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Spanish Investigators finish a clinical study about the non-anticoagulant properties of Bemiparin in the peritoneum

The exploratory clinical trial has not shown that the addition of Bemiparin to a solution for peritoneal dialysis improves the function of the peritoneum, although it may be effective for a subgroup of patients with ultrafiltration failure.

Madrid – December 30, 2009 – Laboratorios Farmacéuticos Rovi S.A. (www.rovi.es) announces the results on the clinical trial “Bemidextrina” which was aimed to evaluate whether the addition of Bemiparin (a second generation low molecular weight heparin) to a solution of icodextrin for peritoneal dialysis (PD) increases the ultrafiltration capacity of the peritoneum of patients under PD who show functional disorders (deficit on ultrafiltration and/or high transportation)¹.

The “Bemidextrina” study is a Phase II clinical trial, designed as a proof of concept, in which 14 Spanish hospitals have participated and 95 patients have been enrolled (46 in Bemiparin group and 49 in control group).

After the analysis of the data, the study hypothesis has not been demonstrated, i.e. Bemiparin neither increases the ultrafiltration capacity nor decreases the creatinine transportation in patients who showed peritoneal functional disorders.

However, in a *post-hoc* analysis made in the subgroup of patients who suffered a failure on peritoneal ultrafiltration capacity (below 400 mL/4 hours), a statistically significant difference was achieved after 8 weeks in patients who received intraperitoneal Bemiparin in contrast to patients who did not.

On the other hand, the administration of Bemiparin through the bag of the PD solution of icodextrin did not raise the incidence of peritonitis in comparison with the control group, and no cases of major bleeding were observed.

Dr. Rafael Selgas, the Trial Investigator Coordinator and Chief of Nephrology Department at Universitario La Paz (Madrid), said that *“although the results have not been what we expected, we believe that a subgroup of patients with a patent deficit on ultrafiltration capacity could get a benefit from the addition of bemiparin to the PD solution of icodextrin, improving their ultrafiltration capacity without increasing the risk of important adverse events. Nevertheless, due to the exploratory nature of the study, further clinical trials are needed to confirm the results in this patient population, for who, up to now, we do not have any therapy for improving their peritoneal functional status.”*

The study “Bemidextrina” is a project sponsored by the Fundación Renal Iñigo Álvarez de Toledo, along with the collaboration of Laboratorios Farmacéuticos Rovi S.A. and Baxter S.L.

About the Peritoneal Dialysis

Peritoneal dialysis (PD) is one of the two types of dialysis that is used to treat people with kidney failure. In PD, the process of dialysis takes place inside the abdomen using the peritoneal membrane as a filter to remove excess waste and water, and employing some solutions to facilitate this purification. The exposure to the PD solutions for a period of time causes frequently a chronic inflammation and some fibrosis in the peritoneum. These changes are considered the main reason for the ultrafiltration failure.

According to the Spanish Society of Nephrology², nowadays PD is consolidated as the preferred home-based dialytic technique, and chosen by a relevant rate of patients as the first option of dialysis. PD, in any of their modalities (i.e. continuous ambulatory peritoneal dialysis -CAPD- or automated peritoneal dialysis -APD-), enhances the autonomy of the patients and their social integration, avoiding an increase of investment on health-care infrastructures.

About Bemiparin

Bemiparin (Hibor®) is a second generation low molecular weight heparin patented and developed by Laboratorios Farmacéuticos Rovi, S.A. Currently, Bemiparin is marketed under Hibor®, Ivor®, Zibor® o Badyket® brands in more than 35 countries for preventing and treating venous thromboembolic disease.

About ROVI

ROVI is a fully integrated, profitable Spanish specialty pharmaceutical company engaged in the research, development, in-licensing, manufacturing and marketing of small molecule and specialty biologic drugs. The Company has a diversified portfolio of products that it markets in Spain through its specialized sales force, calling on specialist physicians, hospitals and pharmacies. ROVI's portfolio of 23 principal marketed products is currently anchored by the internally-developed, second generation low molecular weight heparin, Bemiparin. ROVI's research and development pipeline is focused primarily on addressing currently unmet medical needs by developing new LMWH-based products and expanding applications for its existing LMWH-based products. ROVI manufactures the active biological ingredient (Bemiparin) for its principal proprietary product and product candidates and the injectable pharmaceutical products developed by its in-house research team, and utilizes its state-of-the-art filling and packaging capabilities to provide a broad array of toll manufacturing services to leading international pharmaceutical companies, primarily in the area of pre-filled syringes. Additional information about ROVI is available on the company's website: www.rovi.es

About the Fundación Renal Iñigo Álvarez de Toledo

The Fundación Real Iñigo Álvarez de Toledo is a non-profit organization focused on the clinical assistance to people with kidney diseases and on the promotion of basic and clinical research on Nephrology. Among its activities, the Foundation promotes activities aimed to achieve the innovation and the improvement of the treatments for the kidney failure. Additional information about the Foundation is available on the website: www.friat.es

¹ Selgas R, et al. Nefrología. 2008; 28 (Suppl 6):51-8.

² Spanish Society of Nephrology. Clinical practice guidelines on peritoneal dialysis. Oct. 2005. (www.senefro.org).