Pfizer Logo

Pfizer And Merck To Collaborate On Innovative Anti-Cancer Combination Studies

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Agreement to Combine Merck's Investigational Anti-PD-1 and Key Pfizer Oncology Assets

NEW YORK, N.Y., – Pfizer Inc. (NYSE:PFE) announced today that it has agreed with Merck & Co., Inc., known as MSD outside the United States and Canada ("Merck"), through two Merck subsidiaries, to explore the therapeutic potential of Merck's investigational anti-PD-1 therapy, MK-3475, in combination with two Pfizer oncology assets. A Phase I/II clinical study will evaluate the safety and anti-cancer efficacy of MK-3475 combined with Pfizer's axitinib (INLYTA®) in renal cell carcinoma (RCC). A separate Phase I study will evaluate the safety and tolerability of the combination of MK-3475 and PF-05082566 (PF2566), Pfizer's investigational, fully humanized monoclonal antibody (mAb) that stimulates signaling through 4-1BB (CD-137), a protein involved in regulation of immune cell proliferation and survival.

"There has been notable progress in the cancer immunotherapy field over the last year, with new clinical data showing promising efficacy and tolerability for emerging therapies – particularly those that target the PD-1 pathway," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. "These investigational therapies, which harness the body's immune system to treat disease, may hold the greatest potential for patients with cancer when used in combination with other immunooncology agents, like PF-2566, to amplify anti-tumor immune responses, or with targeted agents, like axitinib, to optimize their effectiveness. We are pleased to collaborate with Merck to study a diverse group of our anti-cancer agents in combination with MK-3475, with the goal of identifying more efficacious treatment options for patients."

"We are pleased to be collaborating with Pfizer to study MK-3475 as part of these novel combination regimens," said Dr. Eric Rubin, vice president, clinical development for oncology, Merck Research Laboratories. "Early evaluation of immunotherapeutic combinations is important toward potentially accelerating the development of new options for patients with cancer."

Pfizer will conduct the clinical studies of MK-3475 plus axitinib and MK-3475 plus PF-2566. This agreement does not provide for any collaboration between Pfizer and Merck following the completion of the specified

studies.

Financial terms were not disclosed.

Under a separate agreement Pfizer and Merck are currently exploring the pre-clinical combination of MK-3475 with Pfizer's investigational therapy palbociclib (PD-0332991). Merck is conducting these pre-clinical studies. Further studies would depend on the outcome of the ongoing pre-clinical studies as well as subsequent agreement by Merck and Pfizer.

About MK-3475

Many tumors are able to evade the immune system through a mechanism that exploits the PD-1 inhibitory checkpoint protein. MK-3475 is an investigational, highly selective anti-PD-1 immunotherapy designed to restore the natural ability of the immune system to recognize and target cancer cells by selectively achieving dual ligand blockade (PD-L1 and PD-L2) of the PD-1 protein. By blocking PD-1, MK-3475 enables activation of the immune system's T-cells that target cancer by essentially releasing a brake on the immune system. For information on Merck's clinical trials please visit http://www.merck.com/clinical-trials/.

About INLYTA® (axitinib) tablets

INLYTA, a kinase inhibitor, is an oral therapy that is designed to inhibit tyrosine kinases, including vascular endothelial growth factor (VEGF) receptors 1, 2 and 3; these receptors can influence tumor growth, vascular angiogenesis and progression of cancer (the spread of tumors). In the United States (U.S.), INLYTA is approved for the treatment of advanced renal cell carcinoma (RCC) after failure of one prior systemic therapy. INLYTA is also approved by the European Medicines Agency (EMA) for use in the European Union (EU) in adult patients with advanced RCC after failure of prior treatment with sunitinib or a cytokine.

Important Safety Information for INLYTA (axitinib) tablets

Hypertension including hypertensive crisis has been observed. Blood pressure should be well controlled prior to initiating INLYTA. Monitor for hypertension and treat as needed. For persistent hypertension, despite use of antihypertensive medications, reduce the dose. Discontinue INLYTA if hypertension is severe and persistent despite use of antihypertensive therapy and dose reduction of INLYTA, and discontinuation should be considered if there is evidence of hypertensive crisis. Arterial and venous thrombotic events have been observed and can be fatal. Use with caution in patients who are at increased risk or who have a history of these events.

