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Committee Secretary
Senate Education and Employment Committees
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Canberra ACT 2600

17 August 2023

RE: RESPONSE TO QUESTIONS ON NOTICE

I write in relation to recent questions placed on notice by senators as a part of the Senate Standing Committee on Education and Employment inquiry into the COVID-19 Vaccination Status (Prevention of Discrimination) Bill 2022 and the Fair Work Amendment (Prohibiting COVID-19 Vaccine Discrimination) Bill 2023 on 3 August 2023. Moderna's responses to questions taken on notice can be found below.

Question:

Senator RENNICK: You can take this on notice. Did you do distribution and degradation studies on that methylpseudouridine?

Dr Clarke: I will have to take that on notice.

Answer:

N1-methylpseudouridine (i.e., "methylpseudouridrine") is a naturally occurring component of human RNA. Therefore, the N1-methylpseudouridine in our mRNA vaccines would be expected to degrade in the same way as the naturally occurring form.

Nonetheless, we have evaluated the tissue distribution and degradation rates of mRNA vaccines made with N1-methylpseudouridine following intramuscular (IM) administration. The tissue distribution and degradation rates were consistent with other IM administered vaccines.

Question:

Senator ANTIC: That is the TGA. I'm not asking about the TGA. I'm asking about Moderna. You must have that information. You are a multinational company. You are before a Senate inquiry. You cannot tell me the rates of serious adverse events. It is quite extraordinary what you are telling me. Nobody can tell me that?

CHAIR: Dr Clarke—

Dr Clarke: I can provide that information on notice. What I can tell you is that in our clinical trials we observed no safety concerns. There were no imbalances of serious adverse events of special interest or deaths between the vaccine group and the placebo group.

Answer:

Rates of serious adverse events are documented by vaccine providers in clinical trial data which is provided to regulators. In Moderna's pivotal Phase 3 observer-blinded, placebo-controlled clinical trial (COVE) which included over 30,000 participants, in the overall safety set, over the whole study after any dose, there were 12 cases in the vaccine arm and 4 cases in the placebo arm assessed as treatment related serious adverse events related to vaccination (representing <0.1% of the trial population). This study is peer reviewed and was published in 2021 in the New England Journal of Medicine [El Sahly et al N Engl J Med 2021;385:1774-85. DOI: 10.1056/NEJMoa2113017 (Appendix)].

Real World Evidence on observed rates of adverse events is collected and reported on by regulators and is available on the Therapeutic Goods Administration (TGA) Website.

Question:

Senator CANAVAN: How many doses of the Moderna vaccine have been delivered in Australia this calendar year?

Dr Clarke: I would have to take that on notice.

Senator CANAVAN: Could you take on notice how many were delivered last year as well for the full calendar year 2022?

Dr Clarke: Yes.

Answer:

In line with our agreement with the Commonwealth Government, Moderna delivered 15 million doses of variant-specific vaccines to the Government to address longer-term immunity and viral variants in 2022 and we are committed to delivering 3 million doses of a variant-specific COVID-19 vaccines in 2023 and early 2024. Moderna is not in a position to provide information on how many of these vaccines were administered as this information is held by the Department of Health and Aged Care.

Question:

Senator CANAVAN: Have you done any further studies with real-world data?

Dr Dawson: The real-world data, there has been a systematic review and metanalysis evaluating the spread of infection to family members, which is called the secondary attack route by vaccination status. It found evidence of a reduction in infectiousness from breakthrough cases of fully vaccinated individuals. Actually, our studies have investigated viral load and viral shedding in

breakthrough cases. The exploratory analysis suggested that viral load was around a hundredfold lower and the duration of shedding was shorter in vaccinated individuals.

Senator CANAVAN: When was that study completed?

Dr Dawson: This was in 2021.

Senator CANAVAN: When in 2021?

Dr Dawson: I would have to get back to you with that answer.

Senator CANAVAN: Are you doing any ongoing investigations on this matter?

Dr Dawson: Moderna continues to do ongoing investigation on this topic.

Senator CANAVAN: On the transmission?

Dr Dawson: Yes.

Senator CANAVAN: Will that be publicly released? On notice, can you provide us the most recent findings that you have on that?

Dr Dawson: Yes.

Answer:

The study referred to was undertaken throughout 2021 and it was subsequently published in Nature Medicine in February 2022. The study was titled "Initial analysis of viral dynamics and circulating viral variants during the mRNA-1273 Phase 3 COVE trial".

Source: Nature Medicine, 2022; 28(4): 823–830.
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9018421/

Moderna appreciated the opportunity to support the work of the Committee's Inquiry.

Yours sincerely

Moderna Australia and New Zealand