TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 16 February, 2023

OTHER RELEVANT INFORMATION

In compliance with the disclosure duties set out in article 227 of the Revised Text of the Securities Market Act, further to the inside information disclosed to the market on 23 November, 2022 and published as inside information number 1671, 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 it has now filed the final responses to the Complete Response Letter received from the United States Food and Drug Administration (FDA) in the third quarter of 2022. These responses likewise included the answers of one of ROVI's suppliers to outstanding questions.

The FDA has notified ROVI that the user fee goal date is 27 July 2023.

Likewise, ROVI has now filed the final report on correction of the deficiencies noted when the FDA inspected its facilities in June 2022. The evaluation of these corrections, as well as the notification as to whether the FDA will need to reinspect the ROVI facilities, is expected within the period ending on the user fee goal date.

Furthermore, in January 2023, the FDA carried out a pending inspection of a ROVI supplier. As a result of the inspection, the FDA issued a series of observations to said supplier, which the latter is working to answer. The time frame for the supplier's response will depend on how the FDA evaluates the observations issued.

Thus, ROVI is continuing with the roadmap that it notified in the presentation of the update of its strategy at its 2022 Capital Markets Day and will continue to report on the milestones deemed relevant in the process to obtain authorisation of Risvan® from the FDA as the timeline for registration in the United States advances.

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Yours faithfully,

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