TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 17 December, 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) reports that the Committee for Medical Products for Human Use (CHMP) has issued a positive opinion on Okedi® (Risperidone ISM®), a medicine developed and patented by ROVI, for the treatment for schizophrenia.

On the basis of the CHMP's recommendation, the European Commission will issue its decision on the approval of Risperidone ISM®, which is expected in approximately 60 days' time. If approved, it could be launched in Europe in the second quarter of 2022.

The press release in relation to the foregoing is attached hereto and will be distributed today. It may be accessed on the Company's website.

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ROVI receives the positive opinion of the CHMP on Okedi® as a treatment for schizophrenia

Madrid – 17 December, 2021 – Today, Laboratorios Farmacéuticos Rovi, S.A. ("ROVI" or the "Company") has announced that the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency has recommended the approval of Okedi® (Risperidone ISM®) for the treatment of schizophrenia.

Risperidone ISM® is a prolonged-release injectable antipsychotic developed and patented by ROVI for the treatment of schizophrenia in adults for whom the tolerability and effectiveness has been established with oral risperidone, since, as of the first injection, it provides immediate and sustained plasmatic drug levels and does not require loading doses or supplementation with oral risperidone.

The positive opinion of the CHMP is based on the positive results of the pivotal PRISMA-3 study on the efficacy and safety of Risperidone ISM® in schizophrenia patients[1]. The results obtained in this study show that the two different doses (75 mg and 100 mg once a month) have achieved the prespecified primary and secondary efficacy endpoints for treatment of patients with acute exacerbation of schizophrenia. The primary efficacy endpoint, the PANSS total score (mean difference, CI: 95%), improved significantly with Risperidone ISM® 75 mg and 100 mg from the beginning until day 85, with adjusted differences of -13.0 (17.3 to -8-8; p <0.0001) and -13.3 (-17.6 to -8.9; p<0.0001), respectively. Significantly improved mean changes for the secondary endpoint, the CGI-S score, were also obtained for Risperidone ISM® in comparison with the placebo, -0.7 (-1.0 to -0.5; p<0.0001), for both doses. The significant statistical improvement for both efficacy results was observed as early as 8

[1] Correll, C.U., Litman, R.E., Filts, Y. et al. Efficacy and safety of once-monthly Risperidone ISM® in schizophrenic patients with an acute exacerbation. npj Schizophr 6, 37 (2020). https://doi.org/10.1038/s41537-020-00127-y

days after the first injection. The most frequently reported treatment-emergent adverse events were increased blood prolactin (7.8%), headaches (7.3%), hyperprolactinemia (5%) and weight increase (4.8%). No important new or unexpected safety information was reported. Likewise, patients who successfully completed the double-blind period were offered the opportunity to continue in a long-term, open-label 12-month extension phase with once-monthly injections of Risperidone ISM® (75 mg or 100 mg). New, clinically stable patients ("de novo" patients) were also able to enter this open phase of the study. The objective of the study extension phase is to check the safety, tolerability and durability of the long-term effect of Risperidone ISM®[2].

"*We are very satisfied to receive the favourable recommendation for Risperidone ISM® announced by the CHMP because we believe that our product can contribute to the clinical management of schizophrenia patients"*, commented Juan López-Belmonte Encina, ROVI's Chairman and Chief Executive Officer.

The European Commission takes the recommendations of the CHMP (EMA) into consideration and usually follows them, issuing its final decision on the basis thereof. The approval of Risperidone ISM® is expected in approximately 60 days' time and it could be launched in Europe in the second quarter of 2022.

Regarding other territories, ROVI filed the application for marketing authorisation of Risperidone ISM® with the United State Health authorities, the U.S. Food and Drug Administration ("FDA") on 24 November, 2020 and the dossier is currently being reviewed by the FDA. Recently, the FDA informed ROVI of a delay in making a decision on the grant of said marketing authorisation.

About schizophrenia

Schizophrenia is a chronic, serious, and disabling mental disorder that affects about 1% of the global population. Schizophrenia patients are characterized by a mixture of symptoms, both positive (delusional ideas, hallucinations, disorganized language and behaviour) and negative (affective flattening, speech poverty, abulia) in nature. The disease usually starts at a critical age for personal development, forcing patients in

[2] Filts Y, Litman RE, Martínez J, Anta L, Naber D, Correll CU. Long-term efficacy and safety of once-monthly Risperidone ISM® in the treatment of schizophrenia: Results from a 12-month open-label extension study. Schizophr Res. 2021 Nov 27;239:83-91.

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 global 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 for oral co-administration or additional boosters or loading injections to achieve and maintain the levels in a predictable and sustained manner, thus having 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 its industrial 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.