Better Health, Brighter Future

Statement

Takeda's Response to the New Incident 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, September 1 – Takeda and Moderna have been notified of a death from the recently recalled lots, in addition to the two deaths previously reported, involving an individual who recently received the Moderna COVID-19 Vaccine for Intramuscular Injection in Japan and reported the case to the Ministry of Health, Labour and Welfare (MHLW). 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.

The additional death occurred on August 12, following a second dose vaccination on August 11 from lot 3004734 – one of the three lots included in the recall announced last week and which lot has no product complaints for observed particulates in unused vials to date. Takeda and Moderna are working with the MHLW to investigate these deaths and the investigation is being conducted with the greatest sense of urgency, transparency and integrity.

There is no indication that any of the deaths following administration of the Moderna COVID-19 vaccine were in any way related to administration of the vaccine. At this point, there is also no reason to believe that the vaccine poses any health hazard or undue safety risk.

As of August 26, 2021, approximately 18 million doses of Moderna's COVID-19 vaccine have been administered to the Japanese population and more than 200 million doses of the Moderna COVID-19 vaccine have been administered to more than 110 million individuals in 45 countries. The vaccine has a well-established safety and efficacy profile.

Additional Background

As previously reported, Takeda announced the decision to suspend the use of three lots of Moderna's COVID-19 Vaccine in Japan in consultation with the MHLW. Moderna's independent analysis identified the particles found in one of the recalled lots as 316 stainless steel, most probably caused by friction between two pieces of metal installed in the stoppering module of the production line at ROVI, Moderna's contract manufacturer, due to an incorrect set-up.

Based on a health assessment conducted by Takeda and Moderna, the 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 those at the local site of injection. It is not expected that injection of the particles identified in these lots in Japan would result in increased medical risk. A detailed analysis of these reports will be published by Takeda and Moderna in the coming days.

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. Takeda initiated the recall of the three suspended lots on September 2. To date, there have been no reported product complaints for observed particulates in unused vials related to the unfortunate passing of the three individuals.

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Previous statements

Joint Statement from Moderna and Takeda on the Investigation of Suspended Lots of Moderna's COVID-19 Vaccine in Japan (September 1, 2021)

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 (August 28, 2021)

Notice of Suspension of Use of Specific Lots of Moderna's COVID-19 Vaccine in Japan (COVID-19 Vaccine Moderna Intramuscular Injection) (August 26, 2021)

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE: 4502/NYSE: TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people's lives by advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in healthcare in approximately 80 countries. For more information, visit https://www.takeda.com.

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