TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 28 July, 2023

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 16 February, 2023 with register number 20446, Laboratorios Farmacéuticos ROVI, S.A. (ROVI) informs on the evaluation process to obtain marketing authorisation for Risvan® (Risperidone ISM®) in the United States and reports that the United States Food and Drug Administration (FDA) has issued a Complete Response Letter. In this letter, the FDA informs ROVI that it considers the responses to the evaluation of the Risvan® dossier to be complete and makes no additional observations.

Likewise, the letter states that ROVI must close the observations made by the FDA during its inspection in May 2023. ROVI will submit a response to reinitiate the procedure providing details of the responses that have already been filed. ROVI will then await a further notification from the FDA with the estimated User Fee Goal Date for the closure of the procedure, which is expected to be in February 2024.

Furthermore, there are no observations that have not yet been resolved by ROVI's suppliers.

Therefore, ROVI will continue to report on the milestones deemed significant in the process to obtain authorisation of Risvan® from the FDA.

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Yours faithfully,

Mr Juan López-Belmonte Encina
Chairman and Chief Executive Officer
Laboratorios Farmacéuticos ROVI, S.A.