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ROVI obtains FDA approval of its injectables plant

- **The FDA has approved ROVI's injectables plant for filling syringes that are prefilled with Water for Injection.**
- **The syringes, prefilled with Water for Injection by ROVI at its contract manufacturing plant, will be able to be commercialized in the United States in the coming months.**

Madrid – 18 September 2012 – Laboratorios Farmacéuticos Rovi (ROVI) announces that as of today the Food and Drug Administration in the United States has approved the company's contract manufacturing injectables plant in Madrid, for filling syringes that are prefilled with Water for Injection using the terminal sterilization process. Syringes prefilled with Water for Injection by ROVI at its contract manufacturing plant will be able to be commercialized in the United States in the coming months.

"FDA approval represents a significant milestone in our manufacturing capacity and an excellent opportunity to penetrate the US market and maximize the plant's potential. In addition, it reflects our continuous interest in serving the globalized pharmaceutical market," said Juan López-Belmonte Encina, the Chief Executive Officer of ROVI.

With more than fifteen years of experience, ROVI specializes in filling and packaging parenteral solutions in prefilled syringes and vials. ROVI is currently one of the world's leading manufacturers of prefilled syringes, with annual production capacity of 180 million prefilled syringes.

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 30 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 the expansion of applications, indications and alternative mechanisms of action for the heparin-derived products and other glycosaminoglycans and on the development of new controlled release mechanisms based on ISM™ technology, with the aim of obtaining new pharmaceutical products that enable the regular administration of formulations which are administered daily in chronic and prolonged treatments. 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. In addition, ROVI provides contract manufacturing and packaging services of solid oral pharmaceutical dosage forms, using the most enhanced technology, Roller Compaction. Additional information about ROVI is available on the company's website: www.rovi.es