Protalix BioTherapeutics Completes Enrollment in Phase I/II Clinical Trial of PRX-102 for Fabry Disease

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Interim Efficacy and Safety Results to be Presented at WORLD Symposium

CARMIEL, Israel, Feb. 2, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the Company has completed enrollment in its phase I/II clinical trial of PRX-102 for the treatment of Fabry disease. All patients that completed the trial have opted to continue to receive PRX-102 in an open-label extension trial. PRX-102 is a proprietary plant cell-expressed, chemically modified recombinant alpha-galactosidase-A enzyme that is designed to be a more stable enzyme than currently marketed enzyme replacement therapies for Fabry disease.

"The enthusiasm surrounding this open label study continues to mount, as evidenced by physicians' reactions to the interim data from the 0.2mg/kg dosing cohort," said Mr. Moshe Manor, President and Chief Executive Officer of Protalix BioTherapeutics. "Not only has PRX-102 shown benefits across all disease parameters, including remarkable results in pain, PRX-102 has also shown exciting cardiac and kidney function at only six months of treatment. We look forward to reporting additional interim results, including patient by patient data and cardiac and renal functions, at the WORLD Symposium."

On February 12, 2015 at 10:45AM ET Dr. Ozlem Goker-Alpan, President and Chief Medical Officer of the Center for Clinical Trials, O&O Alpan, LLC., and Director of the Lysosomal Research and Treatment Unit, will present interim results from the phase I/II trial in an oral presentation titled, "Novel treatment for Fabry disease, IV administration of plant derived α-GAL-A enzyme phase 1/2 safety and efficacy study: interim clinical report" at the Lysosomal Disease Network WORLD Symposium in Orlando, FL.

Additionally, the Company expects to report interim results from the 1mg/kg cohort in the third quarter of 2015, and full top-line results from all dosing cohorts in the fourth quarter of 2015. Management will request an end of Phase II meeting with the U.S. Food and Drug Administration in the fourth quarter of 2015, and anticipates initiating a phase III pivotal trial in early 2016.

The phase I/II clinical trial of PRX-102 is an open-label, dose-ranging study treating 18 naïve male and female patients with Fabry disease. 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.

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.

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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