Protalix Initiates a Phase I Clinical Trial of Acetylcholinesterase for Biodefense Indications

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CARMIEL, Israel, March 17 /PRNewswire-FirstCall/ -- Protalix BioTherapeutics, Inc. (NYSE-Amex: PLX) announced today that it has initiated a phase I clinical trial of PRX-105, the Company's plant cell expressed pegylated recombinant human acetylcholinesterase product candidate in development for biodefense indications. The trial is designed to study the safety of PRX-105 by administering a bolus intravenous injection of PRX-105 in healthy volunteers. The U.S. Food and Drug Administration (FDA) and the Israeli Ministry of Health have each accepted the Company's exploratory Investigational New Drug application to commence the phase I clinical trial of PRX-105. Pre-clinical studies have previously indicated that PRX-105 successfully protects animals exposed to organophosphate nerve gas agent analogs, in both the prophylactic and post-exposure settings. In addition, the safety of PRX-105 has been demonstrated in a well-controlled study in rodents performed under good laboratory practices.

Before applying for marketing approval from the FDA and comparable foreign regulatory authorities, the Company will be required to perform additional safety studies in healthy volunteers, as well as additional studies in animals. Efficacy trials of PRX-105 in humans (phase II and phase III) are not required given the nature of the indication for which PRX-105 is being developed.

Nerve gas agents, such as organophosphates, bind to, and inhibit, the action of acetylcholinesterase, an endogenous enzyme that breaks down the neurotransmitter, acetylcholine, in humans. The loss of the acetylcholinesterase function results in an accumulation of toxic levels of acetylcholine, which has deleterious effects on major organ systems, including the heart, lung and central nervous system. PRX-105 acts as a bioscavenger of the organophosphates that affect the acetylcholinesterase, thereby causing a re-balancing of acetylcholine levels.

"We are excited that a second product candidate produced through our ProCellEx(TM) protein expression system has advanced to the clinical stage," said Dr. David Aviezer, President and Chief Executive Officer of Protalix. "The treatment options currently available to victims of nerve gas attacks are limited and current rescue therapies have significant, life threatening side effects which give rise to the urgent need for an alternative biological solution, as recently indicated by U.S. government agencies."

The PRX-105 program 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, and based on patents that were licensed to Protalix Ltd. by Yissum, the Technology Transfer Company of the Hebrew University. "The acetylcholinesterase project is important project to me, both as an inventor and as a scientist, as Protalix is developing the acetylcholinesterase in its facility in Carmiel, Israel, and the protein appears to be available for use for multiple clinical needs, especially in the neurological degenerative disease area," said Professor Soreq.

The Company is in discussions with both civil and military agencies in the United States and Israel with respect to this project.

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 the Company believes will allow for the 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 preclinical development of our product candidates; the completion of 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; 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; 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; 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, Trade and Labor which may lead to our being required to refund grants previously received together with interest and penalties; the risk that the Office of the Chief Scientist may not deliver to us all of the funds awarded to us; uncertainties related to the ability to attract and retain partners for our technologies and products under development; and other factors described in our filings with the U.S. 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.


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