Protalix BioTherapeutics Announces AIR DNase(TM) Data Presented at the 38th European Cystic Fibrosis Conference

June 12, 2015

CARMIEL, Israel, June 12, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX) announced today that pre-clinical data for AIR DNase™ (PRX-110) for the treatment of Cystic Fibrosis will be presented at the 38th European Cystic Fibrosis Conference being held June 10-13 in Brussels, Belgium. AIR DNase is the Company's inhaled, chemically-modified, plant cell-expressed recombinant form of human deoxyribonuclease I, or DNase, that is resistant to actin, a potent inhibitor of DNase that is found in high concentrations in the lungs of CF patients.

"AIR DNase works by cleaving extracellular DNA and thinning the thick mucus that accumulates in CF patients' lungs. We are very optimistic about the results thus far and are excited to proceed to the clinic. We believe that AIR DNase has the potential to address some of the significant unmet medical needs of the cystic fibrosis community," commented Dr. Yoseph Shaaltiel, Executive Vice President, Research and Development.

On Friday, June 12, in an oral presentation titled, "AIR DNase™: Actin Inhibition Resistant Plant Cell Recombinant Chemically Modified Deoxyribonuclease I (DNase I) for the Treatment of Cystic Fibrosis," Dr. Shaaltiel will present data from an in vitro assay demonstrating that concentrations of actin and DNase remain high with inhibition by only 15% for AIR DNase, as compared to inhibition by 85-100% for Pulmozyme®, following treatment with each product.

Additionally, a rheology data analysis of human sputum samples shows lower stress reduction from control for AIR DNase compared to Pulmozyme. The mean viscosity reduction as a measure of activity on patients' sputa by AIR DNase is 70% compared to 30% for Pulmozyme.

The Company is currently evaluating clinical sites for a proof of concept trial for AIR DNase. This study is planned to launch around year-end, with top-line results expected in the first half of 2016.

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, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, by the Australian Therapeutic Goods Administration(TGA) in May 2014 and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel and 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-112, an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, also for the treatment of Gaucher disease; PRX-106, an orally-delivered anti-inflammatory treatment; AIR DNase™ 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; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations under our supply and technology transfer; risks related to the commercialization efforts for taliglucerase alfa in the United States, Israel, Brazil, Canada, Australia and other countries; 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.

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