



BlueWillow Biologics' Intranasal Bird Flu Vaccine Shows Signs of Broad Immune Response in Phase I Clinical Trial Published in Nature Communications

New study published in Nature Communications paves the way for next-generation pandemic preparedness, demonstrating safety and immunogenicity of adjuvanted intranasal bird flu vaccine

ANN ARBOR, Mich., November 6, 2025 (GLOBE NEWSWIRE) – [BlueWillow Biologics, Inc.](#), a clinical-stage biotech company pioneering the future of intranasal vaccines, today announced results from a peer-reviewed [Nature Communications study](#) demonstrating that its intranasal, adjuvanted H5N1 influenza vaccine candidate successfully primed broad immune responses across multiple avian flu strains. The randomized, controlled Phase I clinical trial, conducted by researchers at University of Maryland School of Medicine, demonstrated BlueWillow's NanoVax® W₈₀5EC adjuvanted A/H5 vaccine effectively primed broad immune responses in trial patients with a strong safety profile against diverse strains of bird flu, highlighting its potential as a next-generation approach for pandemic preparedness.

"The continued spread of H5N1 on European farms and human fatality in Louisiana earlier this year highlights the urgent need for effective preventive measures," said Chad Costley, MD, MBA, CEO of BlueWillow. "The results from this clinical trial show that our NanoVax® W₈₀5EC adjuvanted A/H5 vaccine is capable of safely inducing strong and broad immunogenicity with the promise of preventing both disease symptoms and contagiousness."

In the Phase I clinical trial, 40 healthy adults were randomized to receive low, medium and high A/H5 vaccine doses combined with BlueWillow's proprietary, intranasal, oil-in-water W₈₀5EC emulsion adjuvant, high-dose antigen alone or placebo. Adjuvanted intranasal vaccination was safe and well-tolerated in all subjects. Only the subjects who received the intranasal adjuvanted vaccines showed broad immune systemic priming, which was revealed by a single dose of a currently licensed intramuscular H5 vaccine. Importantly, the NanoVax® W₈₀5EC adjuvanted vaccination also elicited mucosal, cellular and systemic immune responses on its own, something that has not been previously demonstrated in clinical trials of other recombinant H5 mucosal flu vaccine candidates.

BlueWillow's NanoVax® W₈₀5EC adjuvanted vaccine also demonstrated significant cross-clade immune system priming against multiple H5N1 strains, signifying that the vaccine stimulates the immune system to recognize variations of the virus which is critical to protection as the flu virus mutates over time. The study also indicates a potential antigen dose-sparing benefit of the NanoVax® W₈₀5EC adjuvant. Antigen dose-sparing is important to lowering the cost and increasing the tolerability and safety of vaccination.

"The spread of H5N1 influenza in animals with spillover into human populations globally highlights the critical need for effective countermeasures to protect our communities from this and other pathogens with pandemic potential," said Justin Ortiz, MD, MS, lead author on the study and professor at the University of Maryland School of Medicine. "This trial shows that this intranasal, shelf-stable H5N1

vaccine could play a major role in pandemic preparedness, offering a practical and scalable way to help protect people from evolving strains of the virus.”

BlueWillow’s NanoVax® W₈₀5EC adjuvant, previously named NE01, is the most advanced intranasal adjuvant in development and warrants further investigation as a platform technology for advancing mucosal vaccination against a range of respiratory pathogens.

For more information about BlueWillow Biologics and its intranasal platform technology, please visit www.BlueWillow.com.

About BlueWillow

Based in Ann Arbor, Michigan, [BlueWillow Biologics, Inc.](http://www.BlueWillow.com) is a clinical-stage biotech company pioneering the future of intranasal vaccines to transform the prevention and treatment landscape for pandemic preparedness and infectious disease. By eliciting comprehensive immune responses, BlueWillow’s technology offers robust protection against a broad range of health threats, preventing symptomatic disease and transmission. Steered by physician-scientists who have proven success building life science ventures, leadership combines an expertise in vaccine development, chemical engineering, intranasal adjuvant and antigen delivery, and an experienced management team that has built numerous successful biotechnology ventures. Visit www.BlueWillow.com.

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