TO THE NATIONAL STOCK MARKET COMMISSION

Madrid, 9th of May, 2018

In compliance with the provisions of article 228 of the Securities Market Law and with Article 17 of the EU Regulation No. 596/2014 of European Parliament and Council, of the 16th of April, on market abuse, Laboratorios Farmacéuticos ROVI, S.A. ("**ROVI**" or the "**Company**") informs that after a prespecified Interim Analysis on the pivotal PRISMA-3 study for the once-monthly injectable formulation of Risperidone ISM®, DORIA®, an independent Data Monitoring Committee has recommended to continue the clinical trial and not increasing the currently planned number of randomized patients.

The PRISMA-3 study is a multicentre, randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of monthly intramuscular injections of DORIA® in patients with acute exacerbation of schizophrenia[1], having initiated patients' recruitment in May 2017, as previously informed the 25th of October 2017 on a relevant fact (number 257753).

As expected, ROVI has carried out one unblinded interim analysis that was planned to be conducted when approximately 50% of randomized patients have either reached study day 85 or withdrawn from the study to re-estimate the sample size required for the final analysis. In this sense, an independent DMC has received unblinded results from this interim analysis and has communicated to ROVI the blinded outcome, concluding that the clinical trial can continue and an increase of the study sample size is not needed.

[1] https://clinicaltrials.gov/ct2/show/NCT03160521

Consequently, the company plans to file an NDA (*New Drug Application),* US Registration Dossier for the FDA (*Food and Drug Administration)*, the second half 2019.

Thanking you in advance for your attention, I remain yours sincerely,

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