Protalix BioTherapeutics Announces FDA Approval to Operate its Current Facility as a Multi-Product Facility

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Multi-product facility to support the potential manufacturing of both pegunigalsidase alfa and taliglucerase alfa on a commercial scale

CARMIEL, Israel, June 01, 2017 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today that a Supplemental New Drug Application (sNDA) submitted to the U.S. Food and Drug Administration (FDA) has been approved by the FDA. Approval of the sNDA allows the Company to convert its manufacturing facility in Carmiel, Israel, from a single dedicated product facility to a multi-product facility.

The facility's current capacity can serve all of the Company's current and expected commercial and clinical needs. The Company believes that conversion of the facility to a multi-product facility will serve the Company's production needs for the anticipated commercialization of pegunigalsidase alfa (PRX-102) for the treatment of Fabry disease together with the current and expected significant increase in the manufacturing of taliglucerase alfa, mainly due to the increased activities in Brazil. The Company expects that the conversion will allow the Company to realize potentially significant operational savings as it progresses towards the anticipated commercialization of pegunigalsidase alfa.

"We have been producing drug substance for our clinical trials of pegunigalsidase alfa in our facility and have already upgraded our manufacturing facility to become a multi-product facility to support the potential manufacturing of both pegunigalsidase alfa and taliglucerase alfa in a commercial scale," said Moshe Manor, Protalix's President and Chief Executive Officer. "Given the unique aspects of our ProCellEx® protein expression system, the conversion of the facilities did not entail substantial additional capital expenditures and will allow us to use our capital resources more efficiently in the commercial production of pegunigalsidase alfa, if approved. We are excited to have reached this milestone in our progression towards the commercialization of pegunigalsidase alfa alongside the expected increase in activities in Brazil."

About 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 and, subsequently, by the regulatory authorities of other countries. Protalix has licensed to Pfizer Inc. the worldwide development and commercialization rights for taliglucerase alfa, excluding Brazil, where Protalix retains full rights. Protalix's development pipeline includes the following product candidates: pegunigalsidase alfa (PRX-102), a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; PRX-106, an orally delivered anti-inflammatory treatment; alidornase alfa (PRX-110), a chemically modified DNase I for the treatment of Cystic Fibrosis; 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: failure or delay in the commencement or completion of our preclinical and clinical trials which may be caused by several factors, including: slower than expected rates of patient recruitment; unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; inability to monitor patients adequately during or after treatment; inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; and lack of sufficient funding to finance clinical trials; the risk that the results of the clinical trials of our product candidates will not support our claims of safety or efficacy, that our product candidates will not have the desired effects or will be associated with undesirable side effects or other unexpected characteristics; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the successful conclusion of our negotiations with the Brazilian Ministry of Health regarding the purchase of alfataliglicerase, and our commercialization efforts for alfataliglicerase in Brazil generally; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our convertible notes or any other indebtedness; risks relating to the compliance by Fundação Oswaldo Cruz with its purchase obligations and related milestones under our supply and technology transfer agreement; our dependence on performance by third party providers of services and supplies, including without limitation, clinical trial services; delays in our preparation and filing of applications for regulatory approval; delays in the approval or potential rejection of any applications we file with the FDA or other health regulatory authorities, and other risks relating to the review process; 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 press release are valid only as of the date hereof and we disclaim any obligation to update this information, except as may be required by law.

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