

ROVI provides an update on its research strategy for diabetic foot ulcers

ROVI has decided to suspend the development of Nautiol® for the treatment of diabetic foot ulcers, and to refocus this research line on the development of glycosaminoglycan compounds for topical application.

Madrid –14 December 2010 – Laboratorios Farmacéuticos Rovi, S.A. (www.rovi.es) states that after a careful evaluation of the results of the clinical trial on the effectiveness and safety of subcutaneous Bemiparin in the treatment of diabetic foot ulcers, it has decided not to continue with the clinical development of Nautiol®. In addition, ROVI announces that this research line has been refocused onto the development of various compounds (including Bemiparin) for the topical treatment of a range of different types of torpid ulcers, including both skin ulcers and corneal ulcers.

On 10 May, the company informed the market that the results of the Phase III clinical trial of Bemiparin for patients with diabetic foot ulcers did not confirm the positive results that had previously been obtained in another clinical trial, as the placebo group had unexpectedly performed much better than had been forecast when the trial was designed. Although the group of patients with deeper ulcers (Wagner grade II) had a higher incidence of healing (not statistically significant) when treated with Bemiparin (22.9%) than the placebo group (18.8%), the percentage of patients who attained the primary efficacy endpoint, complete healing or improvement of the ulcer (reduction \geq 50% of the ulcer area and/or a decline of one Wagner grade), was not different between the two groups (66.1% and 65.8%, for the Bemiparin and placebo group respectively).

However, although these results were not positive, ROVI remains committed to the development of glycosaminoglycan derivatives and formulations for the topical treatment of torpid ulcers, both skin ulcers and corneal ulcers. This type of ulcers can

be associated with systemic problems, above all diabetes, but also autoimmune diseases such as rheumatoid arthritis, lupus, Behçet's syndrome or sarcoidosis. In addition, it is estimated that between 5 and 30% of the population suffers from dry eye syndrome, which in serious cases can result in corneal ulcers. ROVI has already begun the animal testing phase with some of these glycosaminoglycan candidates, using the topic route of administration as it is considered that this route can present more advantages than the subcutaneous one, especially in terms of the acceptance and adherence to the treatment by the patient. ROVI expects to start the clinical phase in the first quarter of 2012.

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 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 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. For more information, visit https://www.rovi.es