FDA Issues Complete Response Letter for Taliglucerase Alfa New Drug Application

February 25, 2011

CARMIEL, Israel, Feb. 25, 2011 /PRNewswire via COMTEX/ --

Protalix BioTherapeutics, Inc. (NYSE Amex: PLX; TASE: PLX), announced today that the U.S. Food and Drug Administration (FDA) issued a Complete Response Letter (CRL) regarding the Company's New Drug Application (NDA) for taliglucerase alfa for the treatment of Gaucher disease. Taliglucerase alfa is a plant-cell expressed form of glucocerebrosidase (GCD).

A CRL is issued by the FDA's Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form.

The main questions raised by the FDA regarding the NDA relate to clinical and chemistry, manufacturing and controls (CMC). In the clinical section, the FDA requested additional data from the Company's switchover trial and long-term extension trial. At the time the NDA was submitted, full data from these trials was not available. In the CMC section, the FDA requested information regarding testing specifications and assay validation.

"While we are disappointed by the receipt of the Complete Response Letter, we appreciate the FDA's efforts to complete the review of our NDA. We noted that the FDA did not request additional clinical studies. Moreover, the FDA inspected our manufacturing facilities finding them acceptable. FDA also did not identify any issues in its audit of our clinical sites," said Dr. David Aviezer, the Company's President and Chief Executive Officer. "Protalix will work with the FDA to determine next steps."

On November 30, 2009, Pfizer and Protalix BioTherapeutics, Inc. entered into an agreement to develop and commercialize taliglucerase alfa.

"Pfizer remains dedicated to the Gaucher community worldwide," said David Simmons, President and General Manager, Emerging Markets and Established Products Business Units, Pfizer Inc. "We will work closely with Protalix to address the requests from the FDA in a timely manner by providing technical, analytical and regulatory expertise."

Protalix will request a meeting with the FDA as soon as possible to clarify the path to regulatory approval.

Patient enrollment remains open in Protalix's multi-center, double-blind pediatric trial of taliglucerase alfa. Patients currently enrolled in the switchover study and extension study will continue to receive the drug. In addition, taliglucerase alfa is currently being provided to Gaucher patients in the U.S. under an Expanded Access protocol, under special access agreements such as in France and Brazil, as well as to patients in the rest of the world under Named Patient provisions.

Conference Call & Webcast

The Company will host a conference call and webcast today, February 25, 2011, at 08:00 a.m. Eastern Time (15:00 Israel time). The conference call may be accessed by dialing 877-407-8031 for U.S. callers and 201-689-8031 for international callers. The conference call will also be webcast live under the investor relations section of the Company's website at www.protalix.com and will be archived there for 14 days following the call.

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). The Company'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 development. To date, marketing applications have been submitted for taliglucerase alfa in the United States, European Union, Brazil and Israel. 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. The terms "anticipate," "believe," "estimate," "expect" 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, risks relating to: the review process of the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMEA), 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, including the information we provide the FDA after our receipt of a complete response letter from the FDA in February 2011 relating to the new drug application (NDA) we filed for taliglucerase alfa, is insufficient for regulatory approval; delays in the FDA's, the EMEA'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 EMEA 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 successful preclinical development of our other product candidates; the completion of our clinical trials for our other product candidates; 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, EMEA 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, 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
646-378-2927
mnanus@troutgroup.com

Media Contact
Jennifer Conrad or Douglas MacDougall
MacDougall Biomedical Communications
781-235-3060
jconrad@macbiocom.com

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