Protalix BioTherapeutics Completes Phase I Clinical Trial for PRX-105

June 8, 2010

CARMIEL, Israel, June 8, 2010 /PRNewswire via COMTEX/ --Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX) announced today the completion of its phase I clinical trial of PRX-105, a plant cell expressed pegylated recombinant human acetylcholinesterase in development for biodefense indications. The trial established the pharmacokinetics of the protein and demonstrated that single dose, intravenous administration of PRX-105 is safe and well tolerated.

"We are very pleased with the favorable safety and pharmacokinetic results from our phase I clinical trial of PRX-105," said Dr. David Aviezer, Protalix's President and Chief Executive Officer. "The positive results also provide further validation of the safety and breadth of our ProCellEx(TM) plant cell based expression system."

The Company plans to perform additional safety studies in healthy volunteers and animals in collaboration with civil and military agencies in the United States and Israel, for which discussions have been initiated. Given the nature of the biodefense indications for which the Company is developing PRX-105, efficacy trials of PRX-105 in humans (phase II and phase III) are not required.

The phase I clinical trial of PRX-105 is a first in human, open label, non-randomized, single-dose study. PRX-105 is administered intravenously by slow bolus injection to 10 healthy volunteers in the trial. The trial is being conducted in collaboration with Professor Hermona Soreq, from the Hebrew University in Jerusalem, Israel, a world leader in the field of acetylcholinesterase research. The production of PRX-105 is based on patents that were licensed to Protalix Ltd. by Yissum, the Technology Transfer Company of the Hebrew University, Jerusalem.

Pre-clinical studies have indicated that PRX-105 successfully protects animals exposed to organophosphate nerve gas agent analogs, in both the prophylactic and post-exposure settings.

About Protalix

Protalix is a biopharmaceutical company focused on the development and commercialization of proprietary 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. In August 2009, the FDA granted orphan drug status and fast track designation to taliglucerase alfa for the treatment of Gaucher disease and Protalix filed a rolling NDA submission with the FDA in December 2009. In November 2009, Protalix granted Pfizer Inc. exclusive, worldwide rights to develop and commercialize taliglucerase alfa for the treatment of Gaucher disease, except in Israel. Protalix retained the right to commercialize taliglucerase alfa in Israel.

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 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; 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 or 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 operation 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

Media Contact:
Brad Miles
BMC Communications Group, LLC
Telephone: 212-477-9007 x17
Email: brad@bmccommunications.com

SOURCE Protalix BioTherapeutics, Inc.