Protalix BioTherapeutics Presents Positive Six and Twelve Month Interim Clinical Data on PRX-102 for the Treatment of Fabry Disease at the 12th Annual WORLDSymposium™ 2016

March 3, 2016

Demonstrated Effectiveness Across All Disease Parameters Including Cardiac and Kidney Functions

PRX-102 Safe and Well Tolerated With Very Low Formation of Antibodies

CARMIEL, Israel, March 03, 2016 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE:PLX) (TASE:PLX), announced today that positive interim data from the Company's phase I/II dose-ranging clinical trial of PRX-102 for the treatment of Fabry disease will be presented on March 3, 2016 at 3:15 PM PT at the Lysosomal Disease Network 12th Annual WORLD*Symposium* 2016 in San Diego, CA. PRX-102 is a recombinant plant cell expressed, Pegylated modified version of the human alpha-Galactosidase-A enzyme. A slide presentation featuring these data will be posted at the time of the presentation on the Company's web site, under the Presentations tab.

"PRX-102 has the potential to be a meaningful treatment for patients suffering from Fabry disease," said Dr Derralynn Hughes, Senior Lecturer in Hematology at the Royal Free & University College Medical School and Director of the lysosomal storage disorders research program, and Principal Investigator in the clinical trial. "The pharmacokinetic data and scientific rationale behind why PRX-102 has the potential to be next generation enzyme replacement therapy is supported by the current Phase I/II efficacy and safety data. I look forward to collaborating with Protalix as the Company moves into Phase III development."

Dr. Hughes will be presenting interim results from the global, open-label, phase I/II dose-ranging trial. In the trial, 18 naïve male and female patients (11 male and 7 female) were enrolled across three dosing cohorts of 0.2 mg/kg, 1mg/kg and 2mg/kg for which intravenous infusions were administered every two weeks, with six and twelve month initial efficacy follow-ups.

Clinical Data on Cardiac and Kidney Functions

Based on an analysis of kidney biopsies with randomized blinded scoring, PRX-102 demonstrated a major reduction from baseline in renal peritubular capillary Gb3 using the quantitative Barisoni Lipid Inclusion Scoring System (BLISS). The following table denotes the mean change from baseline at six months.

0.2 mg/kg Dosing Cohort	**Percentage Reduction of Gb3**	
Overall (n=5)	75.5	%
Male (n=3)	82.2	%
Female (n=2)	65.4	%

1.0 mg/kg Dosing Cohort	**Percentage Reduction of Gb3**	
Overall (n=4)	86.5	%
Male (n=3)	89.6	%
Female (n=1)	77.3	%

In general, the leading causes for death of Fabry patients include cardiovascular disease and renal failures. All patients that participated in the trial exhibited stable cardiac and kidney function as measured by mean left ventricular mass (LVM), left ventricular mass index (LVMI), ejection fraction (EF), estimated Glomerular filtration rate (eGFR) and urine protein.

The table below sets forth the mean absolute values, at baseline, six and twelve months of treatment, including percentage changes, which were scored in a randomized blinded manner.

0.2 mg/kg Dosing Cohort

Timeframe	LVM (gr)	LVMI (gr/m2)	EF (%)	eGFR (mL/min/1.73m2)	Urine Protein (mg/g creatinine)
Baseline	98	55.1	55.1	109.1	185.3
6 months	94.4	52.6	55.8	108.5	193.3
12 months	94.8	53	54.6	111.8	176.7

1.0 mg/kg Dosing Cohort

Timeframe	LVM (gr)	LVMI (gr/m2)	EF (%)	eGFR (mL/min/1.73m2)	Urine Protein (mg/g creatinine)
Baseline	104.1	55.8	62.6	104.8	92.2
6 Months	101.1	54.1	57.4	106.6	101.2

Mean annualized eGFR slope for male patients was found to be 0.16 for the 0.2mg/kg and 0.72 for the 1.0mg/kg. The reduction in the eGFR slope suggests that PRX-102 has the potential to attenuate the symptoms experienced by patients suffering from renal disease, and may introduce other potential benefits to those patients.

Reductions of plasma Lyso-Gb3 and plasma Gb3 concentrations were also observed at six months. For the 0.2 mg/kg cohort, males (n=4) demonstrated a -72.2 ng/mL and a -3.9 µg/mL change, respectively. For the 1.0 mg/kg cohort, males (n=4) demonstrated a -67.6 ng/mL and a -5.4 µg/mL change, respectively.

A meaningful reduction in the total score of Mainz Severity Score Index (MSSI), which looks at general, neurological, cardiovascular and renal parameters, was demonstrated in both the 0.2 and 1.0 mg/kg dosing cohorts at six months.

Safety Data

The safety analysis for adverse events represents a total of approximately 15 patient years (n=18). PRX-102 was well tolerated, with the majority of events being mild and moderate. Only one of the 18 patients evaluated for safety experienced a related serious adverse event of hypersensitivity and was discontinued per protocol.

There was a low incidence of treatment-induced anti-drug antibodies (ADA) with low titers that are reduced by one year of treatment. Only 3 out of 18 patients had treatment induced ADA in at least one visit (2 in the 0.2mg/kg dose group; one in the 1mg/kg dose group). Two patients of the 0.2mg/kg dose group had neutralizing antibodies, 1 of which was positive only in 2 out of 8 samples.

Overall, PRX-102 showed a favorable trend in kidney function, stable cardiac function and reduction in kidney peritubular capillaries, plasma Gb3, Lyso-Gb3 and MSSI score.

Enrollment in the phase I/II clinical trial of PRX-102 was completed in February 2015. All patients that completed the trial opted to continue to receive PRX-102 in an open-label extension study. The Company expects to report data on the 2mg/kg dose and additional interim 12 month data and full 24 clinical trial results throughout 2016 and 2017 at various medical meetings and symposia.

The Company filed a Special Protocol Assessment (SPA) with the FDA for its planned phase III trial and expects to commence the trial in the first half of 2016.

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(R). 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: 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; PRX-110 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; 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 release are valid only as of the date hereof and we disclaim any obligation to update this information.

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