ROVI Press Release

ROVI MOVES FORWARD IN THE APPROVAL OF ITS DRUG RISPERIDONE ISM® FOR SCHIZOPHRENIA

- The Committee for Medical Products for Human Use of the European Medicines Agency has issued a positive opinion in which it recommends approval of the prolonged-release injectable antipsychotic developed and patented by ROVI
- The approval of this new drug is expected in approximately 60 days' time and it could be launched in Europe in the second quarter of 2022
- The medicine will increase the diversified portfolio of more than 40 products currently marketed by ROVI
- In Spain, there are around 600,000 people with schizophrenia or associated disorders. Schizophrenia is a chronic, serious and disabling mental disorder that affects about 1% of the world population

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Laboratorios Farmacéuticos Rovi, a pan-European pharmaceutical company specializing and engaging in the research, development, contract manufacturing and marketing of pharmaceutical products, has announced that the Committee for Medical Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion recommending approval of ROVI's product Risperidone ISM® -commercially known as Okedi®- for adult patients with schizophrenia.

This medicine is a monthly 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. *"We are very excited and satisfied at receiving the favourable recommendation of 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 positive opinion of the CHMP is based on the positive results of the PRISMA-3 study on the efficacy and safety of the treatment. The results obtained in this study show that the prespecified primary and secondary efficacy endpoints were achieved with two different doses (75mg and 100 mg monthly) for the treatment of patients with acute exacerbation of schizophrenia. The primary efficacy endpoint improved significantly with the treatment from the beginning until Day 85. Significantly improved mean changes for the secondary endpoint were also obtained with the two doses. The significant statistical improvement for both efficacy results was observed as early as 8 days after the first injection.

The European Commission usually follows the recommendations of the CHMP (EMA), issuing its final decision on the basis thereof. The approval of this new drug 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 for Okedi® 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 this agency. The new Risperidone ISM® product will increase the diversified portfolio of more than 40 products currently marketed by ROVI.

In Spain, there are around 600,000 people with schizophrenia or associated disorders. Schizophrenia is a chronic, serious and disabling mental disorder 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 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 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 58 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.