Protalix BioTherapeutics Announces Presentation of Results from the Phase I/II Clinical Trial of PRX-102 for the Treatment of Fabry Disease at the Society for the Study of Inborn Errors of Metabolism

September 7, 2016

CARMIEL, Israel, Sept. 07, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today an oral presentation highlighting the results of the phase I/II clinical trial of PRX-102 for the treatment of Fabry disease will be given at the Society for the Study of Inborn Errors of Metabolism (SSIEM) Annual Symposium being held September 6-9, 2016 in Rome, Italy.

The oral presentation titled, “A novel treatment for Fabry disease – IV administration of plant derived alpha-gal-a enzyme safety and efficacy, 1 year experience,” will be given by Raphael Schiffmann, M.D., Lead Investigator at the Metabolic Neurology Branch of the National Institute of Neurological Disorders and Stroke (NINDS), a part of the National Institutes of Health, and a principal investigator of the phase I/II clinical trial of PRX-102, on Thursday, September 8, 2016 between 10:30am – 12:00pm GMT. A copy of the presentation will be available following the conference on the Company’s website under the presentations tab of the investor page.

PRX-102 is a recombinant, plant cell expressed, pegylated, modified version of the human alpha-Galactosidase-A enzyme. The phase I/II clinical trial is an open-label, dose-ranging study designed to treat up to 18 naïve male and female adult patients across three dosing cohorts (0.2 mg/kg, 1mg/kg and 2mg/kg), with intravenous infusions of PRX-102 every two weeks. The clinical results indicate that PRX-102 demonstrated improvements or stabilization across all disease parameters including, plasma Lyso-Gb3, kidney function, cardiac function and pain. Additionally, PRX-102 was well tolerated, with the majority of adverse events being mild and moderate.

Currently, all 16 patients enrolled in the phase I/II trial continue to receive 1 mg/kg of PRX-102 in an open label extension trial. The Company is recruiting patients for a phase III pivotal trial of PRX-102 for the treatment of Fabry disease in centers in the United States.

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; OPRX-106, an orally-delivered anti-inflammatory treatment; 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.

Investor Contact
Marcy Nanus
The Trout Group, LLC
646-378-2927
mnanus@troutgroup.com

Protalix BioTherapeutics, Inc.