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# ROVI announces new positive results for the monthly injectable formulation of Risperidone-ISM

## The company plannes to initiate phase III program in 2015

**Madrid – 16 December 2014** – Laboratorios Farmacéuticos Rovi S.A. (www.rovi.es) informed of the positive results from the clinical trial PRISMA-1, performed with a long acting formulation of risperidone in schizophrenic patients. PRISMA-1 is an open label, randomized, parallel study, to evaluate the pharmacokinetics, safety and tolerability of one intramuscular injection of Risperidone ISM® at three different concentrations (50 mg, 75 mg y 100 mg) in 36 patients with schizophrenia or schizoaffective disorder[1].

As announced previously, the ISM® technology was validated by the development of a first Phase I study as "proof of concept" in healthy volunteers[2]. Along the same line, the results of PRISMA-1 pharmacokinetic study confirm that ISM® technology provides sustained delivery of risperidone, reaching therapeutic levels from day one and enabling administration once-monthly without the need for supplementary oral risperidone during the first weeks or initial dose injections. Likewise, Risperidone ISM® was, in general terms, well tolerated and the adverse reactions registered were the expected ones of this antipsychotic. Therefore, the pharmacologic profile of Risperidone ISM® would not only facilitate adherence with treatment for schizophrenic patients, but also could be proposed as a correct medication to treat acute exacerbations of the disorder.

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[1] *Pharmacokinetic, Safety, and Tolerability Study of Risperidone ISM® at Different Dose Strengths (PRISMA-1). [http://www.clinicaltrials.gov/show/NCT01788774].*

[2] *Farré M. et al. A clinical trial to evaluate the pharmacokinetics, safety and tolerability of single doses of risperidone with the novel long-acting injectable technology ISM® in healthy volunteers. Eur Arch Psychiatry Clin Neurosci 2011; 261 (Suppl 1): S57.*

Furthermore, it has already been completed patients recruitment of phase II of "PRISMA-2"[3] study, in several centres of the U.S.A. to evaluate safety and pharmacokinetic profile of Risperidone ISM® after the administration of four intramuscular doses (gluteal or deltoid injection) of 75 mg monthly in schizophrenic patients. Both PRISMA-1 and PRISMA-2 studies are expected to provide reliable information to adjust the design of phase III program, expected to start in 2015.

Juan López-Belmonte Encina, Chief Executive Officer of ROVI, said that "*these results confirm our expectations in Risperidone ISM and strengthen our confidence to continue with the development of other candidates for our ISM® technological platform for extended released systems"*.

**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.

[3] *Pharmacokinetics and Tolerability Study of Risperidone ISM® in Schizophrenia (PRISMA-2). [http://clinicaltrials.gov/show/NCT02086786].*

## 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