NEWS RELEASE

Vaxxas Initiates Phase I Clinical Trial of Pre-Pandemic Avian Influenza A Virus (H7N9) Vaccine Delivered Using Vaxxas' Novel High-Density Microarray Patch (HD-MAP)

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- Multi-center Phase I clinical study will evaluate the safety and tolerability of a monovalent strain of avian influenza A (H7N9) vaccine delivered intradermally by Vaxxas' high-density microarray patch (HD-MAP);
- This project has been supported in whole or in part with federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number 75A50120C00180 to advance capabilities against pre-pandemic avian influenza outbreak through the assessment of the H7N9/HD-MAP vaccine;
- All strains of avian influenza, or bird flu, including H7N9 and H5N1, represent a potential serious pandemic threat to livestock and humans;
- Led by Vaxxas' team and clinical collaborators, this Phase I study is being conducted under an approved Investigational New Drug submission approved by the US FDA.

CAMBRIDGE, Mass. & BRISBANE, Australia--(BUSINESS WIRE)-- Vaxxas today announced that it has initiated a multi-center Phase I clinical trial of a vaccine against pre-pandemic avian influenza strain H7N9, using the company's high-density microarray patch (HD-MAP).

Vaxxas' high-density microarray patch (HD-MAP) technology uses an array of microprojections – invisible to the naked human eye – to deliver the vaccine to the skin via a small patch sitting inside a small applicator device. When applied to the skin, the patch

Conducted in collaboration with Australian clinical sites, the multi-center trial is being led by

delivers the vaccine to the abundant immune cells immediately below the skin surface.

Source: Vaxxas

Vaxxas with oversight by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, and is designed to expand foundational novel countermeasure capabilities in response to potential future pandemic threats to public health.

Vaxxas' HD-MAP platform delivers vaccines by applying a small patch briefly to the skin, avoiding many of the costs and complexities of needle and syringe vaccination. The HD-MAP enables the delivery of vaccine directly to the dense populations of skin-resident immune cells enhancing immune responses with **potential dose-sparing benefits** . The HD-MAP is easy to use, and vaccines can be **stable at room temperature** , avoiding or minimizing the need for cold-chain refrigeration and facilitating distribution of vaccine patches by mail and courier for potential self-administration.

The clinical study includes 258 healthy participants between the ages of 18 and 50 years, making it the largest Phase I trial conducted-to-date by Vaxxas with its HD-MAP technology.

The trial will compare the safety and immune response of participants to this H7N9 vaccine, when dosed with Vaxxas' novel HD-MAP as well as through conventional needle and syringe. Initial results from the trial are expected in 2025 and will be provided to BARDA and published by Vaxxas and its clinical collaborators.

"Global pandemic threats require the world's health organizations to have better and more accessible vaccine delivery options. With potential benefits such as thermostability, ease of use, and patient acceptability, Vaxxas' HD-MAP is designed to be rapidly and broadly deployed to accelerate vaccination uptake and rates," David L. Hoey, President and CEO of Vaxxas, said. "Market research indicates that – given the choice – vaccination by HD-MAP is significantly preferred over conventional needle-and-syringe."

The influenza A virus circulates as numerous strains across the globe. **The World Health Organization (WHO) states the H7N9 avian influenza strain is 'of concern' as most patients have become severely ill** .

This Australian-based Phase I clinical study is being conducted at three of the University of the Sunshine Coast's clinical trial centers in Queensland and the Doherty Clinical Trial center in Melbourne, Victoria.

About Avian influenza A (H7N9)

This selected variant of avian influenza A (H7N9), or bird flu, is a subtype of influenza viruses that have been detected in birds, livestock, and people in the past.

The World Health Organization (WHO) states the H7N9 avian influenza strain is 'of concern' as most patients have become severely ill .

H7N9 has an observed Infection Fatality Rate (IFR) of 39%, meaning for every 100 infected people 39 people are likely to die and many are likely to become seriously sick. **To date, more than 1,500 people have been infected by H7N9 worldwide since early 2013, according to WHO** .

About HD-MAP needle-free vaccines

The Vaxxas high-density microarray patch (**HD-MAP**) is comprised of thousands of microscopic projections molded into a small patch. Each microprojection is 'printed' with a small dose of vaccine in a dried formulation. When applied to the skin, the patch delivers the vaccine to the abundant immune cells that naturally reside immediately below the skin surface.

HD-MAP vaccine delivery offers many potential benefits over more traditional ways of administering vaccines. For example, the dried form of the vaccine is more stable at higher temperatures than vaccines in liquid formulations, therefore potentially reducing the need for cold-chain storage and distribution.

Vaxxas's **HD-MAPs have proven safe and tolerable in hundreds of trial participants to date** , and have been shown to induce equal or greater immune responses to injected vaccines at lower doses. Compared with needle and syringe systems, HD-MAP vaccines are also much easier to administer and are likely to have greater acceptability.

Ultimately, HD-MAP patches could enable a future in which vaccine patches could be delivered directly to peoples' homes, workplaces, and schools for self-administration, avoiding the delay and inconvenience of traditional needle-and-syringe vaccine scheduling and administration. In a pandemic situation, this distribution method could also avoid large groups of people having to congregate in central locations for vaccination, reducing the risk of further infections.

About Vaxxas

Vaxxas is a privately held biotechnology company focused on enhancing the performance of existing and next-generation vaccines with its proprietary high-density microarray patch (HD-MAP). Vaxxas is targeting initial applications in infectious diseases and oncology.

With success in several completed human clinical trials involving more than 500 participants; additional ongoing Phase I clinical studies targeting pandemic influenza, funded by the Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, Vaxxas' HD-MAP vaccine delivery platform is advancing toward

commercialization.

Vaxxas' core technology was initially developed at The University of Queensland (UQ), and the company was established as a start-up in 2011 by UQ's commercialization group UniQuest. The company was founded with the completion of an initial equity financing led by OneVentures Innovation Fund I with co-investors Brandon Capital Partners and US-based HealthCare Ventures, followed by a further financing led by OneVentures with UQ joining the most recent financing.

OneVentures Innovation Fund I and Brandon BioCatalyst are supported by the Australian Government's Innovation Investment Fund (IIF) program. The IIF is an Australian Government venture capital initiative that provides investment capital and managerial expertise through licensed venture capital fund managers to investee companies. Learn more at **One-Ventures** and **Brandon Capital** .

CAUTION

The Vaxxas HD-MAP delivered vaccines are under investigation and available only for investigational uses. They are not available anywhere in the world for sale or purchase. As such, Vaxxas makes no claim that the vaccines are reliable, durable, dependable, safe, or effective, and makes no claim that it is superior to any other vaccine or vaccine delivery technology.

MEDIA

Vaxxas - In United States:
Kathryn Morris
The Yates Network
+1 914 204 6412
kathryn@theyatesnetwork.com

Vaxxas - In Australia:
Amy Miller
WE Communication
+61 431 072 422
amymi@we-worldwide.com

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