



TO THE NATIONAL SECURITIES MARKET COMMISSION

Madrid, 1 September 2021

OTHER RELEVANT INFORMATION

Following the public relevant information published on 26 and on 29 of August 2021 with registered numbers 11377 and 11399 respectively, 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 about the joint statement from Moderna and Takeda on the investigation of suspended lots of the vaccine published today and hereby attached together with a loose translation into Spanish for information purposes.

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



Joint Statement from Moderna and Takeda on the Investigation of Suspended Lots of Moderna's COVID-19 Vaccine in Japan

September 1, 2021

This statement updates the separate [announcement](#) on August 26, 2021, JST, in which Takeda announced the suspension of the use of three lots of the Moderna COVID-19 Vaccine for Intramuscular Injection in Japan following reports from vaccination sites of a potential foreign particulate substance found in vials. It also updates the [joint statement](#) on August 28, 2021, in which Takeda and Moderna confirmed that they were notified of the deaths of two individuals, both of whom received Moderna's COVID-19 vaccine in Japan from one of the three lots.

Working with the Ministry of Health, Labour and Welfare (MHLW), Moderna, the vaccine manufacturer, ROVI Pharma Industrial Services, S.A. in Spain, Moderna's European contract manufacturing organization, and Takeda, the authorized distributor, have conducted a thorough investigation, which includes:

- Identification of the root cause of the particles and the corrective and preventive actions being taken; An
- assessment of the nature of a particle from one vial from Lot 3004667; and
- An associated medical safety assessment, to determine if the identified particle poses a health or safety risk.

Root Cause Investigation, and Corrective and Preventive Actions

Three lots of the Moderna COVID-19 Vaccine (Lots 3004667, 3004734 and 3004956) were suspended following reports from vaccination sites of a potential foreign particulate substance observed in unused vials from Lot 3004667.

According to the root cause analysis report, conducted by ROVI, the most probable cause of the particulates identified in lot 3004667 is related to friction between two pieces of metal installed in the stoppering module of the production line due to an incorrect set-up. The two pieces are the star-wheel and the stoppers feeding device piece which feeds stoppers into the star-wheel. It is believed that this condition occurred during the assembling of the line prior to production of batch 3004667 and was a result of improper alignment during a line changeover before starting this batch. Based on the analysis conducted by ROVI, the manufacturing issue only impacted the lots that were included in the suspension. The following steps have been taken by ROVI to correct and prevent future defects:

- Full inspection of the manufacturing line;
- Improving standard operating procedure for changeover of manufacturing line; and
- Setting alert inspection limits in the automatic visual inspection, as an internal process control.

Takeda, as the Japan Marketing Authorization Holder, is planning to initiate the recall of the three suspended lots 3004667, 3004734, and 3004956 from the market as of September 2, 2021, in consultation with MHLW and Osaka Prefecture. Moderna as the Global Marketing Authorization Holder is in full agreement with this decision.

Preliminary Particulate Analysis

According to Moderna's independent analysis, the particle from lot 3004667 has been thoroughly analyzed and is confirmed to be grade 316 stainless steel. This is consistent with the root cause determination described above. Grade 316 is a high grade of stainless steel commonly used in manufacturing and in food processing.

Current Medical Safety Assessment

After a health assessment conducted by Moderna and Takeda, the rare presence of stainless steel particles in the Moderna COVID-19 vaccine does not pose an undue risk to patient safety and it does not adversely affect the benefit/risk profile of the product. Metallic particles of this size injected into a muscle may result in a local reaction, but are unlikely to result in other adverse reactions beyond the local site of the injection. Stainless steel is routinely used in heart valves, joint replacements and metal sutures and staples. As such, it is not expected that injection of the particles identified in these lots in Japan would result in increased medical risk.

Investigation of Two Deaths Following Administration of Vaccine

At this time, there is no evidence that the two tragic deaths following administration of the Moderna COVID-19 vaccine (from lot 3004734) were in any way related to administration of the vaccine. The relationship is currently considered to be coincidental. It is important to conclude a formal investigation to confirm this. The investigation is being conducted with the greatest sense of urgency, transparency and integrity and is of the highest priority.

To date, more than 200 million doses of the Moderna COVID-19 vaccine have been administered to more than 110 million individuals in 45 countries, representing a critical component of the global fight against COVID-19.

For additional updates and resources about the COVID-19 vaccine program in Japan please go to the official [COVID-19 information center](#).

Forward Looking Statements

This statement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding: the Company's development of a vaccine against COVID-19 (mRNA-1273); the root cause and remediation of issues leading to the inclusion of particles in certain lots of the Company's COVID-19 vaccine; the recall of suspended lots of the vaccine; the medical safety, risk and potential for adverse reactions associated with particulate in the vaccine; and ongoing investigations into deaths following administration of the

English loose translation

vaccine. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond Moderna's control and which could cause actual results to differ materially from those expressed or implied by these forward-looking statements. These risks, uncertainties, and other factors include those other risks and uncertainties described under the heading "Risk Factors" in Moderna's most recent Annual Report on Form 10- filed with the U.S. Securities and Exchange Commission (SEC) and in subsequent filings made by Moderna with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, Moderna disclaims any intention or responsibility for updating or revising any forward-looking statements contained in this press release in the event of new information, future developments or otherwise. These forward-looking statements are based on Moderna's current expectations and speak only as of the date hereof.