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

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™ 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.

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