Vaxxas Awarded US$5 million [AU$7.5 million] Grant for Clinical Study of Measles and Rubella Vaccination using Vaxxas' High Density Micro-Array Patch

Funding Accelerates Vaxxas' Clinical Pipeline of Innovative Vaccines

Cambridge, Mass., USA, and Brisbane, Queensland, Australia – March 17, 2020 (USA)/March 18, 2020 (Australia) – Vaxxas, a biotechnology company commercializing a novel vaccination platform, today announced that it has received a US$5 million [AU$7.5 million] grant to conduct initial human clinical studies using Vaxxas' High Density Microneedle Array Patch (HD-MAP) for measles and rubella vaccination. This funding is provided by the Bill & Melinda Gates Foundation and builds on an earlier grant by the foundation of US$4.5 million [AU$6.75 million] focused on preclinical development.

The new funding will be used for IND-enabling studies and a first-in-human clinical study for measles and rubella vaccination using Vaxxas' advanced HD-MAP platform. The measles and rubella vaccine formulation used to coat the HD-MAP has been engineered to be stable at higher temperatures than required for needle/syringe vaccination. This improved thermal stability can reduce the cost and complexity of the cold distribution chain that is required for many conventional vaccines, enabling distribution of HD-MAP vaccines to parts of the world where refrigeration is unreliable or even nonexistent.

According to the World Health Organization, more than 140,000 deaths in 2018 occurred due to measles, mostly in children under five years of age. "Measles virus is a sensitive measure of universal health coverage, so measles virus detects and announces failure of the health system to reach all children," said Professor David Durrheim, University of Newcastle and Chair of the Western Pacific Measles and Rubella Regional Verification Commission. "Despite global goals for measles elimination before 2020, progress has stalled. In 2018 and 2019, inadequate measles vaccine coverage resulted in a massive global resurgence of preventable measles cases and deaths."

"New vaccine delivery methods are urgently needed that overcome the current limitations of needle and syringe vaccine delivery by skilled health professionals with reliable refrigeration," Professor Durrheim continued. "We need methods that reach every child no matter how remote they are with potent vaccine. Micro-array patches may be this game-changer."

"We are excited to continue this important work with the Bill & Melinda Gates Foundation to advance the HD-MAP into clinical testing for measles and rubella vaccination," said David L. Hoey, President and CEO of Vaxxas. "We believe our HD-MAP platform can play a key role by extending the reach of this life-saving vaccine. Building upon the recent success of our HD-MAP in human clinical studies using influenza vaccine, we are committed to advancing multiple clinical programs to further validate the significant benefits the HD-MAP can bring to a range of vaccines for major diseases, including polio, bacterial infections, and cancer."

The clinical program using HD-MAP in measles and rubella builds on the body of human clinical studies with more than 270 volunteers that have validated the safety, tolerability, and vaccine delivery potential of Vaxxas' HD-MAP. The proprietary HD-MAP platform induces robust immune system activation by targeting relevant vaccine components to the abundant immunological cells immediately below the surface of the skin. In Vaxxas' most recent clinical study evaluating performance using influenza vaccine, the HD-MAP using 1/6 dose induced similar immune response to full dose by needle and syringe.

Through the grant funding of the foundation, Vaxxas will optimize its HD-MAP measles and rubella vaccine in a number of important ways, including ensuring the vaccine is stable for a period at room temperature combined with a product design that will allow the vaccine to be administered by individuals with minimal to no formal medical training as may be necessary in certain countries and regions.

Vaccines save millions of lives each year and are among the most cost-effective health interventions ever developed. Indeed, between 2000 and 2018, there has been a 73 percent reduction in childhood deaths from measles. Despite these great strides, there remains an urgent need to reach all children with life-saving vaccines. One in five children worldwide is not fully protected with even the most basic vaccines, and an estimated 1.5 million children die each year—one every 20 seconds—from vaccine-preventable diseases. Tens of thousands of other children suffer from severe or permanently disabling illnesses. Vaccines are often expensive for the world's poorest countries, and supply shortages and a lack of trained health workers are challenges as well. Unreliable transportation systems and storage facilities also make it difficult to preserve high-quality vaccines that require refrigeration.

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.