Vaxxas Publication in *PLoS Medicine* Reveals Groundbreaking Clinical Research on Broad Potential of Novel High-Density Microarray Patch (HD-MAP) to Efficiently Deliver Vaccines Directly to the Skin, Enhancing Immunogenicity

- *Largest microarray patch clinical vaccination study ever performed*
- *First clinical microarray patch study to show dose sparing against standard intramuscular injection with comparable immune responses at a 1/6 dose*
- *HD-MAP immune response significantly higher, faster than by IM injection at comparable doses*
- *Vaccine on HD-MAP shown to be stable for 12 months at temperatures as high as 40°C*

Cambridge, Mass., USA, and Brisbane, Queensland, Australia – March 17, 2020 (USA)/March 18, 2020 (Australia) – Vaxxas, a clinical-stage biotechnology company commercializing a novel vaccination platform, today announced the publication in the journal *PLoS Medicine* of groundbreaking clinical research indicating the broad immunological and commercial potential of Vaxxas' novel high-density microarray patch (HD-MAP). Using influenza vaccine, the clinical study of Vaxxas' HD-MAP demonstrated significantly enhanced immune response compared to vaccination by needle/syringe. This is the largest microarray patch clinical vaccine study ever performed.

In addition, using the HD-MAP, a 2.5 µg dose (1/6 of the standard dose) induced immune responses comparable to those induced by a standard dose of 15 µg injected IM, validating the dose-sparing potential of Vaxxas platform. In situations such as response to a pandemic, smaller doses could enable many more patients to be vaccinated by HD-MAP than by IM injection from a limited available volume of vaccine.

At higher doses of 10 and 15 µg, HD-MAP produced significantly high titers and faster onset kinetics than 15 µg injected IM (the standard dose). The CDC estimates that each year as many as 500,000 deaths occur due to influenza globally, and that in the United States, average mortality associated with influenza is more than 37,000 people for each year since 2010. Faster immune response achieved from the HD-MAP provides the potential to establish protection from infection in days instead of weeks, a significant public health benefit that could be extremely important for both seasonal and pandemic influenzas. In addition, higher overall immune responses provide the potential for disease protection that could span the duration of the annual flu season.

"We are extremely excited to publish these compelling clinical results showing the potential of our proprietary vaccination platform to deliver vaccines safely and effectively – including at lower doses -- than conventional approaches," said David L. Hoey, President and CEO of Vaxxas. "Microarray patches – like Vaxxas' HD-MAP – have long been viewed as having game-changing potential by targeting the active immune cells in the skin. With the significant demonstrated immune responses in this study, Vaxxas' HD-MAP is the first-ever needle-free platform to clinically validate such a compelling immunological profile."

In the journal article published in *PLoS Medicine*, the vaccine HD-MAP was stable when stored at 40°C (104°F) for at least 12 months, providing the potential for easy distribution without the cost and complexity of continuous refrigeration. Furthermore, the company is currently performing a clinical study in which self-administration of the HD-MAP is being studied. The combination of these features could be extremely beneficial, subject to regulatory approval, in situations such as annual seasonal influenza vaccinations and pandemic response to prevent the need for populations to congregate to have a vaccine administered.

"With vaccine coated onto Vaxxas HD-MAPs shown to be stable for up to a year at 40°C, we can offer a truly differentiated platform with a global reach, particularly into low and middle income countries or in emergency use and pandemic situations," said Angus Forster, Chief Development and Operations Officer of Vaxxas and lead author of the *PLoS Medicine* publication. "Vaxxas' HD-MAP is readily fabricated by injection molding to produce a 10 x 10 mm square with more than 3,000 microprojections that are gamma-irradiated before aseptic dry application of vaccine to the HD-MAP's tips. All elements of device design, as well as coating and QC, have been engineered to enable small, modular, aseptic lines to make millions of vaccine products per week."

The *PLoS* publication reported results and analyses from a clinical study involving 210 clinical subjects. The clinical study was a two-part, randomized, partially double-blind, placebo-controlled trial conducted at a single Australian clinical site. The clinical study's primary objective was to measure the safety and tolerability of A/Singapore/GP1908/2015 H1N1 (A/Sing) monovalent vaccine delivered by Vaxxas HD-MAP in comparison to an uncoated Vaxxas HD-MAP and IM injection of a quadrivalent seasonal influenza vaccine (QIV) delivering approximately the same dose of A/Sing HA protein. Exploratory outcomes were: to evaluate the immune responses to HD-MAP application to the forearm with A/Sing at 4 dose levels in comparison to IM administration of A/Sing at the standard 15 µg HA per dose per strain, and to assess further measures of immune response through additional assays and assessment of the local skin response via punch biopsy of the HD-MAP application sites. Local skin response, serological, mucosal and cellular immune responses were assessed pre- and post-vaccination.

The publication in *PLoS Medicine*, "Safety, tolerability, and immunogenicity of influenza vaccination with a high-density microarray patch: Results from a randomized, controlled phase I clinical trial," by Angus H. Forster et al, is available here.

About Vaxxas

Vaxxas is a privately held biotechnology company focused on enhancing the performance of existing and next-generation vaccines with its proprietary HD-MAP technology platform, which uses an ultra-high density array of projections – invisible to the naked human eye – applied to the skin to rapidly deliver vaccine to the abundant immune cells immediately below the skin surface. This approach can enhance efficiency and effectiveness of immune response. Vaxxas uses proprietary dry-coating technology that can eliminate or significantly reduce the need for vaccine refrigeration during storage and transportation – easing the resource and logistics burden of maintaining the "cold chain." Leveraging the potent immunogenic response and thermostability of HD-MAP, Vaxxas is targeting initial applications in infectious disease and oncology.

Vaxxas was founded in August 2011 with the completion of an initial equity financing led by OneVentures Innovation Fund I with co-investors Brandon Capital, the Medical Research Commercialisation Fund (MRCF), and US-based HealthCare Ventures, followed by a further financing in 2015, led by OneVentures. OneVentures Innovation Fund I and the MRCF 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 www.one-ventures.com and www.brandoncapital.com.au.