Protalix BioTherapeutics Signs Clinical Development Agreement With Pfizer for ELELYSO(TM) (taliglucerase alfa)

December 6, 2012

CARMIEL, Israel, Dec. 6, 2012 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX) (TASE:PLX), announced today that it has entered into a Clinical Development Agreement with Pfizer Inc. under which Protalix will continue to manage, administer and sponsor current, ongoing clinical trials relating to ELELYSO™ (taliglucerase alfa). Protalix is currently sponsoring adult and pediatric extension studies of ELELYSO. New clinical trials for ELELYSO will be conducted and sponsored by Pfizer.

Under the terms of the agreement, Protalix is eligible to receive a milestone payment of $8.3 million upon the achievement of certain near-term clinical development milestones.

This agreement helps to maintain the continuity of the ongoing clinical trials for Gaucher patients and physicians and reinforces the companies' mutual commitment to the Gaucher community.

On November 30, 2009, Pfizer and Protalix entered into an agreement to develop and commercialize taliglucerase alfa, an enzyme replacement therapy for the treatment of Gaucher disease. Under the terms of the agreement, Pfizer received exclusive worldwide licensing rights for the commercialization of taliglucerase alfa, while Protalix retained the exclusive commercialization rights in Israel.

Protalix BioTherapeutics, Inc.

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®. Protalix's unique expression system presents a proprietary method for developing recombinant proteins in a cost-effective, industrial-scale manner. Protalix's first product manufactured by ProCellEx, Elelyso™ (taliglucerase alfa), was approved for marketing by the U.S. Food and Drug Administration in May 2012, and by the Israeli Ministry of Health in September 2012. Protalix is partnered with Pfizer Inc. for worldwide development and commercialization, excluding Israel, where Protalix retains full rights. Marketing applications for taliglucerase alfa have been filed in additional territories as well. 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®) 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," "plan" 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 and uncertainties related to our ability to perform under the clinical development agreement and, accordingly, to earn the milestone payment set forth therein; risks related to Pfizer's performance of its obligations under the clinical development agreement; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; other factors described in our filings with the U.S. Securities and Exchange Commission. 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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