Protalix BioTherapeutics Announces First Patient Treated in Phase I/II Study of Fabry Patients With PRX-102

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CARMIEL, Israel, Dec. 10, 2012 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX) (TASE:PLX), announced today that the first patient has been treated in the Company's phase I/II clinical trial of Fabry patients with PRX-102. PRX-102 is the Company's proprietary plant cell-expressed, chemically modified recombinant alpha-galactosidase-A enzyme in development as a long-term enzyme replacement therapy (ERT) for the treatment of Fabry disease.

"We are pleased to have PRX-102 enter the clinic this year as planned. We believe PRX-102 may eventually serve as an alternative treatment for Fabry patients with the potential to be an improved enzyme replacement therapy," said Dr. Einat Brill Almon, the Company's Senior Vice President, Product Development. "PRX-102 is manufactured using ProCellEx®, our proprietary recombinant protein expression system which uses genetically engineered plant cells to produce specific protein products. ELELYSO™, our first commercial product which was approved by the U.S. Food and Drug Administration in May 2012, is also manufactured through ProCellEx."

The phase I/II clinical trial is a worldwide, multi-center, open label, dose ranging study to evaluate the safety, tolerability, pharmacokinetics and exploratory efficacy parameters of PRX-102 in adult Fabry patients. The trial is designed to enroll 18 adult Fabry patients, each in one of three dosing groups. Each patient will receive intravenous infusions of PRX-102 every two weeks for 12 weeks. After the completion of the protocol, the Company intends to offer enrolled trial 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 by Israel's Ministry of Health in September 2012. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of ELELYSO™, 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 U.S. Food and Drug Administration, 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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