Protalix BioTherapeutics Enrolls First Patient in Phase II Clinical Trial of OPRX-106 for the Treatment of Ulcerative Colitis

November 30, 2016

CARMIEL, Israel, Nov. 30, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that the first patient has been enrolled in its phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis. OPRX-106 is a plant cell-expressed recombinant human tumor necrosis factor receptor II fused to an IgG1 Fc domain (TNFRII-Fc).

"With the enrollment of the first patient in our OPRX-106 phase II trial, clinical studies are now underway for our three lead assets," said Mr. Moshe Manor, Protalix's President and Chief Executive Officer. "We look forward to announcing phase II data from our AIR DNase ™ clinical program around year-end, and data from our OPRX-106 phase II clinical trial in the second half of 2017."

The phase II clinical trial is a randomized, open label, 2-arm study of OPRX-106 in 20 patients with active mild to moderate ulcerative colitis. Patients will be randomized to receive 2 mg or 8 mg of OPRX-106 administered orally, once daily, for 8 weeks. The primary endpoint of the study is safety, including monitoring for adverse events following daily administration of the drug. Key efficacy endpoints include relevant disease parameters of the drug, including Mayo score and rectal bleeding. If successful, OPRX-106 will be the first ever oral enzyme treatment as currently there are no other oral enzyme treatments available.

The Company completed a phase I clinical trial of OPRX-106 in 15 healthy volunteers, and the drug was found to be safe and well tolerated. The results of the phase I clinical trial were announced in August 2015. Immunomodulatory effect was observed, including activation of T Regulatory cells showing biological activity in the gut. In addition, early efficacy signals of OPRX-106 have been demonstrated in preclinical studies using inflammatory bowel disease immune-mediated mouse models. The results of the preclinical studies show that OPRX-106 attributes to a positive change in symptoms and in serum levels of anti-inflammatory markers.

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; PRX-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.

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