



Protalix to Present New Data on taliglucerase alfa and Preclinical Data on Oral Enzyme glucocerebrosidase at the WORLD Lysosomal Disease Network Symposium

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Protalix BioTherapeutics, Inc. (NYSE-AMEX: PLX, TASE: PLX), announced today that new clinical data from the switchover trial of taliglucerase alfa in Gaucher disease patients and preclinical data on oral enzyme glucocerebrosidase (oral GCD) will be presented today at the 7th Annual Meeting of the Lysosomal Disease Network: WORLD Symposium 2011 in Las Vegas, Nevada. Both drug candidates are unique in that they are produced through the Company's proprietary plant-cell protein expression system.

Switchover Trial of taliglucerase alfa

Gregory Pastores, M.D., Associate Professor of Neurology and Pediatrics and Director of the Neurogenetics Laboratory at New York University School of Medicine and a study investigator, will present new data from the Company's switchover trial during an oral session titled: "Plant Cell Expressed Recombinant Glucocerebrosidase taliglucerase alfa as Therapy for Gaucher Disease in Patients Previously Treated with Imiglucerase."

"Interim results from the switchover trial support the safety and maintenance of efficacy of taliglucerase alfa in patients with Gaucher disease who were previously on imiglucerase," said Dr. Gregory Pastores.

The switchover trial is a phase III multicenter, open-label clinical trial designed to assess the safety and efficacy of taliglucerase alfa in Gaucher disease patients who are currently being treated with imiglucerase (Cerezyme(R)) enzyme replacement therapy. Patients eligible for the switchover trial are evaluated for 12 weeks to establish the stability of their disease. Patients with confirmed stable disease are switched from imiglucerase (doses ranging from 10-60 U/kg every other week) to an equivalent dose of taliglucerase alfa using the same number of units for a nine-month period. Adult enrollment in the study has been completed (n=25); pediatric enrollment remains open. The trial is being conducted in 10 centers throughout North America, Europe, Israel and Australia.

Dr. Pastores will present clinical trial data from an interim report completed in August 2010 which includes efficacy data from 15 patients and safety data from 25 patients. The data indicate that patients can safely be switched to taliglucerase alfa from imiglucerase.

The efficacy analysis from the interim report (n=15) demonstrates that, on average, hemoglobin and platelet count, spleen volume and liver volume all remained stable over the nine-month period, and no patients showed a sustained clinical deterioration.

The safety analysis from the interim report (n=25, as performed at the time of data lock) demonstrates that taliglucerase alfa was well tolerated and no drug related severe adverse events were reported. No patients experienced hypersensitivity reactions, one patient developed antibodies to taliglucerase alfa and no patients developed neutralizing antibodies. Most adverse events were considered unrelated to taliglucerase alfa. The most frequent mild to moderate adverse event was nasopharyngitis, a viral infection of the upper respiratory system.

The Company and Pfizer Inc. have filed a new drug application (NDA) or a marketing authorization application (MAA), as applicable, for taliglucerase alfa in the United States, European Union, Brazil and Israel. The Company received a Prescription Drug User Fee Act (PDUFA) date of February 25, 2011 from the U.S. Food and Drug Administration for the taliglucerase alfa NDA.

Oral Enzyme glucocerebrosidase

Yoseph Shaaltiel, Ph.D., the Company's Executive Vice President, Research and Development, will present preclinical data on the Company's oral enzyme glucocerebrosidase (oral GCD) during an oral session titled: "Oral Delivery of Recombinant Glucocerebrosidase Enzyme Naturally Encapsulated in Carrot Cells." Oral GCD is a plant cell expressed form of GCD that is naturally encapsulated within carrot cells genetically engineered to express the GCD enzyme.

Preclinical studies of oral GCD demonstrate the stability of the enzyme in the cell and the capacity of the cell's 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 lyophilized carrot cells expressing GCD have accumulated the active enzyme in the target organs, the spleen and liver.

Oral GCD is being developed for the treatment of Gaucher disease. The Company intends to initiate phase I clinical trials in carriers of Gaucher disease who show reduced enzymatic activity at baseline.

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(TM). Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner in an environment free of mammalian components and viruses. Protalix's lead compound, taliglucerase alfa, an enzyme replacement therapy for the treatment of Gaucher disease, completed phase III clinical development. Regulatory applications have been submitted for taliglucerase alfa in the United States, the European Union, Brazil and Israel. Taliglucerase alfa is available to patients with Gaucher disease in the United States under an Expanded Access protocol, in Brazil under a supply agreement, in France under an ATU program, as well as to patients in several member states of the European Union, Israel and other countries under Named Patient provisions.

Protalix's development pipeline also includes: PRX-105, a pegylated recombinant human acetylcholinesterase in development for several therapeutic and prophylactic indications, a biodefense program and an organophosphate-based pesticide treatment program; PRX-102, a modified version of the recombinant human alpha-GAL-A protein, for the treatment of Fabry disease; an orally-delivered glucocerebrosidase enzyme that is naturally encased in carrot cells, also for the treatment of Gaucher disease; and pr-antiTNF, a biosimilar version of etanercept (Enbrel(TM)), for the treatment of rheumatoid arthritis.

Safe Harbor Statement

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 U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), other foreign regulatory bodies and other governmental regulatory bodies, 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 EMA's or other health regulatory authorities' approval of any applications we file or refusals to approve such filings, including the new drug application (NDA) and the marketing authorization applications (MAAs) we filed with the FDA, the EMA and other health regulatory authorities 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 or submit for any such drug product; the identification of lead compounds; the risk that we may fail to satisfy certain conditions relating to grants we have received from the Office of the Chief Scientist of Israel's Ministry of Industry and Trade which may lead to our being required to refund grants previously received together with interest and penalties; 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, EMA or any other foreign regulatory authority may not accept or approve an NDA filed or MAA submitted by a pharmaceutical or biotechnology company for such drug product. Failure to obtain approval from the FDA, EMA 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.

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