Hemorrhagic events, including fatal events, have been reported. INLYTA has not been studied in patients with evidence of untreated brain metastasis or recent active gastrointestinal bleeding and should not be used in those patients. If any bleeding requires medical intervention, temporarily interrupt the INLYTA dose.

Gastrointestinal perforation and fistula, including death, have occurred. Use with caution in patients at risk for gastrointestinal perforation or fistula. Monitor for symptoms of gastrointestinal perforation or fistula periodically throughout treatment.

Hypothyroidism requiring thyroid hormone replacement has been reported. Monitor thyroid function before initiation of, and periodically throughout, treatment.

Stop INLYTA at least 24 hours prior to scheduled surgery. Reversible Posterior Leukoencephalopathy Syndrome (RPLS) has been observed. If signs or symptoms occur, permanently discontinue treatment.

Monitor for proteinuria before initiation of, and periodically throughout, treatment. For moderate to severe proteinuria, reduce the dose or temporarily interrupt treatment.

Liver enzyme elevation has been observed during treatment with INLYTA. Monitor ALT, AST, and bilirubin before initiation of, and periodically throughout, treatment.

For patients with moderate hepatic impairment, the starting dose should be decreased. INLYTA has not been studied in patients with severe hepatic impairment.

Women of childbearing potential should be advised of potential hazard to the fetus and to avoid becoming pregnant while receiving INLYTA.

Avoid strong CYP3A4/5 inhibitors. If unavoidable, reduce the dose. Grapefruit or grapefruit juice may also increase INLYTA plasma concentrations and should be avoided.

Avoid strong CYP3A4/5 inducers and, if possible, avoid moderate CYP3A4/5 inducers.

The most common (?20%) adverse events (AEs) occurring in patients receiving INLYTA (all grades, vs sorafenib) were diarrhea (55% vs 53%), hypertension (40% vs 29%), fatigue (39% vs 32%), decreased appetite (34% vs 29%), nausea (32% vs 22%), dysphonia (31% vs 14%), hand-foot syndrome (27% vs 51%), weight decreased (25% vs 21%), vomiting (24% vs 17%), asthenia (21% vs 14%), and constipation (20% vs 20%).

The most common (?10%) grade 3/4 AEs occurring in patients receiving INLYTA (vs sorafenib) were hypertension (16% vs 11%), diarrhea (11% vs 7%), and fatigue (11% vs 5%).

The most common (?20%) lab abnormalities occurring in patients receiving INLYTA (all grades, vs sorafenib) included increased creatinine (55% vs 41%), decreased bicarbonate (44% vs 43%), hypocalcemia (39% vs 59%), decreased hemoglobin (35% vs 52%), decreased lymphocytes (absolute) (33% vs 36%), increased ALP (30% vs 34%), hyperglycemia (28% vs 23%), increased lipase (27% vs 46%), increased amylase (25% vs 33%), increased ALT (22% vs 22%), and increased AST (20% vs 25%).

Please see full Prescribing Information at Inlyta.com.

About PF-2566

PF-2566 is an investigational, fully human monoclonal antibody (mAb) that targets CD-137, a protein expressed in many immune cells. In pre-clinical models, it has shown anti-tumor activity by enhancing T-cell mediated immune responses. Pfizer is currently evaluating PF-2566 in a Phase I study as a single agent in multiple tumor types, as well as in combination with rituxumab in non-Hodgkin lymphoma patients. PF-2566 is not approved for any indications in any markets.

About Palbociclib

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

PFIZER DISCLOSURE NOTICE The information contained in this release is as of February 5, 2014. 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 that involves substantial risks and uncertainties about investigational therapies PF-2566 and palbociclib and about agreements between Pfizer and Merck to study the anti-cancer therapeutic potential of each of three Pfizer oncolocy assets, INLYTA (axitinib), PF2566 and palbociclib, in combination with Merck's investigational therapy MK-3475. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated preclinical and clinical study commencement and completion dates as well as the possibility of unfavorable study results; whether and when drug applications may be filed in any jurisdictions for PF2566, palbociclib or any of the combination therapies; whether and when any such applications may be approved by regulatory authorities, as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of PF-2566, palbociclib or any of the combination therapies; 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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