



Statement

Moderna and Takeda's Response to the Incidents Announced by the Japanese Ministry of Health, Labour and Welfare (MHLW) associated with the Announced Suspension of Use of Specific Lots of Moderna's COVID-19 Vaccine in Japan

Osaka, JAPAN, August 28, 2021 - Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](https://www.takeda.com/stock)) ("Takeda") and Moderna, Inc. ([Nasdaq:MRNA](https://www.moderna.com/)) ("Moderna") announced today the deaths of two individuals who both recently received the Moderna COVID-19 Vaccine for Intramuscular Injection in Japan. At this time, we do not have any evidence that these deaths are caused by the Moderna COVID-19 vaccine, and it is important to conduct a formal investigation to determine whether there is any connection. Please see the attached statement for details.

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Osaka, JAPAN, and Cambridge, Mass, August 28, 2021 - Takeda Pharmaceutical Company Limited ([TSE:4502/NYSE:TAK](#)) and Moderna ([Nasdaq:MRNA](#)) were notified on August 28 JST, of the deaths of two individuals who both recently received the Moderna COVID-19 Vaccine for Intramuscular Injection in Japan. This is a tragic event, and the loss of life is something that we take very seriously. We offer our sincerest condolences to their loved ones.

At this time, we do not have any evidence that these deaths are caused by the Moderna COVID-19 vaccine, and it is important to conduct a formal investigation to determine whether there is any connection.

Takeda, the authorized distributor, and Moderna, the manufacturer, are working with the Ministry of Health, Labour and Welfare (MHLW) to investigate the two deaths. The investigation is being conducted with the greatest sense of urgency, transparency and integrity and is of the highest priority. Takeda and Moderna will keep the public informed as we learn more.

On August 26 JST, Takeda announced the decision to suspend the use of three lots of Moderna's COVID-19 Vaccine in Japan in alignment with MHLW following reports from vaccination sites of a foreign substance found in vials. The complaints that prompted the suspension were isolated to one specific lot, but a total of three lots manufactured in the same series were included in the suspension by MHLW out of an abundance of caution. To date, we have no product quality complaints related to particulate matter in the lot related to the unfortunate passing of the two individuals.

Takeda has requested that Moderna and Moderna's European contract manufacturing organization, urgently conduct a thorough investigation to determine the nature of the foreign substance. We are aware of unofficial reports that have provided initial indication of the type of particle matter in the vials. These reports are inconclusive and it is important to rely on a formal investigation before determining the precise nature of the particle. Moderna is in the process of conducting that investigation and the vials have been sent to a qualified lab for analysis and initial findings will be available early next week.

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](#).

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