



Protalix's Acetylcholinesterase Demonstrates Potential Role in the Treatment of Parkinson's Disease

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Protalix BioTherapeutics, Inc. (NYSE-AMEX: PLX, TASE: PLX) announced today that a paper entitled: "[Adaptive alternative splicing correlates with less environmental risk of Parkinsonism](#)," has been published online in the Journal of Neurodegenerative Diseases. The research includes an investigation of the effect of Protalix's PRX-105 on alternative splicing patterns in the striatum, which may confer protection in Parkinson's disease.

PRX-105 is a plant derived version of the human soluble acetylcholinesterase splice variant R (AChE-R) that is in development for several indications, including a biodefense program and an organophosphate-based pesticide treatment program. Building on prior research supporting a role for disrupted alternative splicing in several neurodegenerative diseases, scientists from the Hebrew University of Jerusalem, Israel and Protalix BioTherapeutics investigated splicing patterns in pre-clinical models of Parkinson's disease to determine a possible role of AChE-R in the brain's protective mechanisms.

The research highlights that a splice shift, either inherited or induced by environmental factors (e.g. neurotoxins), from the more common 'synaptic form' of acetylcholinesterase (AChE-S) to the monomeric 'read-through' variant of AChE (AChE-R), is important in conferring protection against Parkinson-like symptoms. Furthermore, intravenous injection with PRX-105 induced a protective gene expression profile in the striatum of the brain.

Prof. Hermona Soreq, Former Dean of the Faculty of Natural Sciences at the Hebrew University of Jerusalem and the lead author on the paper said, "These findings support the notion that the balance of different forms of AChE in the brain, either inherited or acquired due to environmental factors or toxins, is an important contributor in Parkinsonism. Driving the brain's transcription machinery to follow a protective path could lead to new treatment options for Parkinson's Disease using AChE-R."

In addition, a PCT patent application entitled: "Methods for Treating or Preventing Parkinson's Disease," jointly authored by the Hebrew University and Protalix BioTherapeutics has been recently filed. These filings are part of the continuing collaboration between Protalix and Yissum Research and Development, the technology transfer arm of the Hebrew University of Jerusalem, Israel.

About PRX-105

PRX-105 is a plant-derived PEGylated recombinant version of the human soluble acetylcholinesterase splice variant R (AChE-R), the rare form of AChE. The development program is being conducted under an agreement announced in August 2007, with Yissum Research and Development, part of the Hebrew University of Jerusalem, and with the Boyce Thompson Institute, Inc., affiliated with Cornell University.

PRX-105 is being developed for several indications, including a biodefense program and an organophosphate-based pesticide treatment program. On June 2009, Protalix successfully completed an exploratory Phase 1 study for PRX-105. This micro-dose Phase 1 study provided clinical information on this protein at an early clinical phase of drug development. The study was conducted under FDA approval, and is filed at the NIH clinical trial site ([www.ClinicalTrial.gov](#)). The trial established the pharmacokinetics of the protein and demonstrated that single dose, intravenous administration of PRX-105 is safe and well tolerated. All healthy volunteers successfully completed the clinical protocol with no serious adverse events.

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). Protalix'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, the European Union, Brazil, Israel and Australia. Protalix's development pipeline also includes the following product candidates: PRX-102, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; 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; an orally-delivered glucocerebrosidase enzyme that is naturally encased in carrot cells, also for the treatment of Gaucher disease; pr-antiTNF, a similar plant cell version of etanercept (Enbrel(TM)) for the treatment of certain immune diseases such as rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, psoriatic arthritis and plaque psoriasis; and others.

Forward Looking Statements

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 FDA, the European Medicines Agency (EMA), 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 is insufficient for regulatory approval; risks relating to delays in the FDA's, the EMA's or other foreign 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; applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application we file for the drug product; risks relating to the completion of our clinical trials; 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, EMA 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, EMA 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.

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