Statement on RSVVW Abstract on mRNA-1345

At an upcoming presentation at the RSVVW'24 conference, Moderna will share follow-up data from its ongoing ConquerRSV Phase 3 study of its investigational RSV vaccine candidate, mRNA-1345.

As previously published in the *New England Journal of Medicine*, the primary analysis from this trial demonstrated vaccine efficacy (VE) of 83.7% (95.88% CI: 66.1%, 92.2%; p<0.0001) against RSV lower respiratory tract disease (RSV-LRTD) as defined by two or more symptoms and VE of 82.4% (96.36% CI: 34.8%, 95.3%; p=0.0078) in RSV-LRTD as defined by three or more symptoms with a median follow-up of 3.7 months. Solicited adverse reactions were mostly mild to moderate (grade 1 or grade 2, resolving within 1 to 2 days). The most frequently reported were injection site pain, fatigue, headache, myalgia, and arthralgia. No safety concerns were identified. No cases of Guillain-Barre Syndrome (GBS) have been reported with mRNA-1345 in the Phase 3 RSV trial.

The upcoming presentation includes follow-up data through a data cut off of April 30, 2023, with a median follow-up duration of 8.6 months, with a range of 15 days to 530 days, and including subjects from the Northern and Southern Hemispheres. In this supplemental analysis, mRNA-1345 maintained durable efficacy, with sustained VE of 63.3% (95% CI: 48.7%, 73.7%) against RSV-LRTD including two or more symptoms. VE was 74.6% (95% CI, 50.7, 86.9) against RSV-LRTD with ≥2 symptoms, including shortness of breath, and VE was 63.0% (95% CI, 37.3%, 78.2%) against RSV LRTD including three of more symptoms. The stringent statistical criterion of the study, a lower bound on the 95% CI of >20%, continued to be met for both endpoints.

Comparisons across seasons are challenging with respiratory viruses, particularly in the last several years. For example, the 2022-2023 RSV season in the United States was characterized by higher incidence and hospitalization rates, which at their peak were approximately four-fold higher than in the prior season, with a longer duration of sustained transmission, as demonstrated by CDC data.[1] The 2021-2022 season was shortened significantly by countermeasures that were taken against the Omicron variant during the COVID pandemic.

In the absence of head-to-head clinical trials, comparative conclusions regarding the safety and efficacy of mRNA-1345 relative to other RSV vaccines cannot be made. These trials differed in study populations, geographic locations, infection surveillance methods, and case definitions used for RSV.

Moderna is anticipating approvals of mRNA-1345 in the first half of 2024. The Company is encouraged by the strong competitive profile for its RSV vaccine, with robust efficacy data meeting all pre-specified statistical criteria, a well-established safety and tolerability profile, and as the only pre-filled syringe product available at the time of launch.

The full RSVVW'24 presentation will be available on February 15, 2024 on the Scientific & Medical Meetings section of Moderna's investor website. The abstract from the upcoming presentation is available on page 88, at the following link: https://resvinet.org/wp-content/uploads/2024/02/Abstract-Booklet-08Feb24.pdf

[1] See https://www.cdc.gov/rsv/research/rsv-net/dashboard.html

Forward-Looking Statement Disclaimer

This statement contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including regarding the safety, efficacy and competitive profile for Moderna's RSV vaccine candidate, mRNA-1345. 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 the Company'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 the Company'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 the Company with the SEC, which are available on the SEC's website at www.sec.gov. Except as required by law, the Company disclaims any intention or responsibility for updating or revising any forward-looking statements contained here in the event of new information, future developments or otherwise. These forward-looking statements are based on the Company's current expectations and speak only as of the date hereof.