Protalix BioTherapeutics Initiates Phase II Study With PRX-112, an Orally-Administered Enzyme Replacement Therapy for the Treatment of Gaucher Disease

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CARMIEL, Israel, June 18, 2014 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the first Gaucher patient has been enrolled in the Company's phase IIa clinical trial of oral glucocerebrosidase (GCD), or oral GCD (PRX-112), for the treatment of Gaucher disease. Oral GCD is the Company's proprietary plant cell expressed form of an active glycosylated glucocerebrosidase enzyme (GCD) that is naturally encapsulated within carrot cells and administered orally. The Company expects the trial to be completed during the third quarter of 2014.

The phase IIa trial is a 28 day open-label, sequential dose escalation study to evaluate the safety of oral PRX-112 and study the dose dependant pharmacokinetics of Oral GCD in 10 naïve adult Gaucher patients. Subjects will receive once daily oral administrations of oral GCD for five consecutive days at each dose, with a two-day washout period between doses.

In a phase I study conducted year end 2013, oral GCD was found to be safe and well tolerated in all 16 patients across all of the three doses tested. There were no drug-related serious adverse reactions reported, and no patient discontinued the study prematurely. Presence of the GCD enzyme was detected in patients' blood circulation and the enzyme demonstrated biological activity. With a daily oral administration of oral GCD, the Company expects to achieve a steady state level of active GCD enzyme in the blood circulation of patients similar to the physiological state in healthy individuals.

"Following the completion of our phase I trial of oral GCD last year, we were encouraged to see the clinical proof of concept demonstrated in the study and we look forward to continuing the development of an oral enzyme treatment for Gaucher patients," commented Dr. David Aviezer, Protalix's President and Chief Executive Officer. "We believe oral delivery of GCD has the potential to improve patients' quality of life and possibly clinical maintenance while maintaining the efficacy and safety of an enzyme treatment."

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, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, by the Australian Therapeutic Goods Administration (TGA) in May 2014 and by the regulatory authorities of other countries. 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 and Brazil, where Protalix retains full rights. Protalix's development pipeline 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-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of certain immune and inflammatory diseases, such as rheumatoid arthritis, Crohn's disease, colitis, psoriasis and other autoimmune and inflammatory disorders; PRX-110 for the treatment of Cystic Fibrosis; 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, and other risks relating to the review process; 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 other necessary 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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