Protalix BioTherapeutics Presents Preliminary Data from the BRIGHT Study of pegunigalsidase alfa for the Treatment of Fabry Disease at the 15th Annual WORLDSymposium™ 2019

February 5, 2019

~Pharmacokinetic data from patients treated in the study show that infusion of pegunigalsidase alfa every 4 weeks results in the presence of continuous active enzyme throughout the entire infusion interval~

~Continuous presence and activity of pegunigalsidase alfa detected even in patients with pre-existing anti-drug antibodies~

~Pegunigalsidase alfa is safe and well tolerated~

CARMIEL, Israel, Feb. 05, 2019 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced that preliminary pharmacokinetic (PK) data from its phase III BRIGHT study of pegunigalsidase alfa, or PRX-102, for the treatment of Fabry disease is the subject of an oral presentation at the 15th Annual WORLD*Symposium*™ 2019. The conference is taking place February 4-8, 2019 at the Hyatt Regency Orlando, Orlando, Florida, and the oral presentation is scheduled for Thursday, February 7, 2019 at 8:30 AM ET.

PRX-102 is the Company's plant cell-expressed recombinant, PEGylated, cross-linked α-galactosidase-A drug candidate for the treatment of Fabry disease. The BRIGHT study is a 12-month, open-label switchover study to assess the safety, efficacy and pharmacokinetics of pegunigalsidase alfa 2 mg/kg administered every 4 weeks in up to 30 Fabry patients previously treated with an enzyme replacement therapy (ERT): Fabrazyme® or Replagal®. As of December 23, 2018, 28 patients had been enrolled in the BRIGHT study, and 15 of those patients had completed 9 months of treatment. Samples from these 15 patients underwent pharmacokinetic (PK) evaluation and were tested for the presence of anti-drug antibodies (ADA).

The results of the BRIGHT study demonstrate that PRX-102 was present and remained active in the plasma over the 4-week infusion intervals. The mean concentration of PRX-102 at day 28 was 138 ng/mL. In comparison, published data on Fabrazyme (1mg/kg every 2 weeks) shows a mean concentration of 20 ng/mL at 10 hours post infusion. In addition, the area under the curve (AUC) for PRX-102 was measured to be approximately 2,000,000 ng·hr/mL over 28 days. Based on published data, the AUC of Fabrazyme is approximately 10,000 ng·hr/mL.

Additionally, pre-existing ADAs generated in patients prior to switching to PRX-102 had substantially little effect on the circulation of PRX-102 for the 4-week period evaluated, and PRX-102 concentration in circulation was higher than agalsidase beta, even in the presence of ADAs.

"The preliminary PK data from the BRIGHT study is very encouraging and suggest that PRX-102 has the potential to be effectively dosed every 4 weeks, compared to currently available enzyme replacement therapies (ERT) for Fabry disease which need to be administered every two weeks," said Myrl D. Holida, Physician Assistant at the University of Iowa Health Care in Iowa City, Iowa and BRIGHT Study Investigator. "Fabry disease is a chronic illness for which there is currently no cure. Reducing the number of required treatment infusions for Fabry patients on ERT has the potential to greatly improve their quality of life and compliance with treatment."

A preliminary safety analysis of 19 patients enrolled in the BRIGHT study was also conducted, and indicated that PRX-102 is safe and well tolerated.

A copy of the oral presentation and poster presentations from the conference will be available on Protalix's website under the Presentation tab in the Investors section.

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: pegunigalsidase alfa, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

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 "expect," "anticipate," "believe," "estimate," "project," "plan," "should" 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 and the final results of a clinical trial may be different than the preliminary findings for the clinical trial. 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: risks that the FDA will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX-102; 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 our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the ultimate purchase by Fundação Oswaldo Cruz of alfataliglicerase pursuant to the stated purchase intentions of the Brazilian Ministry of Health of the stated amounts, if at all; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase generally; risks related to our commercialization efforts for alfataliglicerase in Brazil; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; the risk that despite the FDA's grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA's ability to withdraw the fast track designation at any time; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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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Source: Protalix BioTherapeutics, Inc.