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OCAP[®] technology does not result in the gastrointestinal absorption of Bemiparin when administered orally

ROVI decides to discontinue the development of oral Bemiparin based on the OCAP[®] (*Oral Carbohydrate And Protein*) release system for drugs, and to concentrate its efforts on the ISM[®] platform (*In Situ Microparticles*).

Madrid – 14 January 2011 – Laboratorios Farmacéuticos Rovi, S.A. (www.rovi.es) announces the results of the Phase I trial of oral Bemiparin in which healthy volunteers were treated with six oral formulations of Bemiparin using *Oral Carbohydrate And Protein* (OCAP[®]) technology.

The levels of anticoagulant (anti-factor Xa) of the various formulations and doses of sodic Bemiparin administered orally were below the detection limit (0.1 IU/mL) or slightly above it, and hence it was concluded that there had not been sufficient gastrointestinal absorption. Nevertheless, the formulations were tolerated well by the volunteers, with maximum doses of up to 50,000-80,000 IU of Bemiparin.

The clinical trial consisted of a parallel open-label test of increasing single doses in a course of two doses separated by 24 hours and administered orally, and the administration of a single prophylactic dose of Bemiparin administered subcutaneously, on a total of 102 healthy volunteers of both sexes. The main aim of the trial was to assess the anti-factor Xa activity profile of Bemiparin when administered orally in six different formulations (pills and capsules).

In addition, the secondary aims of the trial included the gaining of an understanding of the safety and tolerability of these formulations of Bemiparin, and also the comparison of the bioavailability obtained from the doses administered orally with the information

from the subcutaneous administration of Bemiparin in prophylactic doses for venous thromboembolism (2,500 IU).

OCAP[®] technology is based on the incorporation of active substances, with low levels of bioavailability when administered orally, into polymeric vehicles that enable their systemic absorption in the intestinal lumen. OCAP[®] formulations that are administered orally enable the active substance to be protected from the luminal environment, and provide a vehicle for it to reach the area where absorption takes place. Preclinical results on various animal models (rabbits, dogs and monkeys) were positive and led to approval for this first test on humans.

In light of these Phase I results of oral Bemiparin, ROVI has decided to discontinue the development of OCAP[®] technology for the oral administration of Bemiparin, and to concentrate its efforts and resources on the ISM[®] drug delivery platform. As ROVI recently announced, in September this year it began the experimental stage of the first Phase I trial on healthy volunteers of the anti-psychotic drug Risperidone-ISM[®]. This clinical trial will also serve as a proof of concept for validating ISM[®] technology as a base platform for other developments, some of which are already in advanced pre-clinical phases.

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 <http://www.rovi.es>