Protalix BioTherapeutics to Present Preliminary Data from the BRIGHT Study of pegunigalsidase alfa for the Treatment of Fabry Disease at the 15th Annual WORLDSymposium™ 2019

January 28, 2019

~Oral presentation to include pharmacokinetic and anti-drug antibody data for first 15 patients enrolled~

CARMIEL, Israel, Jan. 28, 2019 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE American:PLX) (TASE:PLX), a biopharmaceutical company focused on the development and commercialization of recombinant therapeutic proteins expressed through its proprietary plant cell-based expression system, ProCellEx®, today announced that the Company will present preliminary pharmacokinetic (PK) data from its phase III BRIGHT study of pegunigalsidase alfa for the treatment of Fabry disease at the 15th Annual WORLD*Symposium*™2019. The conference will take place February 4-8, 2019 at the Hyatt Regency Orlando, Orlando, Florida.

An oral presentation titled, "Once every 4 weeks – 2 mg/kg of pegunigalsidase alfa for treating Fabry disease; Preliminary results of a Phase 3 study," highlighting PK and safety data will be presented by Mr. Myrl D. Holida, PA, of the University of Iowa Health Care in Iowa City, Iowa, a principal investigator in the Company's clinical trial of PRX-102 for the treatment of Fabry disease, on Thursday, February 7, 2019 at 8:30 AM ET.

Pegunigalsidase alfa, or PRX-102, is the Company's plant cell-expressed recombinant, PEGylated, cross-linked α-galactosidase-A candidate for the treatment of Fabry disease. The BRIGHT study is an open-label switchover study to assess the safety, efficacy and pharmacokinetics of pegunigalsidase alfa 2 mg/kg administered every 4 weeks in Fabry patients previously treated with an enzyme replacement therapy: Fabrazyme® or Replagal®. The data to be presented will include pharmacokinetics data from 15 patients undergoing treatment with PRX-102.

In addition to the oral presentation, the following poster presentations will be made at the conference with respect to pegunigalsidase alfa:

- "Once every 4 weeks – 2 mg/kg of pegunigalsidase alfa for treating Fabry disease; Preliminary results of a phase 3 study" to be presented by principal investigator Mr. Myrl D. Holida, PA, of the University of Iowa Health Care in Iowa City, Iowa, a principal investigator in the Company's clinical trial of PRX-102. Poster presentation is scheduled from 4:30-6:30 PM ET on Tuesday, February 5, 2019 (Poster # 160).

- "Pegunigalsidase alfa for the treatment of Fabry disease: Preliminary results from a phase III open label, switch over study from agalsidase alfa," to be presented by Prof. Ales Linhart of the Všeobecná fakultní nemocnice v Praze, Prague Czech Republic, a principal investigator in the Company's clinical trial of PRX-102. Poster presentation is scheduled from 4:30-6:30 PM ET on Tuesday, February 5, 2019 (Poster # 218).

- "Analysis of the baseline characteristics of Fabry disease patients screened for the pegunigalsidase alfa phase III BALANCE study," to be presented by Prof. David Warnock, Professor of Nephrology at the University of Alabama Birmingham, Birmingham, Alabama. Poster presentation is scheduled from 4:30-6:30 PM ET on Wednesday, February 6, 2019 (Poster # 373).

Copies of the oral presentation and the posters will be available on the Company's website under the Presentation tab in the Investors section at the time of the presentations.

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.

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