Protalix Announces Data on Oral antiTNF to be Presented at Digestive Disease Week 2014 Meeting

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CARMIEL, Israel, April 23, 2014 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that preclinical data on oral antiTNF (PRX-106) was accepted for presentation at the Digestive Disease Week (DDW) Annual Meeting being held May 3-6 in Chicago, Illinois.

Yaron Ilan, M.D., Professor of Medicine of the Gastroenterology and Liver Units and Director of the Department of Medicine at Hebrew University-Hadassah Medical Center in Jerusalem, Israel, will present a poster titled: "A novel method for anti-TNF based-oral immunotherapy: Oral administration of a plant cell-expressed recombinant anti-TNF fusion protein for treating Crohn's disease." The poster which was accepted as late breaking research, will be presented on Tuesday, May 6 from 8:00 AM to 5:00 PM, Central Daylight Time, in the in South Hall of the McCormick Place Convention Center, Chicago. A copy of the poster will be posted on the Company's website under the Resources\Medical Presentations tab when presented in the conference.

Oral PRX-106 is the Company's proprietary plant cell recombinant antiTNF fusion protein being developed as an orally-administered treatment for immune mediated disorders. In preclinical studies, oral PRX-106 alleviated immune-mediated hepatic symptoms and reduced interferon gamma levels in a concanavalin A (ConA) inflammatory mouse model. Additionally, oral administration of PRX-106 alleviated immune mediated colitis in a well established mouse model for Inflammatory Bowel Disease, promoting serum levels of anti-inflammatory IL-10 and regulatory T-cells. The drug is also being tested for the treatment fatty liver and other immune mediated disorders.

The Company expects to initiate clinical trials as part of the oral PRX-106 development program during the next few months.

About Digestive Disease Week

Digestive Disease Week® (DDW®) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 3 – 6, 2014, at McCormick Place, Chicago, IL. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

About Protalix

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 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-112, 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 and inflammatory diseases, such as rheumatoid arthritis, Crohn's disease, colitis, psoriasis and other autoimmune and inflammatory disorders; 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. 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 will include 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; and other factors described in our filings with the U.S. Securities and Exchange Commission. These forward-looking statements are based on current information that may change and you are cautioned not to place undue reliance on these forward-looking statements. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information. All forward-looking statements are qualified in their entirety by this cautionary statement.

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