TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, March 2, 2021

PRICE-SENSITIVE INFORMATION

In compliance with the information duties set out in article 226 of the Revised Text of the Securities Market Act, further to Relevant Event No. 286374 of 31 January, 2020, which concerned the beginning of the evaluation process to obtain marketing authorisation for Doria® in the European Union, Laboratorios Farmacéuticos ROVI, S.A. (ROVI) reports that ROVI has requested to European Medicines Agency (EMA) to "stop the clock" on Day 181 of the authorisation process to provide responses within the framework of the centralised registration procedure. The purpose of said clock stop is to have sufficient time to repeat the bioavailability study comparing multiple doses of Doria® with oral risperidone, in response to the major observation of the Committee for Medicinal Products for Human Use (CHMP), which states that the study must be performed using the European reference product. The current dossier of Doria® already includes a clinical trial of bioavailability using the oral risperidone medicine marketed in the United States (U.S.A.). ROVI expected the trial using the U.S.A. reference product to be valid for Europe because the two products - the oral risperidone medicine marketed in the European Union and the one marketed in the U.S.A.- can be considered bioequivalents on the basis of the *in vitro* and *in vivo* studies that ROVI had conducted and submitted to the EMA. Indeed, the therapeutic indication in schizophrenia for oral risperidone was supported by the same efficacy clinical trials in both territories. ROVI considers that the additional clinical information requested can be provided in November this year 2021, thus resuming the regulatory process and enabling the EMA to complete its evaluation. Additionally, the EMA includes a second major observation in its Day 180 evaluation, aimed to prevent possible problems

related to the lack of flexibility in interrupting the treatment with a long-acting formulation, as well as other minor observations that will be answered on Day 181 of the procedure.

ROVI does not foresee any additional information requirements from the EMA and aspires to obtain the indication of "treatment of schizophrenia in adults", which would mean that Doria®, due to its unique pharmacokinetic profile, would not only be indicated for the maintenance treatment of stabilised patients, but could also be used in unstable patients with moderate to severe symptoms who require a fast and prolonged-acting product like Doria®. It would be the only long-acting injectable atypical antipsychotic with said indication in the European Union.

Likewise, ROVI filed the application to obtain marketing authorisation for Doria® with the United States authority, the FDA (U.S. Food and Drug Administration), on 24 November, 2020.

The FDA has completed its filing review and has determined that ROVI's application is sufficiently complete to permit a substantive review. Therefore, in accordance with 21 CFR 314.101(a), this application is considered filed 60 days after the date on which the FDA received it. The review classification for this application is "Standard". Therefore, the user fee goal date is 24 September, 2021. We should remember, however, that the evaluation process is subject to interruptions and extensions in the event that the FDA requires additional information.

ROVI will continue to inform of the milestones considered significant in both the authorisation process for Doria® in Europe and the authorisation process for the same medicine by the FDA, as the registration calendars progress in both Europe and the United States.

Likewise, ROVI will be holding a virtual meeting with analysts and investors today, in order to explain these milestones and answer any queries related to them.

We remain

Yours faithfully,

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