

Pfizer And Kyowa Hakko Kirin To Collaborate On Immuno-Oncology Combination Study

Monday, September 29, 2014 - 04:00pm

Agreement to Combine Kyowa Hakko Kirin's Anti-CCR4 Antibody Mogamulizumab and Pfizer's investigational 4-1BB agonist (PF-05082566) in Clinical Study

Pfizer Inc. (NYSE:PFE) and Kyowa Hakko Kirin (Tokyo:4151), announced today that they have entered into an agreement to explore the therapeutic potential of the combination of Pfizer's PF-05082566, an investigational, fully humanized monoclonal antibody (mAb) that stimulates signaling through 4-1BB (CD-137), a protein involved in regulation of immune cell activation, proliferation and survival, with Kyowa Hakko Kirin's anti-CCR4 antibody mogamulizumab, which suppresses some of the immune cells that shield the tumor from the immune system, in a Phase Ib clinical study evaluating the safety and tolerability of the combination in patients with solid tumors.

Under the terms of the agreement, Pfizer and Kyowa Hakko Kirin will co-fund the clinical study, which will be conducted by Pfizer. This study is expected to establish a recommended dose regimen and assess the safety and preliminary efficacy of the combination. This study is expected to begin in 2015 and the results will determine the future clinical development of the combination.

"We believe that combination therapy in immuno-oncology holds great promise to improve outcomes for patients with cancer and provides an exciting opportunity for Pfizer to maximize the potential of our emerging immuno-oncology portfolio," said Dr. Mace Rothenberg, senior vice president of Clinical Development and Medical Affairs and chief medical officer for Pfizer Oncology. "Our collaboration with Kyowa Hakko Kirin provides an additional important partnership opportunity to explore the potential of 4-1BB as part of a novel immunotherapy combination regimen."

"With recent progress in the field of cancer immunotherapy, the combination therapy of mogamulizumab and Pfizer's 4-1BB agonist has the potential to bring significant benefits to patients," said Yoichi Sato, managing executive officer, vice president, Head of Research and Development Division of Kyowa Hakko Kirin. "Collaborating with Pfizer, a world's leading pharmaceutical company, on a clinical study in emerging immuno-oncology field is an important component of Kyowa Hakko Kirin's ongoing transformation into a global specialty pharmaceutical company. We are excited about this opportunity."

About PF-05082566

PF-05082566 is an investigational, fully humanized mAb that targets 4-1BB (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-05082566 in a Phase I study as a single agent in multiple tumor types, as well as in several combination studies, including a clinical study of PF-05082566 in combination with rituximab in non-Hodgkin lymphoma patients. PF-05082566 is not approved for any indications in any markets.

About Mogamulizumab

Mogamulizumab is a novel, humanized mAb directed against CC chemokine receptor 4 (CCR4). Engineered by Kyowa Hakko Kirin's unique POTELLIGENT[®] Technology, the antibody is designed to kill its target cells through potent antibody-dependent cellular cytotoxicity. Mogamulizumab was launched in Japan in May 2012 for the treatment of patients with relapsed or refractory CCR4-positive adult T-cell leukemia-lymphoma (ATL). The drug was approved for indication expansion and was granted marketing authorization in Japan for the treatment of patients with relapsed or refractory CCR4-positive, peripheral T-cell lymphoma (PTCL) and cutaneous T-cell lymphoma (CTCL) in March 2014. Clinical trials with mogamulizumab in ATL, PTCL, and CTCL are ongoing in the US, EU and other countries.

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 Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

About Kyowa Hakko Kirin

Kyowa Hakko Kirin is a leading biopharmaceutical company in Japan focusing on its core business area of oncology, nephrology and immunology/allergy. Kyowa Hakko Kirin leverages antibody-related leading-edge technologies to discover and develop innovative new drugs aiming to become a global specialty pharmaceutical company which contributes to the health and well-being of people around the world. For more information, visit <http://www.kyowa-kirin.com>.

PFIZER DISCLOSURE NOTICE

The information contained in this release is as of September 29, 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 about an agreement between Pfizer and Kyowa Hakko Kirin to study the therapeutic potential of the combination of Pfizer's PF-05082566 with Kyowa Hakko Kirin's anti-CCR4 antibody mogamulizumab that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated 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 the combination therapy; 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 the combination therapy; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2013 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

Pfizer Media: Sally Beatty, 212-733-6566 Sally.Beatty@pfizer.com Investor: Ryan Crowe, 212-733-8160 Ryan.Crowe@pfizer.com or KHK Media: Public Relations Group Corporate Communication Dept. +81-3-3282-1903 media@kyowa-kirin.co.jp Investor: Investor Relation Group Corporate Communication Dept. +81-3-3282-0009 ir@kyowa-kirin.co.jp