Joint Statement from Moderna and Takeda

October 1, 2021

STATEMENT REGARDING Moderna COVID-19 Vaccine Recall Investigation Report – October 2021

Takeda and Moderna today published a report of the investigation prompted by the observation of foreign particles in unpunctured vials from a single lot of Moderna's COVID-19 vaccine distributed in Japan by Takeda. The lot was suspended on August 26, 2021, JST and voluntarily recalled on September 2, 2021, JST. Two other lots manufactured in the same series were included in the suspension and voluntary recall as a precautionary measure.

The investigation report is intended to provide a clear view into what happened, when, and how it has been addressed. Specifically, it provides details on the particle analysis, root cause analysis and health risk assessment conducted by Moderna (the vaccine developer and manufacturer), ROVI Pharma Industrial Services, S.A. (Moderna's European contract manufacturing organization), and Takeda (the Japan Marketing Authorization Holder and authorized distributor). In addition, the report provides information based on a draft for-cause audit of ROVI, conducted on-site jointly by Moderna and Takeda.

In summary, the root cause analysis, particle analysis and health risk assessment established the following:

- The rare presence of 316L stainless steel particles – observed in one of the recalled lots – presented no undue risk to patient safety and did not adversely affect the benefit/risk profile of the product.
- The most probable cause of the particles identified in one of the recalled lots is related to friction between two pieces of metal installed in the stoppering module of the production line.
- This was the result of incorrect assembly and was due to human error specific to visually misjudging the required 1mm gap between the star-wheel and the stopper.

The investigation conclusion has confirmed the scope of the event, and corrective actions—including improvements to standard operating procedures at the changeover, and the utilization of a new precision tool—will help mitigate the risk of this issue reoccurring. These actions will be directly overseen and confirmed by Moderna, in collaboration with Takeda. A list of corrective and preventive actions following the root cause analysis and for-cause audit are provided in the investigation report.

The Moderna COVID-19 vaccine has a well-established safety and efficacy profile. 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. Takeda and Moderna's top priority is to continue to support the MHLW's efforts to help fight this ongoing pandemic and bring this vaccine to everyone who can benefit from it.

The investigation report can be read here.