Protalix Announces Successful Manufacturing Facility Evaluation by Health Canada

January 23, 2014

CARMIEL, Israel, Jan. 23, 2014 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that Health Canada has completed a successful on-site evaluation of the Company's manufacturing facility in Carmiel, Israel, as part of its ongoing review of the new drug submission (NDS) for taliglucerase alfa for the treatment of Gaucher disease. The purpose of the on-site evaluation was to verify the facility's compliance with certain Canadian food and drug regulations and, upon completion of the evaluation, Health Canada recommended approval from a facility perspective. A decision on final marketing approval of taliglucerase alfa in Canada is expected during 2014.

In addition to Health Canada's evaluation, the Company's manufacturing facility, which utilizes Protalix's ProCellEx® system, has been deemed acceptable by the European Medicine's Agency (EMA), the U.S. Food and Drug Administration (FDA), the Israeli Ministry of Health, the Brazilian National Health Surveillance Agency (ANVISA) and the Australian Therapeutic Goods Administration (TGA).

"We are pleased to have accomplished this regulatory milestone in preparation for the potential approval of taliglucerase alfa in Canada," said Dr. Michal Kahana, Protalix's Vice President of Quality Affairs. "This is further validation of the viability of our proprietary plant-cell based technology platform, which is the engine behind taliglucerase alfa and our growing pipeline."

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: risks related to any failure by our company to comply with GMP with respect to any product candidate in any jurisdiction; 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 risk that applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application we file for the drug product; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; 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; the impact of development of competing therapies and/or technologies by other companies and institutions; 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.

CONTACT: Investor Contact
Marcy Nanus
The Trout Group, LLC
646-378-2927
mnanus@troutgroup.com

Media Contact
Kari Watson
MacDougall Biomedical Communications
781-235-3060

kwatson@macbiocom.com

Protalix BioTherapeutics, Inc.