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Results from the phase III clinical trials for Bemiparin on diabetic foot ulcers

The final results from the Phase III clinical trials do not show that Bemiparin is effective in the treatment of diabetic foot ulcers.

Madrid – 10 May 2010 – Laboratorios Farmacéuticos Rovi S.A. (www.rovi.es) announces today that the analysis of the final results of the clinical trial of the efficacy and safety of Bemiparin in the treatment of diabetic foot ulcers does not show that Bemiparin is better treatment than a placebo.

According to the Chief Executive Officer of ROVI, Juan López-Belmonte “the results do not confirm the positive data that we obtained in an earlier trial”. Juan López-Belmonte added that “we are particularly aware of the disappointment that this may cause to diabetic patients, as there is a clear need to develop more effective treatments to prevent diabetic foot ulcers from being the leading cause of non-traumatic amputations”.

Javier Martínez, Director of Clinical Development at ROVI, said that “the results in the Bemiparin group were similar to our starting hypothesis (70% of patients with complete healing or improvement of the ulcer), but the results from the placebo group were unexpectedly better than those we estimated at the beginning of the study (50% of patients with complete healing or improvement of the ulcer); probably it is reflecting the benefits to patients of participating in the clinical trial, with better care and monitoring of their ulcers”. Javier Martínez also noted that “we are currently working with the Steering Committee of the trial to review and interpret these results, including not only the main analysis but also the planned exploratory analyses and sub-analyses of the protocol; nevertheless, the results do confirm the good safety profile of

Bemiparin, particularly in light of the fact that it was administered to a special group of diabetic patients for up to 3 months”.

Finally, the Chief Executive Officer of ROVI said that “within a few weeks, when the statistical analysis and the review of the data from the trial are complete, ROVI will determine the next steps to take in its research program for Bemiparin in diabetic foot ulcers”.

About the clinical trial for the use of Bemiparin in diabetic foot ulcers

The clinical trial is a phase III multicentric and international study designed to confirm the efficacy and safety of Bemiparin compared to a placebo in the treatment of neuropathic diabetic foot ulcers with Wagner grade I or II. Three hundred and twenty nine patients from 6 countries (Croatia, Poland, Romania, Russia, Serbia and Spain) randomly received daily subcutaneous injection of 3,500 IU of Bemiparin or a placebo, for 3 months or until the complete healing of the ulcer. All patients received the standard care of the ulcers as the base treatment. The percentage of patients in which the primary efficacy endpoint, the complete healing or improvement of the ulcer (a reduction of $\geq 50\%$ in the area of the ulcer and/or a decrease in the Wagner grade of the ulcer), was not statistically different in the Bemiparin group (66.1%) to the placebo group (65.8%). In addition, no significant differences were seen between the two groups in terms of the proportion of patients whose ulcer was completely healed (25.2% for Bemiparin and 25.6% for the placebo group). In the subpopulation of patients with deeper ulcers (Wagner grade II), a higher number of healed ulcers was recorded in the Bemiparin group (22.9%) than in the placebo group (18.8%), but the difference was not statistically significant. No significant differences were observed in the proportion of patients with at least one serious adverse event, with a very low rate of major bleeding events (1 in each group).

The results of the trial will be presented to the scientific community on 13 May 2010 at the 13th Malvern Diabetic Foot Conference (Malvern, Worcestershire, United Kingdom).

Conference Call with ROVI Investors

ROVI will hold a conference call today at 5 pm (CET) to answer questions about this press release. To participate in the conference call, please call 91.414.36.69 within

Spain and +44.1452.555.566 when calling from outside Spain. The Conference ID number is 74132844.

About ROVI

ROVI is a fully integrated 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 27 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 products and for 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