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ROVI announces positive results from the Phase I trial for the monthly injectable formulation of Risperidone-ISM

The result of this proof of concept validates ISM technology for the once-monthly administration of a recognised antipsychotic

Madrid – 11 July 2011 – Laboratorios Farmacéuticos Rovi S.A. (www.rovi.es) discloses today the positive results obtained from a Phase I clinical trial for the once-monthly injectable formulation of Risperidone-ISM. The trial has been developed with a long-acting formulation of this antipsychotic and the analysis of the data shows that ISM technology enables the sustained delivery of Risperidone from the first day, which will allow for once-monthly administration without the need for supplementary oral Risperidone in the first weeks. These characteristics will facilitate the adherence with treatment of schizophrenic patients, and represent an improvement on the Risperidone formulations that are currently available.

The clinical trial was carried out on 17 healthy volunteers and was designed to evaluate the pharmacokinetics, safety and tolerability of the intramuscular administration of Risperidone in escalating single doses (25 mg and 37.5 mg) using the ISM drug delivery system. The plasma concentrations of Risperidone and its active metabolite that were obtained up to 59 days confirm the expected pharmacokinetic profile, which had previously been demonstrated in studies carried out with animals. In general, Risperidone-ISM was well tolerated by the volunteers, and the adverse reactions that were recorded were expected and understood for this antipsychotic.

The full results will be presented on 30 September 2011 in Berlin, in an oral communication at the 3rd European Conference on Schizophrenia Research¹.

"We are very excited by the results of this trial, which provides us with the proof of concept that we needed to validate our ISM prolonged release platform," said Javier Martínez, Director of Clinical Development at ROVI. *"This gives us the confidence and security to continue, not only with our development of Risperidone ISM, but also with the development of other candidates with which we are already in an advanced pre-clinical phase".*

About schizophrenia

Schizophrenia is a chronic, serious and disabling mental disorder, that affects about 1% of the population. Schizophrenic patients are characterised by a mixture of symptoms, both positive (delusions, hallucinations, disordered speech and behaviour) and negative (blunted affect, poverty of speech, aboulia, etc.). The disease usually begins at a critical age for personal development, and can often result in the patient giving up education or work, with great suffering for the person and their family, and a major loss to society as a whole. It is estimated that 3% to 5% of healthcare spending goes towards schizophrenia.

About ISM technology

ISM is a technology platform for the prolonged release of drugs that has been patented by ROVI, and is based on the *in situ* formation of biodegradable matrices following the administration of a liquid carrier. The product is presented in a Kit of two syringes, one of which contains the polymer and the active ingredient in solid state, and the second which contains the solvent needed for reconstitution, which is carried out unseasonably. The ISM technology design leads to a major improvement in the stability of the composition and allows for controlled and reproducible release profiles after subcutaneous or intramuscular administration.

¹ 3rd European Conference on Schizophrenia Research. Berlin (Germany) 29 Sept.-1 Oct. 2011.
<http://www.schizophrenianet.eu/>

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.