

# IVI to develop an adaptive Phase 1b/2a schistosomiasis vaccine clinical trial

SEOUL, REPUBLIC OF KOREA, May 31, 2021 /EINPresswire.com/ -- The International Vaccine Institute (IVI) announced today that the Bill & Melinda Gates Foundation awarded a grant to IVI to develop an adaptive trial design protocol for a Phase 1b/2a clinical trial of a schistosomiasis vaccine.

The grant is a Trial Planning Grant, part of the Gates Foundation's Design, Analyze, Communicate (DAC) program which supports grantees in optimizing clinical studies for informativeness and impact. The goal of IVI's schistosomiasis vaccine project is to advance the development of a safe, effective, and affordable vaccine to reduce morbidity and mortality from schistosomiasis in moderate- to high-transmission settings.

Dr. Florian Marks, Deputy Director General of Epidemiology, Public Health, and Impact at IVI, said: "A safe, effective, and accessible vaccine is the most sustainable solution to breaking the devastating cycle of Schistosomiasis infection and will save lives and improve the livelihoods of hundreds of millions of people. We are grateful to the Gates Foundation for their support and guidance in planning an adaptive Phase 1b/2a clinical trial for a schistosomiasis vaccine candidate which would accelerate the clinical development timeline as well as licensure and pre-qualification processes."

Dr. Thea Norman, PhD, leader of the Design, Analyze, Communicate program, said: "IVI is an exemplar of the type of partner that DAC Program looks for. IVI was an early adopter of our trial planning grants, is operating out in the field in low-resource settings, and now adds an approach to answer more questions during a trial."

IVI's schistosomiasis vaccine project has successfully sourced funding from the National Institute of Allergy and Infectious Diseases (NIH) and EU Horizon 2020 to support Phase 1 clinical trials of the SchistoShield vaccine. These trials include a first-in-human safety study in healthy American adults at an NIH Vaccine and Treatment Evaluation Unit followed by a Phase 1b safety and immunogenicity placebo-controlled study in healthy adults in Burkina Faso and Madagascar. With this Trial Planning Grant from the Gates Foundation, the IVI team will be able to adapt the Phase 1b study design, that could help speed up clinical development of the vaccine.

Dr. Tarun Saluja, Research Scientist at IVI, said: "With the IVI team's experience in designing adaptive trial designs for various vaccine candidates, we are looking forward to this opportunity

to develop a comprehensive, responsive, and efficient protocol to advance a critically needed schistosomiasis vaccine while ensuring the highest standards for patient safety and data integrity.”

#### About Schistosomiasis

Schistosomiasis is a parasitic disease caused by trematode worms of the genus *Schistosoma* and is the cause of significant morbidity for an estimated 200 million people, with an additional 779 million individuals at risk for infection with the highest burden in sub-Saharan Africa. The only currently available treatment is praziquantel (PZQ), which is effective against all *Schistosoma* species; however, PZQ treatment does not prevent re-infection and mass drug administration programs have shown sub-optimal outcomes and low sustainability.

#### About SchistoShield

SchistoShield® (Sm-p80 adjuvanted in GLA-SE) is an anti-schistosomal vaccine candidate that has shown a satisfactory safety and good efficacy profile in non-human primate studies. The candidate exhibits multiple mechanisms of action in the Schistosome life cycle and thus could potentially prove a valuable tool to break the cycle of schistosomiasis infection.

#### About the International Vaccine Institute (IVI)

The International Vaccine Institute (IVI) is a nonprofit inter-governmental organization established in 1997 at the initiative of the United Nations Development Programme (UNDP). IVI has 36 signatory countries and the World Health Organization (WHO) on its treaty, including Korea, Sweden, India, and Finland as state funders.

Our mandate is to make vaccines available and accessible for the world’s most vulnerable people. We focus on infectious diseases of global health importance such as cholera, typhoid, shigella, salmonella, schistosomiasis, chikungunya, Group A Strep, Hepatitis A, HPV, TB, HIV, MERS, COVID-19, as well as antimicrobial resistance. For more information, please visit

<https://www.ivi.int>

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