Protalix BioTherapeutics Reports Positive Interim Data from Phase II Clinical Trial of OPRX-106 in Patients with Ulcerative Colitis

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CARMIEL, Israel, Jan. 02, 2018 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), announced today interim data from the first 14 patients that completed, to date, the Company's phase II clinical trial of OPRX-106 (oral anti-TNF) in patients with ulcerative colitis.

The phase II clinical trial is a randomized, open label, 2-arm study of OPRX-106 in patients with active mild to moderate ulcerative colitis. A total of 24 patients were enrolled and randomized to receive 2 mg or 8 mg of OPRX-106, administered orally, once daily, for 8 weeks. The first 14 patients have completed the study, and four patients are currently in treatment and follow-up. The trial evaluated key efficacy endpoints including clinical response and remission utilizing the Mayo score, as well as safety and pharmacokinetics.

Data generated from the first 14 patients who completed the study demonstrates that 57% of the patients achieved clinical response and 36% achieved clinical remission at week 8.

In the rectal bleeding analysis, a sub category of the Mayo score, 79% of those patients show an improvement.

In addition, the majority of those patients show improvement in the study's additional efficacy endpoints, with 86% of the patients achieved an improvement in calprotectin, a protein biomarker present in the feces indicating intestinal inflammation, and 64% have an improved Geboes score, a histopathological scoring for the assessment of disease activity in ulcerative colitis.

Clinical response at week 8 is defined as a decrease in the Mayo score of at least 3 points and either a decrease in the sub-score for rectal bleeding of at least 1 point from baseline, or rectal bleeding sub-score of 0 or 1. Clinical remission at week 8 is defined as clinically symptom free, a Mayo score ≤ 2, with no individual sub-score exceeding 1 point after treatment.

Treatment was well tolerated and the majority of adverse events have been mild to moderate and transient in nature, with headaches being the most common.

"These initial efficacy results for OPRX-106 are very impressive as they represent clear clinical benefits," said Professor Yaron Ilan, Chairman of the Department of Medicine, and an expert in Gastroenterology, at The Hadassah Hebrew University Medical Center in Jerusalem. "Orally administered OPRX-106 is a tremendous step forward with the potential benefit of significantly lower side effects as it does not suppress the immune system while redirecting it in an anti-inflammatory direction, as opposed to the currently approved anti-TNF treatments, all of which are administered via injection or infusion, and carry potential short and long term side effects."

OPRX-106 is the Company's novel proprietary plant cell-expressed recombinant human tumor necrosis factor receptor II fused to an IgG1 Fc domain (TNFRII-Fc). When administered orally and while passing through the digestive tract, the plant cells function as a natural delivery capsule, having the unique attribute of a cellulose cell wall, which makes them resistant to degradation compared to proteins produced via mammalian cell expression systems.

"We are very excited by these first-in-patient results, which demonstrate that novel, orally administered, OPRX-106 treatment is biologically active in the gut with clear clinical effect," said Mr. Moshe Manor, Protalix's President and Chief Executive Officer.

The Company expects to report full results from this study by the end of the first quarter of 2018.

Recently, the Company has successfully expressed a plant cell based anti TNF alfa protein comparable to adalimumab (Humira®) for oral administration.

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: pegunigalsidase alfa, 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; alidornase alfa for the treatment of Cystic Fibrosis; and others. Protalix has entered into an ex-United States partnership with Chiesi Farmaceutici S.p.A. for the development and commercialization of pegunigalsidase alfa. Protalix maintains full rights to pegunigalsidase alfa in the United States.

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 "expect," "anticipate," "believe," "estimate," "project," "plan," "should" 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: risks related to the amount of our future revenues, operations and expenditures; 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 superiority, 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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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