Pfizer Logo

Pfizer And Protalix Enter Into Agreement To Develop And Commercialize Gaucher's Disease Treatment

Monday, November 30, 2009 - 03:00pm

New Drug Application (NDA) expected to be filed with FDA for novel enzyme replacement therapy with Fast Track Orphan Drug designation

(BUSINESS WIRE)--Pfizer (NYSE: PFE) and Protalix (NYSE-Amex: PLX) today announced that they have entered into an agreement to develop and commercialize taliglucerase alfa, a plant-cell expressed form of glucocerebrosidase (GCD) in development for the potential treatment of Gaucher's disease. Under the terms of the agreement, Pfizer will receive exclusive worldwide licensing rights for the commercialization of taliglucerase alfa, while Protalix will retain the exclusive commercialization rights in Israel. Taliglucerase alfa is the first enzyme replacement therapy derived from a proprietary plant cell-based expression platform using genetically engineered carrot cells.

With the successful completion of Phase III clinical studies, Protalix is preparing to complete a rolling New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA). The FDA has granted Orphan Drug designation and Fast Track status, facilitating the development and expediting the review of drugs to treat rare conditions or diseases, as well as an Emergency Use Authorization. The FDA has also requested, and subsequently approved, an Expanded Access Program (EAP) treatment protocol. Taliglucerase alfa is currently being provided to Gaucher's patients in the U.S. under the EAP protocol, as well as to patients in the European Union under a compassionate use protocol.

"We are excited about this collaboration, which represents a significant step towards bringing, for the first time, a plant-based enzyme replacement treatment option to patients affected by Gaucher's disease," commented Dr. David Aviezer, president and CEO of Protalix. "By joining our advances in biologics manufacturing and protein development with Pfizer's global strengths in patient services and reimbursement we expect to help make taliglucerase alfa an important and cost-effective treatment choice for Gaucher's patients throughout the world."

Under the agreement, Pfizer will make an upfront payment of $60 million to Protalix. In addition, Protalix is eligible to receive additional regulatory milestone payments of up to $55 million. Pfizer and Protalix will share future revenues and expenses for the development and commercialization of taliglucerase alfa on a 60 percent/40 percent basis respectively.

"By combining our respective strengths to advance this innovative therapy, Pfizer and Protalix expect to quickly deliver an alternative treatment for people suffering from Gaucher's disease," said David Simmons, president and general manager of Pfizer's Established Products Business Unit. "This agreement supports our goal to meet the needs of many patient populations, including those affected by rare diseases, and brings the best minds together to challenge the most feared diseases of our time."

Peter L. Saltonstall, President and CEO, National Organization for Rare Disorders (NORD) stated, "NORD is always pleased when treatment options are expanded for people with rare diseases. We welcome Pfizer's commitment to the rare disease arena, and look forward to working with both Pfizer and Protalix in support of increased options for patients and families affected by rare diseases."

About Gaucher's disease

Gaucher's disease, an inherited condition, is the most prevalent lysosomal storage disorder, with an incidence of about 1 in 20,000 live births. People with Gaucher's disease do not have enough of an enzyme, ?-glucosidase (glucocerebrosidase) that breaks down a certain type of fat molecule. As a result, lipid engorged cells (called Gaucher cells) amass in different parts of the body, primarily the spleen, liver and bone marrow. Accumulation of Gaucher cells may cause spleen and liver enlargement, anemia, excessive bleeding and bruising, bone disease and a number of other signs and symptoms.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins expressed through its proprietary plant cell based expression system. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is also advancing additional recombinant biopharmaceutical drug development programs. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with FDA for Gaucher's disease.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer 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 the world's leading biopharmaceutical company, we also 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 about our commitments, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of December 1, 2009, and neither Pfizer nor Protalix assume any 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 taliglucerase alfa, a product candidate that is the subject of a global development and commercialization agreement between Pfizer and Protalix, including its potential benefits and the anticipated filing of a new drug application with the FDA that involves substantial risks and uncertainties. Such risks and uncertainties include, among other things, the uncertainties inherent in research and development; decisions by regulatory authorities regarding whether and when to approve any drug applications that may be filed for such product candidate 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 with respect to Pfizer can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and in its reports on Form 10-Q and Form 8-K. A

further description of risks and uncertainties with respect to Protalix can be found in Protalix's Annual Report on Form 10-K for the fiscal year ended December 31, 2008 and its reports on Form 10-Q.

Pfizer Contacts: (Media) Joan Campion, 212-733-2798 Joan.Campion@Pfizer.com OR (Investors) Suzanne Harnett, 212-733-8009 Suzanne.Harnett@Pfizer.com OR Protalix Contacts: (Media) BMC Communications Group, LLC Brad Miles, 917-570-7340 Bmiles@bmccommunications.com OR (Investors) The Trout Group, LLC Marcy Nanus, 646-378-2927 Mnanus@troutgroup.com