Novavax Prepared to Deliver JN.1 Protein-based Non-mRNA COVID-19 Vaccine This Fall Consistent with U.S. FDA Guidance

June 5, 2024

Updated June 10, 2024

On June 7, the U.S. Food and Drug Administration (FDA) advised manufacturers to update to a monovalent JN.1 COVID-19 vaccine for the fall. This follows the U.S. FDA Vaccines and Related Biological Products Advisory Committee (VRBPAC) unanimous vote on June 5 to recommend that COVID-19 vaccines be updated to a monovalent JN.1-lineage composition for 2024-2025.

The VRBPAC expressed a preference for the JN.1 strain and acknowledged the importance of having a protein-based option available at the start of the vaccination season, alongside other alternatives. Novavax expects to be ready for the commercial delivery of a protein-based JN.1 COVID-19 vaccine in the U.S. in September this fall, pending authorization.

The Committee acknowledged the advantages of a JN.1 vaccine in providing broad protection against circulating and future strains, based upon data presented by all manufacturers, and the need to minimize confusion in making public health recommendations. Novavax's JN.1 COVID-19 vaccine has demonstrated broad cross-neutralizing antibodies for a range of JN.1 descendant viruses, including KP.2 and KP.3. We believe updating to the JN.1 lineage or JN.1, as recommended by the World Health Organization, the European Medicines Agency and the FDA, will provide the protection needed this fall against COVID-19.[1,2]

Our most recent nonclinical data have demonstrated that our JN.1 vaccine candidate induces broad neutralization responses to JN.1 lineage viruses including those with the **F**456**L** mutation (e.g., JN.1.16), the **R**346**T** mutation (e.g., JN.1.13.1), to "**FL**i**RT**" variants that contain both mutations such as KP.2, currently the most common circulating variant in the U.S., and to "FLuQE" variants that are increasing in circulation (e.g., KP.3).[1,3,4] Our JN.1 vaccine candidate also produces conserved polyfunctional, Th1-biased CD4+ T cell responses to a range of JN.1 lineage variants including those containing the **F**456**L**, **R**346**T** and **FL**i**RT** mutations (e.g., KP.2).[1] These responses indicate that our vaccine technology induces broadly neutralizing responses against multiple variant strains, including to circulating forward drift variants.

Forward-Looking Statements

Statements herein relating to the future of Novavax, its operating plans and prospects, the immunogenic response of its vaccine technology against variant strains and the scope, timing and outcome of future regulatory filings and actions, including the plan to be ready to deliver a JN.1 protein-based non-mRNA COVID-19 vaccine, are forward-looking statements. Novavax cautions that these forward-looking statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, without limitation, antigenic drift or shift in the SARS-CoV2 spike protein, challenges satisfying, alone or together with partners, various safety, efficacy, and product characterization requirements, including those related to process qualification and assay validation, necessary to satisfy applicable regulatory authorities; difficulty obtaining scarce raw materials and supplies; resource constraints, including human capital and manufacturing capacity, on the ability of Novavax to pursue planned regulatory pathways; challenges or delays in obtaining regulatory authorization for its product candidates, including an JN.1 protein-based non-mRNA COVID-19 vaccine or for future COVID-19 variant strain changes; challenges or delays in clinical trials; manufacturing, distribution or export delays or challenges; Novavax's exclusive dependence on Serum Institute of India Pvt. Ltd. for co-formulation and filling and the impact of any delays or disruptions in their operations on the delivery of customer orders; challenges meeting contractual requirements under agreements with multiple commercial, governmental, and other entities; and those other risk factors identified in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Novavax's Annual Report on Form 10-K for the year ended December 31, 2023, and subsequent Quarterly Reports on Form 10-Q, as filed with the Securities and Exchange Commission (SEC). We caution investors not to place considerable reliance on forward-looking statements contained in this press release. You are encouraged to read our filings with the SEC, available at www.sec.gov and www.novavax.com, for a discussion of these and other risks and uncertainties. The forward-looking statements in this press release speak only as of the date of this document, and we undertake no obligation to update or revise any of the statements. Our business is subject to substantial risks and uncertainties, including those referenced above. Investors, potential investors, and others should give careful consideration to these risks and uncertainties.

References

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2. European Medicines Agency. ETF recommends updating COVID-19 vaccines to target new JN.1 variant. April 30, 2024. Available at: https://www.ema.europa.eu/en/news/etf-recommends-updating-covid-19-vaccines-target-new-jn1-variant
3. U.S. Centers for Disease Control and Prevention. Variant Proportions [Data set]. In COVID Data Tracker. 2024. Available at: https://covid.cdc.gov/covid-data-tracker/#variant-proportions
4. Focosi D, Spezia PG, Gueli F, Maggi F. The Era of the FLips: How Spike Mutations L455F and F456L (and A475V) Are Shaping SARS-CoV-2 Evolution. *Viruses*. 2023;16(1):3. Published 2023 Dec 19. doi:10.3390/v16010003.