TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 2 April, 2024

OTHER RELEVANT INFORMATION

Complying with the information duties set out in article 227 of Law 6/2923 of 17 March on the Securities Markets and Investment Services, further to the relevant information published on 28 July 2023 with register number 23963, Laboratorios Farmacéuticos ROVI, S.A. (ROVI) reports that the U.S. Food and Drug Administration (FDA) has authorised the marketing of Risvan® (Risperidone ISM®) for the treatment of schizophrenia in adults.

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 FDA's approval of Risvan® as a treatment for schizophrenia

Madrid – 2 April, 2024 – Today, Laboratorios Farmacéuticos Rovi, S.A. ("ROVI" or the "Company") has announced that the U.S. Food and Drug Administration (FDA) has authorised the marketing of Risvan® (Risperidone ISM®) for the treatment of schizophrenia in adults.

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

This approval 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 moderate to severe symptoms of schizophrenia. The primary efficacy endpoint, the PANSS[2] 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, in comparison with the placebo. Significantly

[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

[2] Positive and Negative Syndrome Scale: the Positive and Negative Syndrome Scale is a medical scale based on a semi-structured interview that rates the severity of the symptoms of schizophrenia patients in three domains: positive symptoms, negative symptoms and general psychopathology symptoms.

improved mean changes for the secondary endpoint, the CGI-S[3] 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, from the beginning until day 85. The significant statistical improvement for both efficacy results was observed as early as 8 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 every four weeks 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. Long-term treatment was observed to be effective, safe and well tolerated in adult patients with schizophrenia, regardless the initial severity of the disease or whether they had been treated previously with Risperidone ISM® during an acute exacerbation or switched from stable doses of oral risperidone[4]. Likewise, Risperidone ISM® provided a swift and sustained improvement in functioning (both social and personal) and health-related quality of life. These findings, together with a quick onset of effectiveness, could help strengthen the therapeutic alliance and possibly lead to an earlier hospital discharge. Furthermore, the patient's functioning either continued to improve or remained stable with long-term treatment[5].

"*We are very excited about the FDA's approval of Risvan® because we think our medicine will be able to contribute to the clinical management of schizophrenia patients, helping to improve treatment adherence"*, commented Juan López-Belmonte Encina, ROVI's Chairman and Chief Executive Officer.

[3] *Clinical Global Impression-Severity* scale: la escala de Impresión Clínica Global–Gravedad rates the severity of schizophrenia through a question put to the doctor: "Considering your total clinical experience with this particular population, how mentally ill is the patient at this time?".

[4] 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.

[5] *Litman R, Naber D, Anta L, Martínez J, Filts Y, Correll CU. Personal and Social Functioning and Health-Related Quality of Life in Patients with Schizophrenia Treated with the Long-Acting Injectable Antipsychotic Risperidone ISM. Neuropsychiatr Dis Treat. 2023 Jan 25;19:219-232.*

About schizophrenia

Schizophrenia is a chronic, serious and disabling mental disorder that affects around 1% of the world population. Schizophrenia patients are characterised 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 an age that is critical for personal development, often forcing patients to leave their educational or work activity and resulting in a great deal of suffering for the patients and their family environment, as well as an important loss for society. It is estimated that between 3% and 5% of total global healthcare expenditure is spent on 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 therapeutic levels of the medicine to be obtained quickly after its administration, without the need for oral co-administration, additional boosters or loading injections to achieve and maintain the levels in a predictable and sustained manner, thus having a greater likelihood of meeting 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, already present in more than 60 countries all over the world, should be highlighted. Likewise, in 2017, ROVI commenced the marketing of its Enoxaparin biosimilar, developed in-house, in Europe and it is already marketed in 40 countries. 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 ww.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 hereof. 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.