Protalix BioTherapeutics Receives Marketing Authorization for Elelyso(TM) for the Treatment of Gaucher Disease From the Israeli Ministry of Health

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CARMIEL, Israel, Sept. 27, 2012 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX) (TASE:PLX), announced today that is has received marketing authorization from the Israeli Ministry of Health for Elelyso™ (taliglucerase alfa) for injection, an enzyme replacement therapy (ERT) for the long-term treatment of adults with Type 1 Gaucher disease. Elelyso will be marketed in Israel by Protalix Ltd., the holder of all marketing rights to Elelyso in the Israeli market.

This is the second marketing approval of Elelyso, which was approved by the U.S. Food and Drug Administration (FDA) on May 1, 2012. Marketing applications have been filed in additional territories. Elelyso is marketed in the United States by the Company's commercialization partner, Pfizer Inc. ("Pfizer").

Under its development and commercialization arrangement with Pfizer, the Company maintained the commercialization rights to Elelyso in Israel. Accordingly, the Company has built an internal marketing team designed to serve the Israeli market. The Company intends to sell Elelyso in Israel at a competitive price compared to other products already available to Gaucher patients. Over the past five years, the Company has treated over 60 Gaucher patients in Israel with Elelyso through clinical trials and compassionate use programs and expects that a substantial proportion of these patients will soon be treated through commercial programs.

Elelyso is the first plant cell-based biopharmaceutical approved for marketing by the Israeli Ministry of Health. It is also the first plant cell-expressed drug derived from ProCellEx® to achieve regulatory approval for marketing. ProCellEx is the Company's proprietary plant cell-based protein expression system. Elelyso is a form of the human lysosomal enzyme, glucocerebrosidase, used to treat Gaucher disease.

"We are very excited to have our first drug product approved in our home country," said Dr. David Aviezer, President and Chief Executive Officer of Protalix BioTherapeutics. "In our development efforts, we enjoyed the cooperation of the leading Israeli medical and academic institutions, and we rely in part on support from research grants from the Israeli government. We are proud that our Gaucher disease treatment will be available for commercial sale in Israel."

The Israeli Ministry of Health's marketing authorization of Elelyso was based on its review of data compiled by the Company from its pivotal phase III clinical trial, as well as data from its extension trial in which treatment-naïve patients that were treated with taliglucerase alfa for a 24-month period, and from the Company's switchover trial which collected data from Gaucher patients that had previously been treated with imiglucerase (Cerezyme®) and were switched to treatment with taliglucerase alfa (Elelyso).

"The Israeli approval of Elelyso is important for local Gaucher patients," said Mr. Yossi Cohen, Chairman of the Israeli Association for Gaucher. "Given the inconsistent supply of ERT for the treatment of Gaucher disease worldwide in recent years, we believe the addition of a new treatment for Gaucher patients will provide them with greater confidence regarding treatment. The fact that the product is manufactured locally by an Israeli company increases our excitement about this approval."

"The clinical studies of Elelyso to date, both the pivotal and the extension studies, demonstrate that Elelyso is an effective treatment for Gaucher disease," said Professor Ari Zimran, M.D., Director of the Gaucher Clinic, Shaare Zedek Medical Center, Jerusalem, Israel. "The results of the Company's 24-month naive extension trial and switch over study support Elelyso as an important treatment alternative for Gaucher patients in Israel."

About Gaucher Disease

Gaucher disease is an inherited lysosomal storage disorder in humans that affects an estimated 10,000 people worldwide and can cause severe and debilitating symptoms, including: enlargement of the liver and spleen, various forms of bone disease, easy bruising, and anemia (a low number of red blood cells). Gaucher disease consists of varying degrees of severity; it has been sub-divided into three subtypes - Types 1, 2, and 3 - according to the presence or absence of neurological involvement. Type 1, the most common, is found at a higher frequency among individuals who are of Ashkenazi Jewish ancestry.

About Elylyso (taliglucerase alfa)

Elylyso (taliglucerase alfa) for injection is a hydrolytic lysosomal glucocerebroside-specific enzyme indicated for long-term enzyme replacement therapy (ERT) for adults with a confirmed diagnosis of Type 1 Gaucher disease.

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 on May 1, 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 the timing of a commercial launch and market acceptance of taliglucerase alfa in Israel; risks relating to the review process of other foreign regulatory and other governmental bodies; risks relating to delays in other foreign regulatory authorities' approval of any applications filed for taliglucerase alfa or refusals to approve such filings; the risk that applicable regulatory authorities may refuse to approve the marketing and sale of a drug product even after acceptance of an application filed for the drug product; our dependence on performance by third party providers of services and supplies relating to the commercialization of taliglucerase alfa in Israel; the inherent risks and uncertainties in developing drug platforms and products of the type we are developing; the impact of development of competing therapies and/or technologies by other companies and institutions; potential product liability risks, and risks of securing adequate levels of product liability and other necessary insurance coverage; and 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.

CONTACT: Investor Contact
Tricia Swanson
The Trout Group, LLC
646-378-2953
tswanson@troutgroup.com

Media Contact
Jennifer Conrad or Kari Watson
MacDougall Biomedical Communications
781-235-3060
jconrad@macbiocom.com
kwatson@macbiocom.com

Protalix BioTherapeutics, Inc.