

## Protalix BioTherapeutics and Brazil's Ministry of Health Enter Into Supply and Technology Transfer Agreement for UPLYSO(TM) (alfataliglicerase) in Brazil

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## Exclusive License and Supply Agreement With Pfizer Amended to Facilitate the Technology Transfer

CARMIEL, Israel, June 19, 2013 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE-MKT:PLX) (TASE:PLX), announced today that it has entered into a supply and technology transfer agreement with Fundação Oswaldo Cruz (commonly referred to as Fiocruz), an arm of the Brazilian Ministry of Health for UPLYSO<sup>TM</sup> (alfataliglicerase), the Company's proprietary enzyme replacement therapy for the treatment of Gaucher disease. Gaucher disease is a rare lysosomal storage disorder that affects approximately 10,000 people worldwide.

The technology transfer is expected to take place during a seven-year term and is intended to transfer to Fiocruz the capacity and skills required for the Brazilian government to construct its own manufacturing facility, at its sole expense, and to produce a sustainable, high quality, and cost effective supply of UPLYSO. Under the agreement, Fiocruz has committed to purchase at least approximately US\$40 million worth of UPLYSO during the first two years of the agreement. In subsequent years, Fiocruz is required to purchase at least approximately US\$40 million worth of UPLYSO per year. Additionally, Protalix is not required to complete the final stage of the technology transfer until Fiocruz purchases at least approximately US\$280 million worth of UPLYSO. The agreement may be extended for an additional five-year term, as needed, to complete the technology transfer. All of the terms of the arrangement, including the minimum annual purchases, will apply during the additional term.

"We are excited to be working with the Brazilian government in its efforts to provide UPLYSO to Gaucher patients in Brazil and to collaborate with Fiocruz regarding our plant cell technology," said Dr. David Aviezer, Protalix BioTherapeutics' President and Chief Executive Officer. "We are encouraged by the recognition of our drug and our technology by both Fiocruz and Brazil's Ministry of Health, and believe that this agreement will further establish a reliable supply of treatment for patients living with Gaucher disease."

The technology transfer agreement becomes effective after the parties receive approval of the agreement by the Brazilian National Institute of Industrial Property, which is expected to occur in approximately one month. During the technology transfer period, Fiocruz will apply for its own registration of UPLYSO with the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) and continue to make the product available. Once the technology transfer is complete, the government will be the sole source of this important treatment option for Gaucher patients in Brazil.

"It is an honor to announce this agreement with Protalix for the supply and production of UPLYSO in Brazil," commented Dr. Alexandre Padilha, Brazil's Minister of Health. "Through this collaboration, we are able to strengthen our technological and industrial capabilities in the area of biologics manufacturing and improve the health of Brazilian citizens who are impacted by this rare disorder."

In March 2013, the Brazilian National Health Surveillance Agency (ANVISA, Agencia Nacional de Vigilancia Sanitaria) granted regulatory approval to Pfizer for UPLYSO which is indicated for the long-term enzyme replacement therapy for adults with a confirmed diagnosis of Type I Gaucher disease.

To facilitate the arrangement with Fiocruz, the Company's commercialization partner for UPLYSO, Pfizer Inc., amended its exclusive license and supply agreement and returned commercialization rights in Brazil to the Company. In consideration for the return of these rights, the Company will pay Pfizer a maximum amount of approximately US\$12.5 million from the Company's net profits generated in Brazil per year of the agreement. During the transition of commercial rights back to the Company, Pfizer will continue to support Gaucher disease patients in Brazil who are being treated with UPLYSO.

The Company will pay a fee equal to 5% of the net proceeds generated in Brazil to its agent for services provided in assisting the Company to complete the agreement.

UPLYSO is marketed as ELELYSO<sup>TM</sup> in the United States and Israel.

The Company's management will discuss certain terms and conditions of the agreement during its previously scheduled analyst event on Thursday, June 20, 2013 at 8:00 AM EDT. The event audio and slide presentation will be webcast live and archived on the Company's website for a 30-day period. The webcast will be available at <a href="https://www.protalix.com">www.protalix.com</a> on the Events Calendar page. The slides will be available under the presentation tab on the Company's website after the presentation.

## 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, taliglucerase alfa, was approved for marketing by the U.S. Food and Drug Administration (FDA) in May 2012, by Israel's Ministry of Health in September 2012, by the Brazilian National Health Surveillance Agency (ANVISA) in March 2013, by the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) in April 2013, and by the regulatory authorities of other countries. Marketing applications for taliglucerase alfa have been filed in additional territories as well. Protalix has partnered with Pfizer Inc. for the worldwide development and commercialization of taliglucerase alfa, excluding Israel, where Protalix retains full rights. 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 produced and encapsulated within 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 related to the acceptance and use of UPLYSO by physicians, patients and the Brazilian Ministry of Health; risks related to our and Fiocruz's ability to market UPLYSO to the Brazilian Ministry of Health; our dependence on performance by third party providers of services and supplies relating to the commercialization of taliglucerase alfa in Brazil; 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.

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