TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 26 August 2021

OTHER RELEVANT INFORMATION

Laboratorios Farmacéuticos ROVI, S.A. (ROVI), in compliance with the information duties set out in article 227 of the Revised Text of the Securities Market Act, as an entity participating in the manufacturing process of Moderna’s vaccine against Covid-19, and in relation to the notification of particulate matter having been seen in certain drug product vials of the vaccine distributed in Japan, informs that ROVI is currently conducting an investigation on this event, following the standard procedure for these cases.

The detection of this particulate matter refers to certain vials of one product lot distributed exclusively in Japan. ROVI, as well as Moderna and Takeda, the company distributing the referred vaccine in Japan, are working with health authorities in order to clarify and solve, if applicable, this incident.

The origin of this manufacturing incident may be in one of ROVI’s manufacturing lines. ROVI is working in order to provide with all the information and assistance that may be needed to progress with the investigation. As a precaution, this lot and two adjacent lots have been put on hold.

To date, no safety or efficacy issues have been identified in relation to the vaccine, as Moderna and Japanese authorities have reported.

ROVI will continue assisting proactively with the investigation.

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