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PHARMALINK ANNOUNCES POSITIVE RESULT IN PHASE 2b TRIAL OF NEFECON®

IgA Nephropathy Primary Endpoint Met at a Planned Interim Analysis

NEFIGAN Trial Hits Efficacy Target Based on Highly Statistically Significant Reduction of Proteinuria

Stockholm, Sweden – 14 April 2015. Pharmalink AB, a specialty pharma company, today announces that the NEFIGAN Trial of Nefecon® for the treatment of primary IgA nephropathy has fully met its primary efficacy endpoint at a planned interim analysis and been stopped early with respect to statistical analysis of the endpoint.

The NEFIGAN Trial is a Phase 2b randomized double-blinded, placebo-controlled clinical trial assessing the safety and efficacy of two different doses of Nefecon – a new oral modified-release capsule of the corticosteroid, budesonide – administered daily over a nine-month treatment period to primary IgA nephropathy patients with persistent proteinuria despite optimized standard-of-care therapy. The trial has been conducted in 62 centers in 10 European countries and was originally intended to recruit 90 patients. Over-recruitment has increased this to more than 150 patients.

“Meeting the primary endpoint of the NEFIGAN Trial with such high significance and at this interim analysis is a tremendous result and major milestone for Pharmalink,” said Johan Häggblad, Ph.D., Managing Director of Pharmalink. “The NEFIGAN Trial was conducted with excellent efficiency, and the fact that the patient recruitment target was also exceeded so rapidly indicates the clear unmet medical need for new treatments for IgA nephropathy patients. We would like to thank all the investigators and patients who contributed to this clinical trial and look forward to the further development of Nefecon.”

Bengt Fellström, MD, PhD, Professor of Nephrology at Uppsala University Hospital, Sweden and Principal Investigator of the NEFIGAN Trial, added: “IgA nephropathy is the most common inflammatory renal disease and in real need of new treatment options. Existing options are insufficient to prevent a significant proportion of patients progressing to renal failure, with a devastating impact of patients’ quality of life. No current therapies address the root cause of the disease which makes the results from the NEFIGAN Trial all the more encouraging. A new medicine for early treatment with the potential to stop disease progression and minimize any further loss of renal function would be very welcome news indeed to patients and clinicians alike.”

The interim analysis, conducted by the Data & Safety Monitoring Board (DSMB), demonstrated that Nefecon treatment (both treatment groups combined) resulted in a highly significant improvement [p=0.0066 on an intention-to-treat (ITT) basis] in the primary endpoint, defined as the mean reduction in urine protein creatinine ratio (UPCR) during the nine-month treatment period, as compared to placebo. The result will enable an optimal dose of Nefecon to be selected for a Phase 3 registration trial.

Enrolled patients will conclude the treatment phase by the end of April and complete the three-month follow-up phase of the study, with results expected in Q3 2015. Results from the study will be presented at upcoming scientific meetings and submitted for publication in a peer-reviewed journal.

About IgA Nephropathy

IgA nephropathy (IgAN) is the most common form of glomerulonephritis (inflammation of the kidney glomeruli). The disease is characterized by deposits, predominantly containing polymeric IgA antibody, in the kidney that cause inflammation and renal damage.

IgAN can occur at any age, but the clinical onset is commonly during the second or third decades of life. It has been estimated that 20-40% of patients with IgAN progress to renal failure, often referred to as end-stage renal disease within 5-30 years following diagnosis. This patient population is estimated to at least 200,000 in major markets.

Patients suffering renal failure require dialysis or kidney transplantation. IgAN accounts for 10% of renal transplants among patients with primary glomerulonephritis in the US and between 7-20% of patients in Europe and Australia in long-term dialysis and renal transplantation programs.

About Nefecon®

Nefecon is a potential disease-modifying treatment for patients with primary IgA nephropathy (IgAN) at risk of developing end-stage renal disease (ESRD). Nefecon has shown positive results in an open-labelled Phase 2a trial evaluating safety and efficacy and met its primary efficacy endpoint in a placebo-controlled randomized Phase 2b study (www.nefigan.net/). The study recruited ahead of target and schedule and was designed to enable an optimal dose of Nefecon to be selected for a Phase 3 registration trial. Full data of the Phase 2b NEFIGAN Trial is anticipated in Q3 2015.

Nefecon is an oral formulation of a locally-acting and potent corticosteroid, budesonide, that down-regulates the disease process in the kidney through suppression of the gastrointestinal immune system thus exploiting the pivotal role the gastrointestinal tract plays in the overall immune response. Early treatment with Nefecon of IgAN patients at risk of developing ESRD may slow or halt disease progression and further loss of renal function, and provide an alternative to dialysis and transplantation. Nefecon has received orphan drug designation by the US Food and Drug Administration (FDA).

About the NEFIGAN Trial

The NEFIGAN Trial is a Phase 2b multi-center, randomized, double-blind, placebo-controlled study conducted at 62 centers in ten European countries. The objective of the study is to evaluate efficacy and safety of two different doses of Nefecon in the treatment of IgAN patients at risk of developing ESRD, under standardized rigorous blood pressure control with an angiotensin-converting enzyme inhibitor (ACEI) and/or angiotensin II receptor I blocker (ARB).

Read more at http://clinicaltrials.gov/ct2/show/NCT01738035

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About Pharmalink

Pharmalink is a specialty pharma company developing high value products for patients with significant unmet medical needs. With a highly experienced, dynamic management team, Pharmalink draws on its extensive experience of pharmaceutical development and marketing to efficiently identify and progress valuable and de-risked products. The Company has two late-stage clinical phase products under development, Nefecon® and Busulipo™. Pharmalink is actively seeking assets to acquire or in-license to develop new product opportunities for underserved patient groups. A recent example being an osteoarthritis asset acquired from Synartro AB.

Visit www.pharmalink.se for further information.

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