



## **TO THE NATIONAL SECURITIES MARKET COMMISSION**

Madrid, 21 October, 2021

### OTHER RELEVANT INFORMATION

Complying with the information duties set out in article 227 of the Revised Text of the Securities Market Act, Laboratorios Farmacéuticos ROVI, S.A. (ROVI) issues and publishes the press release attached hereto concerning the delay in the decision on Risperidone ISM® by the U.S. Food and Drug Administration ("FDA"). This press release will be distributed today and may be accessed through the Company's website.

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## **The FDA delays its decision on Risperidone ISM®**

**Madrid – 21 October, 2021** – Laboratorios Farmacéuticos Rovi, S.A. (“ROVI” or the “Company”) ([www.rovi.es](http://www.rovi.es)) has been informed of the delay in the decision on the granting of marketing authorisation for Risperidone ISM® by the U.S. Food and Drug Administration (“FDA”). The FDA will be taking a number of actions, including an in-situ inspection of the European production plant where the product is manufactured, located in Madrid (Spain). The grant of the marketing authorisation for Risperidone ISM® by the FDA is subject to the result of this inspection.

The delay in the inspection of the manufacturing facilities has been caused by the restrictions on movement due to COVID-19 and, thus, the FDA has not yet fixed the inspection date.

ROVI filed the application for marketing authorisation for Risperidone ISM® with the FDA on 24 November, 2020. On 24 September, 2021, ROVI received a Complete Response Letter from the FDA with outstanding questions on the Risperidone ISM® dossier. The Company has either answered them or will be answering them in the near future since, in its letter, the FDA recognises that it did not review some of the responses submitted during the evaluation process. ROVI expects its responses to clarify the outstanding questions.

In the Complete Response Letter, the FDA states that, due to the exceptional situation caused by the pandemic which has prevented the inspection from taking place within

the term defined in the Filing Communication Letter, all the responses to outstanding questions will be evaluated in accordance with the timeline described in the “*2020 Guidance for Industry Review Timelines for Applicant Responses to Complete Response Letters When a Facility Assessment Is Needed During the COVID-19 Public Health Emergency*”, with an estimated review time of 6 months as of the submission of the responses to the questions raised in the Complete Response Letter.

Risperidone ISM<sup>®</sup> is a novel, once-monthly, injectable antipsychotic, currently in the research phase, for the treatment of schizophrenia, developed and patented by ROVI. As of the first injection, it provides immediate and sustained plasma drug levels of the medicine, without the need for loading doses or supplementation with oral risperidone.

### **About ISM<sup>®</sup> technology**

ISM<sup>®</sup> is a technological drug release platform patented by ROVI, based on the formation in situ of biodegradable matrices after administration of a carrier liquid. Its unique characteristics allow therapeutic levels of the medicine to be obtained swiftly after administration, without the need for oral or supplementary doses or additional loading injections to reach and maintain the levels in a predictable manner that is sustained over time, representing a higher probability of meeting the patient’s clinical needs.

### **About ROVI**

ROVI is a pan-European pharmaceutical company specialising and engaging in the research, development, contract manufacturing and marketing of small molecules and biological specialties. The Company, in a continuous international expansion process, has subsidiaries in Portugal, Germany, the United Kingdom, Italy, France and Poland and has a diversified marketing portfolio of more than 40 products, among which its flagship product, Bemiparin, already marketed in 58 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its enoxaparin biosimilar, developed in-house, in Europe. ROVI continues to develop the ISM<sup>®</sup> Platform technology, a leading-edge line of research in the field of prolonged drug release with proven advantages. For more information, please visit [www.rovi.es](http://www.rovi.es).

### **Forward-looking statements**

This news release contains forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial performance or achievements of ROVI, or its industrial results, to be materially different to the future results, financial performance or achievements expressed or implied in such forward-looking statements. The statements in this press release represent ROVI's expectations and beliefs as of the date of this press release. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this press release.