Novavax' H7N9 Avian Influenza VLP Vaccine Candidate With Matrix-M(TM) Delivers Positive Phase 1/2 Clinical Data
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Vaccine and adjuvant were well-tolerated, consistent with the company's prior studies with saponin-based adjuvants
• Hemagglutination-inhibiting antibody responses similar to prior Novavax studies of A(H7N9) with another saponin adjuvant
• Strong neuraminidase inhibiting antibody responses in adjuvanted vaccine groups
• Matrix-M demonstrated a clear dose response

Novavax, Inc. NVAX, +10.13% a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of recombinant nanoparticle vaccines and adjuvants, today announced positive top-line data from a Phase 1/2 clinical trial of its H7N9 Avian Influenza VLP Vaccine Candidate (H7N9 VLP) with proprietary adjuvant Matrix-M™. This trial was conducted under the company's contract with HHS-BARDA (HHSO1002011100012C) for the development of VLPs to address influenza strains with pandemic potential.

The study was conducted in 610 healthy subjects to evaluate the safety and immunogenicity of the H7N9 VLP with Matrix-M. The study was designed as a dose-ranging, randomized, observer-blinded, placebo-controlled clinical trial, to determine the contribution of Matrix-M to potential antigen dose sparing regimens. Subjects were administered two identical doses of either placebo, 15 µg of H7N9 VLP alone, or 3.75, 7.5 or 15 µg of H7N9 VLP in combination with either 25 or 50 µg of Matrix-M. Serology was taken on day 0, 21 and 42.

The H7N9 VLP, with and without Matrix-M, was well tolerated and demonstrated a safety profile similar to the company's prior experience with another saponin-based adjuvant. Matrix-M adjuvanted formulations demonstrated a clear immunogenicity benefit relative to unadjuvanted antigen, and a dose-response within the adjuvanted groups. Antigen dose-sparing was shown, such that even the 3.75µg dose of antigen with either tested dose of adjuvant gave immune responses statistically significantly greater than 15µg dose without adjuvant. Geometric mean titters of hemagglutination-inhibiting antibody after two vaccine doses were comparable to those reported in prior studies with another saponin adjuvant when similar antigen and adjuvant doses were compared. The vaccine also elicited anti-neuraminidase (NAI) antibodies against N9, with 89 to 100% sero-response rates in the adjuvanted vaccine groups, and greater than 11-fold increases in geometric mean titters.

"This study represents the first clinical trial of Matrix-M with our VLPs. We are pleased with the performance of Matrix-M in this study, which increases our confidence in the value of this adjuvant and its future application in this and other recombinant nanoparticle products," said Stan Erck, President and CEO of Novavax. "Based on the data from this trial, we will discuss future clinical studies with our partner, BARDA. Given the Matrix-M safety profile and dose response observed in this study, we believe additional such studies are warranted to identify the best combination of antigen and adjuvant to achieve the greatest practical antigen dose sparing, consistent with a strong immune response, thus potentially making available the maximum number of doses in a pandemic emergency."