Protalix BioTherapeutics Treats First Gaucher Patient in Phase I Study With PRX-112, an Orally-Administered Enzyme Treatment of Gaucher Disease

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CARMIEL, Israel, April 2, 2013 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the first patient has been treated in the Company's phase I clinical trial of PRX-112, or Oral GCD, the Company's orally-administered enzyme product candidate for the treatment of Gaucher disease. Oral GCD is a plant cell expressed form of the glucocerebrosidase enzyme (GCD) that is naturally encapsulated within carrot cells and administered orally. Protalix expects the phase I trial to be completed during the third quarter of 2013.

"With Oral GCD, we are using the natural characteristics of plant cells to deliver active enzyme into the patient's blood stream," said Professor Ari Zimran, M.D., Director of the Gaucher Clinic in Shaare Zedek Medical Center, Jerusalem, Israel and lead clinical investigator. "We believe oral delivery of GCD has the potential to improve patients' quality of life without compromising the efficacy or safety of the treatment."

The phase I clinical trial is an open label safety and pharmacokinetic study designed to assess the delivery of prGCD after oral administration of Oral GCD in 12 Gaucher patients. Subjects receive re-suspended carrot cells in a single oral administration during the first cohort of the trial and three consecutive daily administrations during the second cohort of the trial.

Pre-clinical studies of oral GCD demonstrate the stability of the enzyme in the carrot cell and the capacity of the cell's cellulose wall to protect the enzyme against degradation in the digestive tract in an in-vitro model of the stomach and intestines. Additionally, both rats and pigs fed with PRX-112, lyophilized carrot cells expressing GCD, have demonstrated enzyme levels in the plasma and accumulation of the active enzyme in target organs such as the spleen and liver.

Dr Einat Brill Almon, the Company's Senior Vice President, Product Development, added: "We successfully demonstrated the ability of plant cells to act as an oral delivery mechanism for a number of therapeutic proteins in our animal studies. We believe that the results of our clinical trial of Oral GCD will provide additional support for our belief that this oral delivery mechanism can be developed for other proteins used to treat other indications."

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell based expression system, ProCellEx®. Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (FDA) in May 2012, by Israel's Ministry of Health in September 2012 and by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013. It also has been approved in Uruguay. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel, where Protalix retains full rights. Protalix's development pipeline also includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is naturally encased in carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis; and others.

Forward Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. The terms "anticipate," "believe," "estimate," "expect," "plan" and "intend" and other words or phrases of similar import are intended to identify forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause material differences include, among others: failure or delay in the commencement or completion of our clinical trials which may be caused by several factors, including: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of safety or efficacy, that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our preparation and filing of applications for regulatory approval; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and clinical trial insurance coverage; and other factors described in our filings with the U.S. Securities and Exchange Commission. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

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