Protalix BioTherapeutics Receives FDA IND Clearance to Initiate a Phase I/II Study of Fabry Disease Patients With PRX-102, a Modified Enzyme Replacement Therapy

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Phase I/II Clinical Trial to Initiate Enrollment of Fabry Patients in the Fourth Quarter of 2012

CARMIEL, Israel, Aug. 13, 2012 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX) (TASE:PLX), announced today that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate clinical trials of PRX-102. The Company plans to commence enrollment of Fabry disease patients for a phase I/II trial in the fourth quarter of 2012.

PRX-102 is a proprietary plant cell-expressed, chemically modified, recombinant alpha-galactosidase-A in development as a long-term enzyme replacement therapy (ERT) for the treatment of Fabry disease. The phase I/II clinical trial is designed as a multi-center, open label, dose ranging study to evaluate the safety, tolerability, pharmacokinetics and efficacy of PRX-102 in adult Fabry patients.

"We are very excited to begin the clinical development of PRX-102, which we believe may prove to present an important improvement to the well being of patients with Fabry disease, a rare, genetic lysosomal storage disorder affecting approximately 8,000 people globally," said Dr. David Aviezer, Protalix's President and Chief Executive Officer. "We have designed PRX-102 as a potentially improved version of the currently marketed enzyme replacement therapies for Fabry disease given its potential to be a more stable, potent and specific enzyme. This enzyme is expressed through ProCellEx®, our proprietary, plant cell-based protein expression system. We are also excited that another biotherapeutic protein evolving from our ProcellEx platform technology is anticipated to enter clinical development shortly."

Eighteen adult Fabry patients will be enrolled in one of three dosing groups. Each patient will receive intravenous infusions of PRX-102 every two weeks for 12 weeks, and will be infused sequentially and stepwise in order to evaluate safety. Exploratory efficacy parameters will be evaluated as a preliminary assessment. Following the end of the trial, the Company intends to offer patients the option to continue to receive PRX-102 in an open-label extension study.

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, ELELYSO™ (taliglucerase alfa), was approved for marketing by the U.S. Food and Drug Administration on May 1, 2012 and is partnered with Pfizer Inc. for worldwide development and commercialization, excluding Israel, where Protalix retains full rights. Marketing applications for taliglucerase alfa have been filed in additional territories as well. 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 the clinical trials; the risk that the results of our clinical trial of PRX-102 will not support our claims of safety or efficacy, that PRX-102 will not have the desired effects or includes 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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