Protalix BioTherapeutics Announces Preliminary Top-Line Positive Data from taliglucerase alfa Switchover Trial

November 2, 2010

CARMIEL, Israel, Nov. 2, 2010 /PRNewswire via COMTEX/ --

Protalix BioTherapeutics, Inc. (NYSE-AMEX: PLX, TASE: PLX), announced today positive preliminary data from the first 15 patients that completed the Company's nine month, worldwide, multi-center, open-label, switchover trial of taliglucerase alfa for the treatment of Gaucher disease under a protocol cleared by the U.S. Food and Drug Administration (FDA). The data indicate that patients can safely be switched to taliglucerase alfa from imiglucerase (Cerezyme(R)).

Patients enrolled in the trial were switched from imiglucerase (doses ranging from 10-60 U/kg every other week) to an equivalent dose using the same number of units of taliglucerase alfa. The data from the first 15 patients demonstrate that maintenance of efficacy was achieved over a nine month period with no increased safety concerns. Patients' hemoglobin and platelet counts remained stable demonstrating hematological stability. As measured by MRI, mean spleen volume and liver volume also remained stable. There was no evidence of increased safety concerns in patients switched from Cerezyme(R) to taliglucerase alfa and there were no drug related serious adverse events. Hypersensitivity reactions were not reported in this patient group. One patient developed non-neutralizing IgG antibodies to taliglucerase at the end of the study. Detailed data will be presented at an upcoming medical meeting.

The switchover trial was originally designed and cleared by FDA to enroll 15 patients, however, it was expanded to recruit a total of 30 patients as a result of the shortage of enzyme replacement therapy for Gaucher patients. Adult enrollment in the study has closed; pediatric enrollment remains open.

"We are pleased with the interim results of the switchover trial to taliglucerase alfa," said Dr. David Aviezer, the Company's President and Chief Executive Officer. "Through our Phase III pivotal and extension trial, pediatric study in naïve patients, switch-over trial, expanded access and named patient programs, ATU program in France and supply agreement in Brazil, we are generating a robust clinical database for taliglucerase alfa."

Taliglucerase alfa is under review by the U.S. Food and Drug Administration with a Prescription Drug User Fee Action (PDUFA) date scheduled for February 25, 2011.

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. Taliglucerase alfa is an enzyme replacement therapy in development under a Special Protocol Assessment with the FDA for Gaucher disease. The Company'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.

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 FDA, the EMEA, other foreign regulatory bodies and other governmental regulatory bodies, 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 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 by 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 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.