Protalix Announces FDA Investigational New Drug Clearance to Commence Once-Monthly Dosing Study of pegunigalsidase alfa (PRX-102) for the Treatment of Fabry Disease

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Once Monthly Dosing Would Represent a 50% Reduction in Patient Infusions

Unique Chemical Modifications to pegunigalsidase alfa Result in a Significantly Longer Half-life Allowing for the Potential of Effective Drug Coverage for Four Weeks

Study Planned to Commence in the Third Quarter of 2017

CARMIEL, Israel, May 09, 2017 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the U.S. Food and Drug Administration (FDA) cleared an Investigational New Drug application (IND) for a clinical trial evaluating the safety and efficacy of administering 2 mg/kg of pegunigalsidase alfa (PRX-102) once monthly in Fabry patients. The current dosing regimen for approved enzyme replacement therapies for Fabry disease is once every two weeks. Pegunigalsidase alfa is a PEGylated, chemically-modified version of the recombinant alpha-Galactosidase-A enzyme, in which the protein sub-units are covalently bound via chemical cross-linking using PEG chains, resulting in a longer active and stable molecule compared to currently available enzyme replacement therapies (ERTs).

Pegunigalsidase alfa with a 2 mg/kg was found to be safe and well tolerated with no formation of antibodies in the Company's phase I/II clinical trial of pegunigalsidase alfa for the treatment of Fabry disease. Additionally, in the phase I/II clinical trial, 2 mg/kg of pegunigalsidase alfa demonstrated approximately a 40 times higher circulatory half-life compared with other enzyme replacement therapies, and, as demonstrated in a Fabry mice model, with materially higher active enzyme reaching target organs affected by Fabry disease. Pharmacokinetic (PK) analysis and modeling from the phase I/II clinical trial indicate that pegunigalsidase alfa levels at the second week after infusion remain 10 times higher than published Fabrazyme® levels at the day of infusion. Moreover, the amount of pegunigalsidase alfa in the circulation at weeks three and four, are higher than those of Fabrazyme® during the two-week treatments. These results provide strong rationale for the clinical evaluation of a once-monthly dosing.

Area Under the Curve (AUC) derived from PK data modeling of Fabry patients:

Time (week)	**pegunigalsidase alfa,* 2 mg/kg IV every 4 weeks** (ug•min/mL)		**Fabrazyme®,** 1 mg/kg IV every 2 weeks** (ug•min/mL)	
1	1st infusion	59,364	1st infusion	~700
2		7,144		Nil
3		878	2nd infusion	~700
4		108		Nil

** PK modeling based on Phase I/II data ** Fabrazyme® USPI*

"The unique chemical modifications in pegunigalsidase alfa result in significantly longer circulatory half-life, which we believe will provide effective drug coverage for four full weeks," said Moshe Manor, Protalix's President and Chief Executive Officer. "This once-monthly regimen, if approved, will offer patients and care givers a new treatment option addressing the unmet need of less frequent infusions, and uniquely position Protalix as the only company offering two treatment options. The trial also demonstrates our commitment to the Fabry community and specifically to Fabry patients that are currently underserved by the therapies available today."

"The Fabry International Network (FIN), a global Fabry patient organization, welcomes the news that Protalix is moving forward with a third phase III clinical study infusing pegunigalsidase alfa 2mg/kg once every 4 weeks," sated FIN's President, Christine Lavery. "This study will provide individuals with Fabry disease and their health care providers with alternative treatment option on top of the pegunigalsidase alfa 1mg/kg dose once every two weeks regimen. If proven to be effective, the every four week infusion regime will go a long way to normalizing the lives of those living with Fabry disease."

The Company plans to enroll up to 30 Fabry patients currently treated with an approved enzyme replacement therapy. Participating patients will be switched to 2 mg/kg of pegunigalsidase alfa once-monthly. A safety and efficacy evaluation will occur at twelve months with additional long term follow-up. The Company expects to commence this study in the third quarter of 2017.

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-106, an orally-delivered anti-inflammatory treatment; PRX-110, a chemically modified DNase I 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: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; 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 superiority, 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; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase, and our commercialization efforts for alfataliglicerase in Brazil generally; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our convertible notes or any other indebtedness; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; 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 press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

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