NEWS RELEASE

Protalix BioTherapeutics and Chiesi Farmaceutici S.p.A to Apply for Accelerated Approval of pegunigalsidase alfa for the Treatment of Fabry Disease in the United States

BLA Submission Expected First Quarter 2020

CARMIEL, Israel, June 06, 2019 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American: PLX) (TASE: PLX), or Protalix, and Chiesi Farmaceutici S.p.A, an international research-focused healthcare Group, or Chiesi, today announced that, following a series of meetings and correspondence with the U.S. Food and Drug Administration (FDA), they plan to file a biologics license application, or a BLA, for pegunigalsidase alfa for the treatment of Fabry disease in the first quarter of 2020 via the FDA's Accelerated Approval pathway.

Over the last several months, Protalix and Chiesi have engaged the FDA in a dialogue regarding the potential eligibility of pegunigalsidase alfa for accelerated approval based on readily available data generated by Protalix from its clinical studies of pegunigalsidase alfa.

As a result of this dialogue and a recent letter received from the FDA, Protalix and Chiesi have initiated preparations for a BLA submission based on data from the completed phase I/II clinical trials of pegunigalsidase alfa and from the ongoing phase III BRIDGE clinical trial. Protalix and Chiesi are targeting a BLA submission for the first quarter of 2020.

If approved, Protalix will be eligible to receive a milestone payment from Chiesi.

"We are very excited to be one step closer to an approved product to help a patient population that desperately needs a better option than those currently available on the market. This regulatory approval path is a significant achievement as it means that we can start the application process and potentially attain market approval significantly earlier than the initial plan of data from our ongoing phase III BALANCE clinical trial. We plan to continue the BALANCE study to further strengthen the profile of pegunigalsidase alfa," commented Moshe Manor, Protalix's President and Chief Executive Officer. "Approval will depend on the formal FDA review, but based on communications with the agency, Protalix remains optimistic that the FDA will approve pegunigalsidase alfa on the accelerated basis."

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, a modified version of the recombinant human alpha-GAL-A protein for the treatment of Fabry disease; OPRX-106, an orally-delivered anti-inflammatory treatment; alidornase alfa for the treatment of Cystic Fibrosis; and others. Protalix has partnered with Chiesi Farmaceutici S.p.A., both in the United States and outside the United States, for the development and commercialization of pegunigalsidase alfa.

About the Chiesi Group

Based in Parma, Italy, Chiesi Farmaceutici is an international research-oriented group with over 80 years' experience in the pharmaceutical sector, and is present in 27 countries. The group researches, develops and commercializes innovative medicines in the respiratory disease, special care and rare disease therapeutic areas. The Group's Research & Development center is based in Parma (Italy) and integrated with 6 other important research and development groups in France, the USA, the UK and Sweden, to promote its pre-clinical, clinical and registration programs. The Group employs around 5,700 people. For more information please visit www.chiesi.com.

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 "expect," "anticipate," "believe," "estimate," "project," "plan," "should" 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 and the final results

of a clinical trial may be different than the preliminary findings for the clinical trial. 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: risks that the FDA will not accept an application for accelerated approval of PRX-102 with the data generated to date or will request additional data or other conditions of our submission of any application for accelerated approval of PRX-102; lack of sufficient funding to finance clinical trials; 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; and inability or unwillingness of medical investigators and institutional review boards to follow our clinical protocols; the risk that the results of the clinical trials of our product candidates will not support our claims of superiority, 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 our ability to maintain and manage our relationship with Chiesi Farmaceutici and any other collaborator, distributor or partner; risks related to the amount and sufficiency of our cash and cash equivalents; risks related to the amount of our future revenues, operations and expenditures; the risk that despite the FDA's grant of fast track designation for pegunigalsidase alfa for the treatment of Fabry disease, we may not experience a faster development process, review or approval compared to applications considered for approval under conventional FDA procedures; risks related to the FDA's ability to withdraw the fast track designation at any time; risks relating to our ability to make scheduled payments of the principal of, to pay interest on or to refinance our outstanding notes or any other indebtedness; 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; our ability to identify suitable product candidates and to complete preclinical studies of such product candidates; 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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