



Protalix BioTherapeutics Presents Data on the Company's Fabry Program and Oral Enzyme Gaucher Program With Experts in the Field of Lysosomal Disorders

January 19, 2011

CARMIEL, Israel, Jan. 19, 2011 /PRNewswire via COMTEX/ --

Protalix BioTherapeutics, Inc. (NYSE-AMEX: PLX, TASE: PLX), announced today that management presented data on the Company's preclinical Fabry program and oral enzyme Gaucher program with experts in the field of lysosomal disorders at a Company-sponsored medical meeting which was recently held in New York City.

The primary objective of the meeting was to discuss taliglucerase alfa, the Company's proprietary intravenously administered plant cell expressed form of glucocerebrosidase (GCD) for the treatment of Gaucher disease. Taliglucerase alfa is currently under review in the United States, the European Union, Brazil and other territories. The Company also presented data on the Company's preclinical programs including PRX-102, a modified alpha-Galactosidase-A (alpha-GAL-A) for the treatment of Fabry disease and oral GCD, a naturally encapsulated plant cell expressed form of GCD for the treatment of Gaucher disease.

PRX-102 for the treatment of Fabry Disease

PRX-102 is the Company's proprietary plant cell expressed modified version of the recombinant human alpha-GAL-A protein under development for the treatment of Fabry disease. Fabry disease is a rare hereditary, genetic lysosomal storage disorder caused by an X-linked deficiency of the enzyme alpha-GAL-A. The disease causes harmful accumulations of lipids in the kidneys, autonomic nervous system and cardiovascular system that may lead to kidney failure, increase the risk of heart attack and stroke and can be life-threatening.

In pre-clinical studies, PRX-102 demonstrated preliminary efficacy in a Fabry animal model. Chemical modifications made to the enzyme improved the enzyme activity and stability, resulting in prolonged activity profiles and enhanced bioavailability in animals. The modifications also have the potential to decrease the immunogenicity of the enzyme, which is a major drawback of currently approved therapies for Fabry disease.

The Company recently held a pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) regarding PRX-102. The Company plans to submit an IND application this year, and pending approval of the IND, commence clinical studies.

"We believe our proprietary Fabry product has the potential to be a 'best-in-class' enzyme resulting from the unique modifications made to the protein," said Dr. Yoseph Shaaltiel, Protalix's Executive Vice President, Research and Development. "Following the anticipated IND approval, we intend to conduct a phase I/II clinical trial in Fabry disease patients."

Orally-delivered glucocerebrosidase enzyme (GCD) for the treatment of Gaucher disease

Gaucher disease is an inherited, genetic lysosomal storage disorder caused by mutations or a deficiency of the enzyme GCD. The disease causes harmful accumulations of lipids in the spleen, liver, lungs and brain, and affects patients' bones and bone marrow. Oral GCD for the treatment of Gaucher disease is a plant cell expressed form of GCD that is naturally encapsulated within carrot cells genetically engineered to express the GCD enzyme.

Pre-clinical studies of oral GCD demonstrate the stability of the enzyme in the cell and the capacity of the cellulose wall to protect the enzyme against degradation in the digestive tract in an *in-vitro* model of the stomach and intestines. Additionally, rats fed with lyophilized carrot cells expressing GCD have accumulated the active enzyme in the target organs, the spleen and liver.

The Company's development of an oral delivery of encapsulated GCD has the advantage of leveraging the well-characterized mechanism of action for taliglucerase alfa (an intravenously-delivered plant cell expressed GCD), which has completed phase III clinical trials and has a PDUFA date set by the FDA of February 25, 2011. Furthermore, delivering GCD orally may dramatically change the treatment paradigm for Gaucher patients, as currently approved enzyme replacement therapies are only delivered intravenously.

"Using the plant-cell expression system for oral delivery of GCD is revolutionary because it targets the disease-specific organs without the need for lifetime dependence on repeated intravenous infusions. Moreover, it is unlike substrate reduction therapy which is oral, but may have unpredictable long term untoward effects due to the inhibition of other non-disease-specific compounds. Finally, oral administration of the enzyme for patients with Gaucher disease will increase compliance and facilitate management," said Professor Ari Zimran, Director of the Gaucher Clinic in Shaare Zedek Medical Center, Jerusalem, Israel and lead investigator of the phase III clinical trial of taliglucerase alfa.

The Company intends to initiate phase I clinical trials of oral GCD in healthy individuals who are carriers of Gaucher disease and show reduced enzymatic activity at baseline. The Company expects to present additional data on this program at an upcoming medical meeting.

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. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins in an environment free of mammalian components and viruses. Protalix is also advancing additional recombinant biopharmaceutical drug development programs, including its PRX-105 and PRX-102 development program. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with the FDA for Gaucher disease. Protalix's new drug application (NDA) for taliglucerase alfa has been accepted by the U.S. Food and

Drug Administration (FDA) and granted a Prescription Drug User Fee Act (PDUFA) action date of February 25, 2011.

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. 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 relating to: the successful preclinical development of our product candidates; the completion of our clinical trials; the review process of the FDA, the EMEA, other foreign regulatory bodies and other governmental regulatory bodies relating to our product candidates,, including the FDA's and the EMEA's review of any filings we make in connection with the treatment protocol for taliglucerase alfa and including the risk that regulatory authorities may find that the data from our clinical trials and other studies is insufficient for regulatory approval; delays in the FDA's, the EMEA's or other health regulatory authorities' approval of any applications we file for any of our product candidates or refusals to approve such filings, including the NDA we filed with the FDA for taliglucerase alfa for the treatment of Gaucher disease; refusals by such regulatory authorities to approve the marketing and sale of a drug product even after acceptance of an application we file for any such drug product; and other factors described in our filings with the Securities and Exchange Commission. Companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in advanced or late-stage clinical trials, even after obtaining promising earlier trial results or in preliminary findings for such clinical trials. Further, even if favorable testing data is generated from clinical trials of drug products, the FDA, EMEA or any other foreign regulatory authority may not accept or approve an NDA filed by a pharmaceutical or biotechnology company for such drug product. Failure to obtain marketing approval from the FDA, EMEA or any other foreign regulatory authority of any of our drug candidates in a timely manner, if at all, will severely undermine our business and results of operations by reducing our potential marketable products and our ability to generate corresponding product revenues. The statements in this release are valid only as of the date hereof and we disclaim any obligation to update this information.

Investor Contact

Marcy Nanus
The Trout Group, LLC
Telephone: 646-378-2927
Email: mnanus@troutgroup.com

SOURCE Protalix BioTherapeutics, Inc.