Pharmalink

PHARMALINK ANNOUNCES AN OPEN INVESTIGATIONAL NEW DRUG (IND) APPLICATION FOR NEFECON®

Stockholm, Sweden – 21 January 2015. Pharmalink AB, a specialty pharma company focused on orphan and niche products, announces that its IND for Nefecon® is now open with the US Food & Drug Administration (FDA).

Nefecon is a new oral modified-release capsule of the corticosteroid, budesonide, in clinical development by Pharmalink for the treatment of patients with IgA nephropathy (IgAN) at risk of developing end-stage renal disease (ESRD), despite optimized RAS blockade.

The safety and efficacy of Nefecon is currently under evaluation in a prospective, randomized, double-blinded, placebo-controlled Phase 2b study (NEFIGAN Trial, www.nefigan.net) in 150 patients being conducted at more than 60 centers in ten European countries. Headline results of the NEFIGAN Trial are expected during Q3 2015. Nefecon has Orphan Drug Designation.

Heather Cook, Regulatory Affairs Director of Pharmalink, said: "The opening of the IND for Nefecon in the US is an important step in the development of this potential new therapy for IgAN patients. Recent data presented at American Society of Nephrology's Kidney Week last November confirmed that these patients remain at risk of progression to ESRD despite optimized RAS inhibition, highlighting the need for new treatment options. Should the NEFIGAN Trial produce positive results later this year, reinforcing our earlier Phase 2a study findings, then we are confident in the potential of Nefecon to become a valuable new treatment for IgAN patients."

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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 is now being tested in a placebo-controlled randomized Phase 2b study (www.nefigan.net/). The study has been designed to enable an optimal dose of Nefecon to be selected for a Phase 3 registration trial. Headline data 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 multicenter, randomized, double-blind, placebo-controlled study conducted at more than 60 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

About Pharmalink

Pharmalink is a specialty pharma company developing high value products for niche and orphan indications. Pharmalink draws on its extensive experience of pharmaceutical development and marketing to identify and progress products that address significant unmet medical needs. With a successful history in pharmaceutical sales and marketing, and highly experienced, dynamic management team, Pharmalink is focused on the development and commercialization of valuable, de-risked projects. It has two late-stage clinical phase products under development, Nefecon® and Busulipo™. Pharmalink is actively seeking opportunities to acquire or in-licence product opportunities in niche and hospital care indications. Visit www.pharmalink.se for further information.