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ROVI announces the commencement of the assessment process to obtain marketing authorisation for Doria® in the European Union

Madrid – January 31, 2020 – Laboratorios Farmacéuticos Rovi, S.A. ("ROVI") has today announced that, after the conclusion of the validation phase, the European health authorities have commenced the assessment process to grant marketing authorisation for Doria®, a long-acting anti-psychotic injection for the treatment of schizophrenia, based on the ISM® technology patented by ROVI, in the European Union (EU).

ROVI filed its application for marketing authorisation for Doria® with the European health authorities, the European Medicines Agency (EMA), through the Centralised Procedure on 27 December, 2019. After passing the validation phase satisfactorily, the dossier was admitted for evaluation on 30 January, 2020.

It is forecast that the assessment phase of the Centralised Procedure used by the Company to register this medicine in the EU may take around one year. It should, however, be noted that the assessment process is subject to interruptions and delays in the event that the European health authorities require additional information. Likewise, mention should be made of the fact that the outcome of the registration process (which may be positive or negative) cannot be known until it has concluded.

ROVI will continue to provide information on the milestones deemed significant in this authorisation as the calendar for registration of the medicine in the European Union advances, as well as the registration of the same medicine with the U.S. Food and

Drug Administration (FDA), which it is planned to commence in the second half of 2020.

“We are continuing to progress with the approval phase of Doria® and are now closer to marketing it. We have confidence in the product’s potential and hope that we will soon be able to offer a therapeutic alternative for the treatment of this chronic, serious and progressive disorder”, said Juan López-Belmonte, ROVI’s Chief Executive Officer.

About Schizophrenia

Schizophrenia is a chronic, serious, and disabling mental disorder that affects about 1% of the population. Schizophrenia patients are characterized by a mixture of psychiatric symptoms, both positive (delusional ideas, hallucinations, disorganized language and behaviour) as negative (affective flattening, speech poverty, abulia) in nature. The disease usually starts at a critical age for personal development, forcing patients in many cases to leave their educational or work activity, resulting in a great deal of suffering for the subjects and their family environment as well as representing an important loss for society at large. It is estimated that approximately 3% to 5% of total health expenditure is devoted to schizophrenia.

About the ISM® Technology

ISM® is a Technology Platform for the release of drugs patented by ROVI, which is based on the *in situ* formation of biodegradable matrices after the administration of a liquid carrier. Its unique characteristics allow to quickly obtain therapeutic levels of the medicine after its administration, without the need to for oral coadministration or additional booster or loading injections to achieve and maintain the levels in a predictable and sustained way, which has a greater likelihood of satisfying the patient's clinical needs.

About ROVI

ROVI is a pan-European pharmaceutical company specializing 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, which is already marketed in 56 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its in-house developed enoxaparin biosimilar in Europe. ROVI continues to develop the ISM® 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.

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 condition, performance, or achievements of ROVI or industry results, to be materially different from any future results, performance, or achievements expressed or implied by 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.