PRESS RELEASE

A NEW EFFICIENT AND COST EFFECTIVE DIALYSIS FOR PATIENTS WITH END STAGE RENAL DISEASE

Rome, 18-6-2013 - Thule Therapeutics S.A., an R&D Company of the sigma-tau Group, and Corequest Sagl announce extremely valuable findings on the use of L-Carnitine in peritoneal dialysis solutions which open new opportunities in the treatment of end stage renal disease (ESRD).

The prestigious journal American Journal of Kidney Disease has recently published an article entitled "Effect of an L-Carnitine-Containing Peritoneal Dialysate on Insulin Sensitivity in Patients Treated with Continuous Ambulatory Peritoneal Dialysis: A 4-Month Prospective Multicenter Randomized Trial" that describes the results of a multicenter effort supported by the two Companies and by a research grant from Baxter and coordinated by Mario Bonomini MD, Chieti (Italy), involving over 10 Centers in Italy. The study and reports proof of concept data that validate the effective role of L-Carnitine as an “osmo-metabolic” agent in peritoneal dialysis solutions with concomitant improvement of insulin sensitivity.

Corequest Sagl and Thule Therapeutics S.A. are engaged into a cooperative effort to identify and develop new PD solutions that maintain or improve dialysis effectiveness while sparing glucose. The use of L-Carnitine, a naturally occurring compound involved in intermediary metabolism, in PD bags provides a new, effective and safe crystalloid agent for PD hypertonic solutions. In fact, on one hand, L-Carnitine allows to diminish glucose concentration in the bag while maintaining the same osmotic and ultrafiltrative properties, while, on the other, ameliorates the metabolic profile as shown by the improvement of insulin sensitivity and other biomarkers. The data reported in the article confirm this effect. The use of a very challenging patient population as that selected makes this evidence particularly strong.

ESRD affects approximately over 2,800,000 patients in the world and 76% of them receive either hemodialysis (HD) or peritoneal dialysis (PD). Dialysis patients grow by 7-8% per year (1-4% in Japan, EU or US, 11% in the ROW and in the less developed Countries) and are expected to almost double by 2020, thus creating an enormous pressure on the health system both in terms of resources and organization as well as of safe, efficacious and cost-effective treatments.

Professor Mario Bonomini, Principal Investigator of the trial and Director of the Nephrology Institute at the University “G. d’Annunzio” of Chieti (Italy), confirmed that “we are confronted with patients that experience the daily discomfort of dialysis, the long term perspective of a poor quality of life and the threat of complications. These data are of paramount importance since they pave the way in formulating new hypertonic solutions to improve clinical outcome of PD patients. Moreover, this is the first real innovation in this area over the last several years”.

“This achievement further strengthens our willingness to pursue the clinical development of hypertonic solutions containing agents able not only to spare glucose, but also to actively intervene to improve key dismetabolic issues in PD patients”, Arduino Arduini, CEO of Corequest, said. “Moreover this effort is fully aligned with the activity of Corequest and its sister Company Glomeria Therapeutics to develop and offer a wide platform of products for heart and renal medicine”.
“We are particularly pleased to see a potential use of L-Carnitine for a better treatment of severely ill patients as ESRD individuals undergoing PD, improving their ability to conduct a better life. This is another result of the long-standing know-how on L-Carnitine, on which Thule and sigma-tau have leveraged to expand L-Carnitine role and importance in dialysis” highlighted Alessandro Noseda, Board member of Thule, while Pietro Grossi, R&D Director of the sigma-tau Group pointed out that “this project is fully in line with the Company’s strategy to address high unmet medical needs in specialty areas and is an important addition to the Company’s commitment to the dialytic sector, beyond PD.”

Corequest and Thule/sigma-tau will consider collaborations with industrial partners specialized in this area to complete development and exploit the product potential.

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About Corequest Sagl
Corequest Sagl is a Swiss pharmaceutical and medical device company involved in the development of key components of therapeutic platforms for kidney and cardiac patients.

About Thule Therapeutics S.A.
Thule Therapeutics S.A. is a Swiss biotech engaged in the development of new L-Carnitine containing solutions. Thule belongs to the Italian pharmaceutical group sigma-tau.

About sigma-tau:
Founded in 1957, sigma-tau is an international, privately owned pharmaceutical company, involved in research and development, manufacturing, production, sales and marketing of pharmaceuticals and nutritional supplements. Sigma-Tau’s R&D efforts are focused on the development of integrated approaches to the therapy of cancer and other orphan (niche) indications by means of some innovative immune-oncology platforms and biotechnology systems. With total sales of 688.5 million € in 2012 the sigma-tau Group is a primary player in Europe, with a direct presence also in the USA (increased in 2010 by the acquisition of Enzon “specialty care” business) and Asia (India and China), and a consolidated network of licensees in the rest of the world.

http://www.sigma-tau.it