Protalix BioTherapeutics Discloses Three New Compounds in Development

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- Oral PRX-106 for immune mediated disorders
- PRX-110 for Cystic Fibrosis (CF)
- PRX-107 for emphysema due to hereditary alpha1-antitrypsin deficiency

CARMIEL, Israel, June 20, 2013 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE:PLX) (TASE:PLX), today held an Analyst Event in which included the disclosure of new data regarding three new compounds in development, oral PRX-106 for immune mediated disorders, PRX-110 for Cystic Fibrosis (CF), and PRX-107 for emphysema from heredity alpha1-antitrypsin (AAT) deficiency.

"Our validated plant-cell based platform, ProCellEx®, has the capacity to generate a diverse array of protein therapeutics, each with highly unique characteristics. With this next wave of compounds and oral administration modalities, we are building a strong pipeline and potentially treatment advances to patients," said Dr. David Aviezer, Protalix BioTherapeutics' President and Chief Executive Officer.

PRX-106 is the Company's proprietary plant cell recombinant Anti-TNF fusion protein being developed as an orally-administered treatment for immune mediated disorders. In preclinical studies, oral PRX-106 alleviated immune-mediated hepatitis and reduced interferon gamma levels in a concanavalin A (ConA) mouse model. Additionally, oral administration of PRX-106 alleviated immune mediated colitis, a well established model for Crohn's disease, promoting serum levels of anti-inflammatory IL-10 and regulatory T-cells. The Company is conducting additional preclinical studies for oral PRX-106 in additional attractive indications.

PRX-110 is the Company's proprietary plant cell recombinant human Deoxyribonuclease 1 (DNase 1) under development for the treatment of CF, to be administered by inhalation. PRX-110 works by cleaving extracellular DNA and thinning the thick mucus that accumulates in CF patients' lungs. In preclinical trials, PRX-110 demonstrated improved enzyme kinetics, less sensitivity to inhibition by actin and improved ex-vivo efficacy when compared to Pulmozyme®, the only approved form of recombinant DNase 1 manufactured in Chinese hamster ovary (CHO) cells. The Company held a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) in 2012, and plans to file an IND with the FDA following the completion of toxicology studies, which is expected to occur by year end.

PRX-107 is the Company's proprietary plant cell recombinant human Alpha1-antitrypsin (AAT) under development for the treatment of emphysema due to hereditary AAT deficiency, to be administered by inhalation. PRX-107 is a protein that works by regulating the AAT-dependent inflammatory response in the lungs. Currently, there is no approved recombinant form of AAT. Plasma derived-forms of AAT are available, but are associated with limitations, including inadequate supply, the potential for adventitious agents and poor absorption. In preclinical studies, PRX-107 demonstrated the ability to rescue elastase induced lung damage in rats and as effective as a plasma-derived reagent. The Company plans to hold a pre-IND meeting with the FDA in the second half of 2013 to discuss next steps for this compound.

Additional information on these compounds can be found in the slides presented at the Company's Analyst Day on June 20, 2013. These are available under the presentation tab on the Company's website.

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, 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 also 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-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; an orally-delivered glucocerebrosidase enzyme that is produced and encapsulated within carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel®) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis; PRX-110 for the treatment of Cystic Fibrosis; PRX-107 for the treatment of emphysema due to hereditary alpha1-antitrypsin deficiency; 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 studies 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 the clinical trials; the risk that the results of our clinical trials will not support the applicable claims of safety or efficacy, that our product candidates will not have the desired effects or includes 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; 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; risks related to the potential infringement of a third

party's patents or other intellectual property rights; the uncertainty of obtaining patents covering our products and processes and in successfully enforcing our intellectual property rights against third parties; risks of securing adequate levels of product liability and clinical trial 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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