Protalix BioTherapeutics to Explore Non Alcoholic Steato Hepatitis (NASH) as an Indication for Its PRX 106 Oral Anti TNF

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Positive Pre-Clinical Data for PRX-106 Oral Anti-TNF in NASH

CARMIEL, Israel, Oct. 5, 2015 (GLOBE NEWSWIRE) -- Protalix BioTherapeutics, Inc. (NYSE MKT:PLX) (TASE:PLX), announced today pre-clinical data for PRX-106 in Non-alcoholic Steatohepatits (NASH), a liver disease characterized by an accumulation of fat, along with inflammation and degeneration of hepatocytes. PRX-106 is the Company's orally administered, plant cell-expressed recombinant anti-TNF fusion protein that successfully concluded Phase I clinical trial.

In preclinical studies, PRX-106 alleviated immune-mediated hepatitis and reduced interferon gamma levels in a concanavalin A (ConA) inflammatory mouse model. Furthermore, the drug was shown to alleviate liver damage and reducing liver necrosis and reduction of liver enzymes, ALT and AST, thus leading to an improvement in liver biopsies.

In a high fat diet model (NASH) PRX 106 demonstrated a reduction of liver enzymes, ALT and AST, reduction of serum triglycerides, along with a trend for reduction of liver fat.

Moshe Manor, the Company's President and Chief Executive Officer, commented, "Based on pre-clinical findings for PRX-106, we took action to assess the drug's potential in liver disease. Based on these exciting and encouraging preclinical results, we are now evaluating NASH, in addition to inflammatory bowel disease (IBD), as a potential indication for a proof of concept clinical trials in patients for PRX-106. The NASH market is extremely attractive with patient population that is rapidly increasing and is currently underserved with no approved treatments."

The safety of orally administered PRX-106 was assessed in a 14-day repeated administration study in rats. Three doses representing up to 5x of the highest intended clinical dose were evaluated, along with a control arm. No adverse clinical symptoms presented, with all blood parameters and weight gain persistent and normal. Furthermore, there were no abnormalities in gross necropsy pathology seen in any of the animals.

In addition, a two months toxicology study to support longer duration clinical studies was successfully completed. No treatment-related adverse reactions were observed among all experimental groups.

PRX-106 has also completed a Phase I clinical trial in healthy volunteers conducted at the Hadassah-Hebrew University Medical Center in Israel. The results from this trial demonstrated that PRX-106 is safe and well tolerated, and showed biological activity in the gut and inducement of regulatory T cells.

"Taken together, the data from the pre-clinical and clinical studies suggest the orally administered PRX-106 is safe and can exert a profound anti-inflammatory effect in liver disorders," commented Prof. Yaron Ilan, Chairman of Medicine at the Hadassah-Hebrew University Medical Center in Jerusalem, and former President of the Israel Liver Association. "The data support the notion that PRX-106 can serve as a potent immune modulatory agent that can alleviate inflammation of the liver in a safe manner that will not suppress of the immune system, which is currently one of the main concern in other products candidate currently in development."

Fatty liver disease affects 30% of the Western world population. The disease can deteriorate to its severe form, nonalcoholic steatohepatitis or NASH, which affects 2-8% of the population. NASH resembles alcoholic liver disease, but occurs in people who drink little or no alcohol. The major feature in NASH is fat in the liver, along with inflammation and damage. NASH can be severe and can lead to cirrhosis, in which the liver is permanently damaged and scarred and no longer able to work properly. It can also deteriorate into primary liver cancer. NASH is becoming more common because of the greater number of people with obesity. In the past 10 years, the rate of obesity has doubled in adults and tripled in children, and is considered by many as the next global epidemic. Obesity also contributes to diabetes and high blood cholesterol, which can further complicate the health of someone with NASH.

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, subsequently by Israel's Ministry of Health, by the Brazilian National Health Surveillance Agency (ANVISA) 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 and 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 TNF; 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: unforeseen safety issues; determination of dosing issues; lack of effectiveness during clinical trials; slower than expected rates of patient recruitment; 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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