Protalix BioTherapeutics Announces Last Patient Enrolled in the AIR DNase™ Phase II Clinical Trial for Cystic Fibrosis

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CARMIEL, Israel, Dec. 22, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the last patient has been enrolled in the Company's phase II clinical trial of AIR DNase ™ (PRX-110) for the treatment of Cystic Fibrosis (CF). The Company expects to report interim top-line results from this study during the first week of January 2017, and full results before the end of the first quarter of 2017.

AIR DNase is a plant cell-derived recombinant form of human deoxyribonuclease I (DNase I) that the Company has designed, through chemical modification, to be resistant to inhibition by actin. Given actin is a potent inhibitor of DNase I activity, the Company's AIR DNase has the potential to enhance the enzyme's efficacy significantly in CF patients when compared to the currently approved DNase treatment (Pulmozyme ®).

The phase II trial is a 28-day switch-over study of 15 CF patients previously treated with Pulmozyme® to evaluate the efficacy and safety of AIR DNase in CF patients. Patients that have participated in the trial have undergone a two-week washout period, in which they were not treated with Pulmozyme, before dosing with the Company's AIR DNase. The main efficacy endpoint is the change of forced expiratory volume (FEV1) and forced vital capacity (FVC). Additional endpoints include safety and tolerability, immunogenicity and pharmacokinetic data. In the trial, AIR DNase is administered through Philips Respironics' I-neb AAD Inhaler System, for which the Company has a supply agreement for the exclusive use of the device for the development of an inhaled product based on dornase alfa for the treatment of CF. The I-neb AAD is a small, lightweight, virtually silent device that is fully portable and has a unique vibrating mesh technology that allows for faster administration than conventional jet or ultrasonic nebulizers.

"We believe that our unique enzyme modification, which allows the enzyme to resist actin inhibition, could translate into favorable improvement in FEV1 parameter, compared to those experienced to date, and could be of great help to CF patients coping with this devastating disease. In addition to PRX-110, we have two other product candidates currently in clinical trials in patients; PRX-102 for the treatment of Fabry disease and OPRX-106, a first in the world oral enzyme in development for the treatment of ulcerative colitis. We are excited about these product candidates as they are both specifically designed to be superior to existing products, with the potential to garner significant market share in their respective categories."

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, 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 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 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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