Latest update on U.S. FDA BLA for Novavax's COVID-19 Vaccine

April 23, 2025

We believe that our Biologics License Application (BLA) is approvable based on conversations with the U.S. Food and Drug Administration (FDA), as of our Prescription Drug User Fee Act (PDUFA) date of April 1 and through today.

We have recently received formal communication from the FDA in the form of an information request for a postmarketing commitment (PMC) to generate additional clinical data. We look forward to engaging with the FDA expeditiously to address the PMC request and move to approval as soon as possible.

Cautionary Note Regarding Forward-Looking Statements

This statement includes forward-looking statements including our intention to engage expeditiously with the FDA to address the PMC request and the potential for approval of our BLA. Generally, forward-looking statements can be identified through the use of words or phrases such as “believe,” “may,” “could,” “will,” “would,” “possible,” “can,” “estimate,” “continue,” “ongoing,” “consider,” “anticipate,” “intend,” “seek,” “plan,” “project,” “expect,” “should,” “would,” “aim,” or “assume,” the negative of these terms, or other comparable terminology, although not all forward-looking statements contain these words.

Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs and expectations about the future of our business, events and trends, and other future conditions. Forward-looking statements involve estimates, assumptions, risks, and uncertainties that could cause actual results or outcomes to differ materially from those expressed or implied in any forward-looking statements, and, therefore, you should not place considerable reliance on any such forward-looking statements. Such risks and uncertainties include, without limitation, include challenges or delays in obtaining regulatory authorization for its COVID-19 vaccine, in particular with respect to our BLA submission to the FDA for approval of our COVID-19 vaccine; and other risks and uncertainties identified in Part I, Item 1A “Risk Factors” of our Annual Report on Form 10-K for the year ended December 31, 2024, filed with the Securities and Exchange Commission (“SEC”) on February 27, 2025, and in Part II, Item 1A “Risk Factors”, which may be detailed and modified or updated in other documents filed with the SEC from time to time, and are available at www.sec.gov and at www.novavax.com. You are encouraged to read these filings as they are made.

We cannot guarantee future results, events, level of activity, performance or achievement. Any or all of our forward-looking statements in the statement may turn out to be inaccurate or materially different from actual results. Further, any forward-looking statement speaks only as of the date when it is made, and we undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law. New factors emerge from time to time, and it is not possible for us to predict which factors will arise. In addition, we cannot assess the impact of each factor on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements.