

# **Novavax Statement on US FDA Briefing Document Related to Myocarditis/Pericarditis**

June 3, 2022

Throughout the pandemic, as publicly available vaccines have been administered, there have been numerous investigations into findings related to myocarditis. We have learned that we can expect to see natural background events of myocarditis in any sufficiently large database, and that young males are at higher risk. Myocarditis is most often caused by nonspecific viral infections.

The data from our placebo-controlled studies show that overall, in our clinical development program, the rate of myocarditis was balanced between the vaccine and placebo arms (0.007% and 0.005%). Furthermore, in the post-crossover portions of our studies, the cases we have seen are all within the expected rate.

Based on our interpretation of all the clinical data supporting NVX-CoV2373, including over 50,000 participants in clinical trials, we believe there is insufficient evidence to establish a causal relationship. We will continue to monitor all adverse events, including myocarditis and pericarditis.