Alfataliglicerase Approved for Pediatric Indications in Brazil for the Treatment of Gaucher Disease in Children Four years and Older

November 22, 2016

Approval further supports the advanced ongoing discussions with the Brazilian Ministry of Health for the supply of a significant amount of alfataliglicerase for Gaucher patients in Brazil

CARMIEL, Israel, Nov. 22, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) announced today that the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) has granted regulatory approval for alfataliglicerase as a long-term enzyme replacement therapy for children four years old and above with a confirmed diagnosis of Type I Gaucher disease. Gaucher disease is a rare lysosomal storage disorder, with approximately 700 patients treated in Brazil. Brazil has the third largest number of identified Gaucher patients worldwide, after the United States and Israel.

Alfataliglicerase was approved by ANVISA in March 2013 for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type I Gaucher disease.

"ANVISA's approval of a pediatric indication for alfataliglicerase is an important milestone for Protalix in our commitment to the Gaucher community," commented Moshe Manor, Protalix's President and Chief Executive Officer. "It is also an important element in our ongoing advanced negotiations with the Brazilian Ministry of Health, as alfataliglicerase is now approved for the majority of Gaucher patients in Brazil. It is estimated that pediatric patients represent approximately 30% of the total Gaucher patient population in Brazil."

Pursuant to the Company's amended and restated exclusive license and supply agreement with Pfizer Inc. of October 2015, the Company owns all rights to alfataliglicerase in Brazil.

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(R). 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: 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 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 2018 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 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.