Protalix BioTherapeutics Reports Positive Interim Data from Phase I/II Clinical Trial of PRX-102 for the Treatment of Fabry Disease

Meaningful Clinical Benefits Demonstrated Across All Key Disease Parameters

Favorable Safety Profile

CARMIEL, Israel, January 8, 2015 /GlobeNewswire /Protalix BioTherapeutics, Inc. (NYSE MKT:PLX, TASE:PLX), announced today positive interim efficacy and safety data from the Company's ongoing phase I/II clinical trial of PRX-102 for the treatment of Fabry disease. PRX-102 demonstrated meaningful clinical benefits across the following key disease parameters already in the low dose of 0.2 mg/kg:

- Major reduction in Gb3 in Renal Peritubular Capillaries
- Significant improvement in all pain parameters
- Stabilization of cardiac and kidney function with favorable trends
- Low level of antibody formation

"We are very enthusiastic about the encouraging efficacy and safety data presented today for PRX-102," commented Mr. Moshe Manor, Protalix's President and Chief Executive Officer. "Given that the efficacy results are for the lowest dose cohort and were achieved after only six months, we believe PRX-102 has the potential to be a significantly improved product compared to the enzyme replacement therapies currently available to the Fabry patient community."

The phase I/II clinical trial of PRX-102 for the treatment of Fabry disease is an open-label, dose-ranging study treating up to 18 naïve male and female patients. The three dose cohorts include dosage groups of 0.2 mg/kg, 1mg/kg and 2mg/kg with intravenous infusions of PRX-102 every two weeks, with a six-month efficacy follow up period.

The interim efficacy analysis includes 6 patients enrolled in the 0.2mg/kg dose group at six months of treatment (for Gb3 in renal peritubular capillaries n=5). The interim safety analysis includes 12 patients; 6 patients enrolled in the 0.2mg/kg dose group and 6 patients enrolled in the 1mg/kg dose group.

<u>Interim Efficacy Results</u>

Based on an analysis of kidney biopsies with randomized blinded scoring, PRX-102 demonstrated a reduction in renal peritubular capillary Gb3 of 82.2% for males and 65.4% for females using a quantitative Barisoni Lipid Inclusion Scoring System (BLISS) for a combined reduction of 75.5%. Applying the semi quantitative scoring method, commonly used by approved enzyme replacement therapies, PRX-102 demonstrated a reduction of 69.6% in abnormal capillary score. Using the well-accepted Brief Pain Inventory scale, a 100% reduction in Worst Pain and an average of 78.8% improvement on patients' Impact On Functioning were observed. Furthermore, all patients had stable cardiac function, with favorable trends after only six months, as measured by left ventricular mass (LVM), left ventricular mass index (LVMI) and ejection fraction (EF). Stable kidney function was also observed, with favorable trends after only six months, as measured by estimated glomerular filtration rate (eGFR) and urine protein.

Safety Results

The safety analysis for adverse events represents a total of 6.7 patient years. PRX-102 was well tolerated, with the majority of events being mild and moderate. Only one of the 12 patients evaluated for safety experienced hypersensitivity. Six patients receiving the 0.2mg/kg dose and 2 patients receiving the 1m/kg dose were evaluated for antibody formation. Of these 8 patients, only 2 patients, or 33% of the 0.2 mg/kg dose cohort, developed antibodies.

"The safety and clinical benefits of PRX-102 demonstrated in the interim results are extremely exciting and promising. Meaningful improvement or stability was seen across all disease parameters studied, including Gb3 levels, renal function, pain and cardiac parameters," said Professor Raphael Schiffmann, Director, Institute of Metabolic Disease at the Baylor Research Institute, Dallas, Texas, and a principal investigator in the PRX-102 clinical trial. "The safety profile reported is favorable, with most adverse events mild to moderate and transient in nature. The potential to treat patients with an improved alternative of enzyme replacement therapy would be a significant advance in the treatment of Fabry disease."

Dr. Derralynn Hughes of the Lysosomal Storage Disease Unit, Institute of Immunity and Transplantation, Royal Free London NHS Foundation Trust, London, UK, and a principal investigator in the PRX-102 clinical trial commented, "These interim results provide very encouraging efficacy and safety data with PRX-102, a plant-cell expressed alpha-GAL-A, in Fabry patients. Of particular note are the meaningful reductions in pain and renal Gb3 levels and favorable safety profile. Fabry disease is a rare, life-threatening condition for which there is a clear need for alternative treatment options."

Currently, patients are being treated in all three dose groups of the Phase I/II trial, and the Company expects to conclude enrollment by the end of first quarter of 2015. All patients that have completed the initial six-month efficacy follow-up have opted to be enrolled in the extension studies. The Company is planning to present additional interim results at the WORLD symposium which is being held February 9-13, 2015 in Orlando, Florida. Efficacy results for the 1mg/kg dosing cohort are expected to be announced in the third quarter of 2015 and full trial results are anticipated in the fourth quarter of 2015.

About Protalix BioTherapeutics, Inc.

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, also for the treatment of Gaucher disease; PRX-106, an orally-delivered treatment for the treatment of Inflammatory Bowel Disease; PRX-110 for the treatment of Cystic Fibrosis; and others.

About Baylor Research Institute

Established in 1984 in Dallas, Texas, Baylor Research Institute (BRI) promotes and supports research to bring innovative treatments from the laboratory workbench to the patient bedside. To achieve this bench-to-bedside concept, BRI focuses on basic science, clinical trials, healthcare effectiveness and quality of care research. Today, BRI is conducting more than 930 active research protocols with 400 research investigators, spanning more than 22 medical specialties, and has research and development projects in areas ranging from human immunology and orphan metabolic diseases to diabetes, cardio-vascular disease and many other unmet medical needs.

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 preclinical and 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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