Protalix BioTherapeutics Announces Additional Positive Results from Final Analysis of the Phase II Clinical Trial of OPRX-106 for the Treatment of Ulcerative Colitis

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Mucosal Improvement Observed in 61% of the Patients and 33% achieved Mucosal Healing

Clinical Responses Observed in 67% of the Patients
and Clinical Remission Observed in 28% of the Patients

89% of the Patients Experienced a Reduction in Mayo Score, and 61% of the Patients
Experienced a Reduction in Endoscopic Sub Score

No Systemic Absorption Observed

CARMIEL, Israel, June 05, 2018 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), announced today that additional positive results from the Company's phase II clinical trial of OPRX-106 for the treatment of ulcerative colitis (UC) were presented at the Digestive Disease Week® (DDW) 2018 Annual Meeting. OPRX-106 is a plant cell-expressed recombinant human tumor necrosis factor receptor II fused to an IgG1 Fc domain (TNFRII-Fc), in development for oral administration. When administered orally and passing through the digestive tract, the plant cells function as a natural delivery vehicle. The unique attribute of a cellulose plant cell wall provides resistance to degradation as opposed to proteins produced via mammalian cell expression. The Digestive Disease Week® (DDW) 2018 Annual Meeting is taking place in Washington, D.C., June 2-5, 2018.

The phase II clinical trial is a randomized, open label, 2-arm study of OPRX-106 for the treatment of ulcerative colitis (UC). A total of 24 patients were enrolled in the study, 18 patients completed the study with 6 patients who did not complete the study. The dropout rate is consistent with other trials in similar patient populations, and none of the patients dropped out due to a side effect or serious adverse event. Patients were randomized to receive 2 mg or 8 mg of OPRX-106, administered orally, once daily, for 8 weeks. The average baseline Mayo score was 7.1 (from a scale of 0-12) and the average baseline mucosal endoscopy sub score was 2.1 (from a scale of 0-3). For the 18 patients who completed the study, 89% had a baseline Mayo score between 6 and 9, which meets the criteria of moderate disease activity, and 84% had a baseline mucosal endoscopy sub score of 2 and above indicating moderate to severe disease based on mucosal appearance.

The key efficacy endpoints of the study were met at week 8:

- 67% of patients experienced a clinical response in each of the 2mg dose and 8mg dose cohorts;
- 44% of patients experienced a clinical remission in the 8mg dose and 11% in the 2mg dose for an overall average of 28%.

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.

In addition to clinical response and remission, efficacy was also observed in mucosal healing, an important prognostic parameter in ulcerative colitis and other inflammatory bowel diseases, measured by endoscopy:

- 61% of patients experienced mucosal improvement; and
- 33% of patients experienced mucosal healing.

Mucosal improvement is defined as a decrease in endoscopy sub-score at week 8. Mucosal healing is defined as a reduction in, and achievement of, endoscopy sub-score ≤1 at week 8.

Other key efficacy endpoints were also achieved, as follows:

- 72% of patients showed an improvement in rectal bleeding scores;
- 72% of patients demonstrated an improvement in fecal calprotectin; and
- 61% of patients showed improved Geboes score (a histopathological scoring for the assessment of disease activity in ulcerative colitis).

The positive trend in efficacy is consistent in substantially all patients. This trend is demonstrated by 89% of the patients having showed an improvement in Mayo score in both doses, with an average decrease in Mayo score of 46% at week 8 in the 8mg dose and 40% in the 2mg dose. In addition, all of the patients also showed an improvement in at least one of the other efficacy parameters.

No anti-drug antibodies were detected. In addition, no systemic absorption was observed. OPRX-106 was safe and well tolerated with only mild to moderate adverse events, which were transient in nature. Headaches were the most common adverse event reported.

"The full set of data from the study is very compelling, and suggests that OPRX-106 is an effective anti-inflammatory agent. OPRX-106 is delivered orally and is biologically active in the gut without triggering the formation of anti-drug or systemic absorption. OPRX-106 has the potential to address the loss of response and to avoid critical safety concerns of infections and malignancies currently seen in anti–TNF alpha treatment, which is driven by

the high presence of neutralizing antibodies and systemic absorption respectively," said Professor Yaron Ilan, Chairman of the Department of Medicine, and an expert in Gastroenterology, at The Hadassah Hebrew University Medical Center in Jerusalem, and a consultant to the Company. "I am looking forward to participating in additional trials of OPRX-106 and to continue to see this program progress as it offers new hope for patients with ulcerative colitis by addressing significant unmet medical needs of patients."

"We are very pleased by these excellent results, particularly with respect to the significant percent of patients demonstrating mucosal healing and clinical remission at eight weeks," commented Moshe Manor, Protalix's President and Chief Executive Officer. "OPRX-106 may bring a new therapy paradigm in the ulcerative colitis space potentially offering better safety, longer term efficacy and oral administration in place of most therapies which are administered via injection and infusion and bear serious safety concerns."

The presentation made at the DDW 2018 Annual Meeting is available 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 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 "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 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; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; 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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