Protalix BioTherapeutics Reports Positive Phase I Clinical Study Results for PRX-106 Oral Anti-TNF

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Favorable Safety and Tolerability Data Demonstrates Biological Activity in the Gut and Activation of Regulatory T Cells

CARMIEL, Israel, Aug. 3, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today positive clinical study results from the Company's Phase I trial of PRX-106, an orally administered plant cell-expressed recombinant anti-TNF fusion protein. PRX-106 demonstrated a favorable safety and tolerability profile and biological activity in the gut.

The Phase I trial is a randomized, parallel-design, open-label study designed to evaluate the safety and pharmacokinetics of PRX-106 in healthy volunteers. The trial enrolled 14 subjects that were randomized to one of three dosing cohorts receiving PRX-106 doses equivalent to 2mg, 8mg or 16mg Tumor Necrosis Factor receptor-Fc fusion protein. Subjects received once daily oral administrations for 5 consecutive days.

The results demonstrated that oral administration of PRX-106 is safe and well tolerated. No major side effects were noted, and no suppression of the immune system was observed. Regulatory T cell activation showing biological activity in the gut was observed. Fluorescence-activated cell sorting analysis (FACS) was performed using various antibodies for surface markers, and it was observed that all three dosages of PRX-106 promoted the induction of various subsets of T cells, some of which are correlated with anti-inflammatory response.

"The results demonstrated in the Phase I trial are very exciting and encouraging. As T regulatory cells have a central role in the immune system, PRX-106 has the potential to be an effective agent for numerous immune-mediated indications," said Prof. Yaron Ilan of the Gastroenterology and Liver Units, Director of the Department of Medicine of the Hebrew University-Hadassah Medical Center in Jerusalem.

In preclinical studies evaluating oral PRX-106 the compound alleviated immune-mediated hepatitis and reduced interferon gamma levels in a concanavalin A immune mediated hepatitis mouse model. Additionally, oral administration of PRX-106 alleviated immune mediated colitis in a well-established mouse model, promoting serum levels of anti-inflammatory IL-10 and regulatory T-cells.

Protalix is currently evaluating the best indication to take forward with PRX-106. The Company anticipates identifying this shortly and initiating a proof of concept trial in patients around year end.

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, subsequently by Israel's Ministry of Health, by the Brazilian National Health Surveillance Agency (ANVISA) 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-106, an orally-delivered anti TNF; 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.

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