastatic melanoma.

Study 200344 is a dose-escalation, open-label study designed to determine the recommended combination regimen (RCR) for trametinib plus palbociclib in patients with melanoma. The study will also evaluate the effect of the combination on tumor biomarkers, safety and anti-cancer activity in patients with BRAFV600 wild type melanoma, including those with NRAS mutations.

"Pfizer Oncology is committed to maximizing the value of our portfolio for patients through the study of novel combinations. This includes combining our own cancer medicines with each other, as well as with those of other companies where there is strong scientific rationale," said Garry Nicholson, president and general manager, Pfizer Oncology Business Unit. "Emerging data suggest the potential for trametinib and palbociclib to work together to treat melanoma. We look forward to collaborating with

GSK to explore this potential and evaluate the clinical activity of this combination in melanoma."

The two companies will collaborate on the study, which GSK will conduct. Financial terms of the agreement were not disclosed.

Trametinib, a reversible inhibitor of MEK1 and MEK2, is approved by the U.S. Food and Drug Administration (FDA) under the name Mekinist® for the treatment of adult patients with unresectable or metastatic melanoma with BRAF V600E or V600K mutation as detected by an FDA-approved test. Mekinist is not indicated for the treatment of patients who have received a prior BRAF inhibitor therapy.

Palbociclib is an investigational oral and selective inhibitor of cyclin dependent kinases (CDK) 4 and 6. In April 2013, palbociclib received Breakthrough Therapy designation by the FDA for the potential treatment of patients with breast cancer. Palbociclib is not approved for any indication in any markets.

About Pfizer Oncology

Pfizer Oncology is committed to the discovery, investigation and development of innovative treatment options to improve the outlook for cancer patients worldwide. Our strong pipeline of biologics and small molecules, one of the most robust in the industry, is studied with precise focus on identifying and translating the best scientific breakthroughs into clinical application for patients across a wide range of cancers. By working collaboratively with academic institutions, individual researchers, cooperative research groups, governments, and licensing partners, Pfizer Oncology strives to cure or control cancer with breakthrough medicines, to deliver the right drug for each patient at the right time. For more information, please visit www.Pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of November 21, 2013. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about an investigational combination therapy of trametinib and palbociclib for the potential treatment of melanoma, including its potential benefits, that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things:

· *the uncertainties inherent in research and development including, without limitation, the ability to meet anticipated clinical trial commencement and completion dates, as well as the possibility of unfavorable clinical trial results;*

· *whether and when any applications may be filed with regulatory authorities in various jurisdictions for the combination therapy for the treatment of melanoma, and whether and when regulatory authorities may approve any such applications, as well as their decisions regarding labeling and other matters that could affect its availability or commercial potential; and*

· *competitive developments.*

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K/A for the fiscal year ended December 31, 2012 and in its reports on Form 10-Q and Form 8-K.

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