



## **Recall Notification of Lot #000190A**

**Madrid – 08 April, 2022** - Moderna and ROVI Pharma Industrial Services, S.A.U. today announced a recall of one lot (lot #000190A) of the Moderna COVID-19 vaccine (Spikevax®). The lot is being recalled due to a foreign body being found in one vial in the lot manufactured at the Company's contract manufacturing site, ROVI, in Spain. The impacted vial was punctured and was not administered.

Moderna, through its marketing authorization holder, Moderna Biotech Spain, S.L., and ROVI, were alerted to this issue through a product complaint from a vaccination center in Málaga, Spain. The vial was returned for forensic assessment and investigation. This lot, which consisted of 764,900 doses, was distributed in Norway, Poland, Portugal, Spain, and Sweden from 13-14 January 2022.

Moderna conducted a cumulative search of its global safety database, and no safety concerns were reported in individuals who received the Moderna COVID-19 vaccine from this lot. To date, no safety or efficacy issues have been identified.

More than 900 million doses of the Moderna COVID-19 vaccine have been administered to date worldwide. Moderna does not believe that this poses a risk to other vials in the lot and does not believe that this affects the significant benefit/risk profile of the vaccine.

Given the Company's priority to assure quality, and out of an abundance of caution, this lot is being recalled. Moderna is proactively communicating with health authorities as the investigation proceeds. Moderna and Rovi remain committed to working transparently and expeditiously with regulators to address any potential concerns.

Direct consignees or healthcare professionals that have impacted product with this lot number should contact [000190AAction@modernatx.com](mailto:000190AAction@modernatx.com) with any inquiries regarding recalled product.

### **Moderna's 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 recall of one lot of its COVID-19 vaccine (mRNA-1273); the lack of safety concerns or reports related administration of vaccines from this lot; the risks associated with administration of the vaccine; and the steps the Company will take to coordinate with regulators. The forward-looking statements here 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-K 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](http://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.

### **ROVI's Forward Looking Statements**

This notification contains forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other factors which might cause the actual results, financial performance or achievements of ROVI, or its Moderna and ROVI expand long-term collaboration for the manufacture of mRNA medicines over the next ten years industrial results, to be materially different to the future results, profitability or achievements expressed or implied in such forward-looking statements. These risks, uncertainties, and other factors include, among others: the Company's

recall of one lot of its COVID-19 vaccine (mRNA-1273); the lack of safety concerns or reports related administration of vaccines from this lot; the risks associated with administration of the vaccine; and the steps the Company will take to coordinate with regulators. The statements in this notification represent ROVI's expectations and beliefs as of the date hereof. ROVI anticipates that subsequent events and developments may cause these expectations and beliefs to change. However, while ROVI may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing ROVI's expectations or beliefs as of any date subsequent to the date of this notification.