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Human Vaccines Project presents initial findings from first clinical trials

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Scientists leading the clinical programs for the Human Vaccines Project reported today high-level outcomes from two concurrent clinical studies aimed at deciphering the components and mechanisms used by the human immune system to prevent and control disease at the World Vaccine and Immunotherapy Congress in San Diego, Calif. The findings from the studies may provide important new insights on human immunity that the Human Vaccines Project - a public-private partnership aimed at decoding the immune system to advance human health - will leverage to launch expanded studies in 2018.

The Project's first program, the Human Immunome Program, aims to identify the core components that exist across everyone's immune systems and utilize this information to enable development of new and improved vaccines. The team is sequencing millions of recombined and expressed B and T cell genes in healthy adults and cord blood samples at an unprecedented depth, seeking to identify shared elements of the human immune system not previously recognized. The team is led by James E. Crowe, Jr., MD, Director of Vanderbilt University Medical Center's Vaccine Center, the scientific hub of the Human Immunome Program.

"We are studying the immune systems of healthy individuals to identify common elements, which could be important for facilitating new and improved vaccines," explained Dr. Crowe. "We also plan to expand these studies to complete the catalog across different demographics and geographies and compare healthy subjects with individuals with immune-

mediated diseases such as multiple sclerosis, cancer and Alzheimer's, which could also reveal novel diagnostic markers."

Early findings from a second and complementary clinical research program of the Human Vaccines Project, aimed at revealing the key principles or rules that the human immune system follows when it comes to the prevention and control of disease, will be shared in two separate presentations by Manish Sadarangani, MD, PhD, Director of the Vaccine Evaluation Center of the University of British Columbia and BC Children's Hospital Research Institute and Richard Scheuermann, PhD, Director, J. Craig Venter Institute. The long-term goal of this program is to understand the rules of the human immune system that will enable one-shot vaccines to provide long term protective immunity in all populations. The aim of this study is to understand why some people respond effectively to a single immunization of a licensed Hepatitis B vaccine, while others require up to three immunizations for generating protective immunity.

Using novel artificial intelligence and machine-learning techniques to analyze large sets of data, the team sought to determine if activation of marker genes from innate immune cells - non-specific defense mechanisms - would distinguish between responders to vaccines and non-responders.

Preliminary data, comparing three HepB vaccine responders to three non-responders showed that activation of marker genes in subsets of innate immune cells could predict those people that made detectable serum antibody responses against HepB vaccine after a single immunization.

"These preliminary data points toward strategies to understand why some people respond better to vaccines than others," suggested Dr. Sadarangani. "We plan to expand this trial to include populations of all ages across all resource settings to provide the most comprehensive

analysis of any vaccine ever undertaken."

"Using single cell analyses, we now have the opportunity to probe vaccine-induced responses more effectively, to not only learn what happens immediately after vaccination, but to monitor responses over time and utilize machine learning to eventually predict the human immune response to vaccines," said Dr. Scheuermann.

"We are optimistic about the outcome of these early stage findings. They provide important insights into the scale and complexity of the human immune system and how vaccines confer protective immunity. With our network of academic and corporate partners, we aim to build on these findings and decode the human immune system, giving the world the tools required to advance the development of future vaccines and therapies to defeat major global diseases," added Wayne C. Koff, PhD, President and CEO of the Human Vaccines Project.

More information: www.humanvaccinesproject.org/

Provided by Human Vaccines Project