Protalix BioTherapeutics Reports Positive Long Term Data on PRX-102 for Fabry Disease

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Significantly Improved PK Characteristics Result in:

Higher Active Enzyme Quantities, Induced Immune Tolerance

Meaningful Clinical Benefit Demonstrated Across All Key Disease Parameters

Reversal in eGFR Slope Achieved Suggesting Improvement in Kidney Function

CARMIEL, Israel, Oct. 19, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today positive long term data from the 0.2mg, or lowest dose, of the Company's phase I/II dose ranging clinical trial of PRX-102 for the treatment of Fabry disease. PRX-102 is a recombinant plant cell expressed, chemically modified version of the human alpha-Galactosidase-A enzyme.

"We continue to see excellent results from PRX-102 and are very pleased with what we see in our lowest dose of the study," said Moshe Manor, Protalix's President and Chief Executive officer. "Now that we have viewed results from 12 months of the study, we believe that PRX-102 has a significant potential to improve the condition of Fabry patients, particularly compared to the currently available enzyme replacement therapies."

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. The data presented herein is from patients in the 0.2mg/kg dose group following 12 months of treatment.

"The results to date from the 12 month interim report of the 0.2mg/kg of the Phase I/II clinical trial are promising on both efficacy and safety," commented Prof. David G Warnock, Professor of Nephrology at UAB Hospital, Birmingham, Alabama, USA, and a member of the Medical Advisory Board for PRX-102. "I am looking forward for the further development of PRX-102 that could potentially be beneficial to the Fabry patients' community."

The Company has scheduled an end of phase II meeting with the U.S. Food and Drug Administration to be held during the month of November to discuss the design of the pivotal phase III trial which the Company expects to start in early 2016.

Clinical Data on Kidney Functions

Among the leading causes for death of Fabry patients include renal failures. On average, patients that participated in the 0.2mg/kg cohort of the PRX-102 trial exhibited stability in kidney function with favorable trends shown, as measured by estimated Glomerular filtration rate (eGFR).

In a typical Fabry patient, the eGFR deteriorates over time, showing that kidney function is worsening. After dosing with 0.2mg/kg of PRX-102 for 12 months, a majority of the patients (4/6) experienced a stabilization or improvement in kidney function; a reversal of the decline shown by annualized eGFR slope was observed.

Detailed Clinical Data on Other Biomarkers and Scales

Lyso-Gb3 is a sensitive and reliable biomarker of Fabry disease. It is used as a biomarker as it dramatically increases and accumulates in the plasma of Fabry patients. Throughout the study, continuous and durable reduction of up to 61.8% of plasma lyso-Gb3 levels from base line was observed in patients in the 0.2mg/kg cohort. This represents a meaningful positive outcome of PRX-102 treatment.

In addition, Fabry patients of the 0.2mg/kg cohort of the PRX-102 trial showed a continuous reduction and durable improvement in Mainz Severity Score Index (MSSI), a tool for disease status evaluation of a variety of signs and symptoms of Fabry disease including cardiovascular, renal and neurological.

Pharmacokinetics

PRX-102 unique and enhanced PK properties resulted in long half-life, high AUC and measured levels of enzyme found throughout the entire two weeks infusion intervals in all patients of the 0.2mg/kg cohort of the trial, potentially contributing to an immune tolerance phenomenon. This resulted in low incidence of antibody formation with low titers in general, and moreover, in antibody positive patients it resulted in a transient and reversible shift of overall drug availability. Mean values for Cmax, and AUC were found to have briefly shifted at three and six months in antibody positive patients, where at 12 months, PK parameters returned to the high AUC levels observed at baseline, demonstrating that the antibody presence and its impact was transient, leading to full active dose availability for effective treatment.

In addition, PRX-102 continues to be well tolerated with a favorable safety profile, with the majority of adverse events being mild and moderate in severity with a very low rate of antibody formation.

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 and, subsequently, by the regulatory authorities of other countries. Protalix

has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding 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; PRX-106, an orally-delivered treatment for the treatment of Inflammatory Bowel Disease; 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 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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