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News Release

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Humanitarian Effort to Eradicate Schistosomiasis Enters Important Stage

Siddiqui Research Advances as First Human Receives SchistoShield® Vaccine

As the needle delivered the first-ever dose of SchistoShield® vaccine into the waiting arm of a human being infected with schistosomiasis, its developer, Afzal A. Siddiqui, Ph.D., director of the Center for Tropical Medicine and Infectious Disease at the Texas Tech University Health Sciences Center (TTUHSC), experienced a mishmash of emotions. Similar to witnessing the birth of a child, he was simultaneously filled with joy and fear and other feelings were new to him.

"You are very happy that what you have done has reached a stage where it could, if it works, help a lot of people," Siddiqui described. "And you're also scared because you are responsible for putting this into humans, so you have to believe 100% in your studies and in your research. I think it was the kind of feeling which I never experienced before, the feeling of satisfaction as a scientist because that's what we shoot for: to take things from bench all the way to bedside."

Primarily found in sub-Saharan Africa, the Middle East, Southeast Asia and the Caribbean, schistosomiasis is second only to malaria as a deadly tropical parasitic disease. Also called snail fever, schistosomiasis is caused by parasitic flatworms known as schistosomes that inhabit contaminated fresh water. When a person comes into contact with contaminated water, the schistosomes access the human bloodstream through the skin, and then most often make their way to the urinary tract or the intestines. Long-term schistosomiasis can lead to liver damage, kidney failure, infertility, bladder cancer and death. It also can lead to increased vulnerability to many sexually transmitted diseases, including HIV.

An estimated 250 million people are currently infected with schistosomiasis and approximately 800 million more are at risk in the 79 countries where the disease is considered to be endemic. Praziquantel, which was developed more than 40 years ago, is currently the only effective drug treatment for the disease, though re-infection frequently occurs following its use.

Siddiqui, a Grover E. Murray Distinguished Professor in TTUHSC's School of Medicine, began his quest to develop a schistosomiasis vaccine in 1991. With funding from the National Institutes of Allergies and Infectious Diseases (NIAID) at the National Institutes of Health (NIH) and the Thrasher Foundation, he began conducting bench studies and pre-clinical development of what was known as the *Sm-p80/GLA-SE schistosomiasis vaccine*, which would eventually be branded SchistoShield®.

In 2014, Siddiqui became the first at TTUHSC to secure funding from the Bill and Melinda Gates Foundation, which he used to conduct proof of concept studies on *Sm-p80/GLA-SE*. As his march toward a viable vaccine picked up momentum, Siddiqui also became the first TTUHSC investigator to receive funding from the European Union's Vaccine Against Schistosomiasis for Africa (VASA) Program, the United Kingdom's Wellcome Trust and South Korea's Right Fund.

Since he first began working on a schistosomiasis vaccine, one of Siddiqui's fundamental goals was to develop a treatment that would be produced for humanitarian purposes rather than profit. In fact, when current Texas Tech University System Chancellor Tedd L. Mitchell, M.D., was serving as TTUHSC president, he and Siddiqui convinced others within the system to do the project as a humanitarian effort.

"This was a real effort on the part of TTU to get this thing out and not have any royalty or anything of that sort," Siddiqui explained. "I'm not getting anything; the university and the system isn't getting anything with regards to dollars. We just want to get this thing out, and if it helps, that's what we would like to see."

The NIH also played a major role in supporting Siddiqui's humanitarian goals through its Small Business Initiative, which provides funding to small businesses conducting such efforts. Siddiqui said he also was lucky to cross paths with PEI Life Sciences, a Seattle-based company with an interest in neglected tropical diseases.

"With PEI we got more than $10 million in funding from the NIH over the last 10 years to do this work, so they were the really the engine which moved this further," Siddiqui added.

To maintain the humanitarian effort, Siddiqui in 2016 received a patent for SchistoShield® in several countries. He took another important step in February 2018 when he signed TTUHSC's first-ever license agreement related to SchistoShield with PAI Life Sciences. The company has worked with Siddiqui since that time to meet certain Gates Foundation requirements, such as conducting double blinded, clinical, non-human primate trials. In those initial trials, SchistoShield® demonstrated it could kill adult schistosomes and significantly reduce their ability to lay eggs and reproduce.

During the upcoming Phase 1, open-label, dose-escalation trial, Siddiqui, PAI and others will evaluate the vaccine's safety and the immunogenicity in 45 healthy adults between the ages of 18 and 55 years. The study participants will be divided into five treatment groups, each consisting of nine individuals who will receive three intramuscular injections of different dosages. One group will receive the vaccine without an adjuvant, which increases the body's immune responses, while the other four will receive the vaccine without an adjuvant. That study is expected to run through April 2024.

After Phase I trials in the U.S. and Phase 1b trials in Madagascar and Burkina Faso in Africa, Siddiqui said vaccine efficacy trials in schistosome human challenge models in The Netherlands and Uganda (Africa) will begin in 2023. He and PAI are currently negotiating Phase 2 trials with the Gates Foundation, which he expects to be in place by the coming fall.

If everything goes according to plan during the Phase 1, Phase 1-B and Phase 2 human challenge models, licensing the vaccine could be accelerated. Siddiqui said that means the vaccine could be ready for distribution through WHO, Gavi (the Vaccine Alliance) and other nonprofits in five to 10 years. The vaccine's performance during efficacy trials will be a key factor in firming up that timeframe.

"It's a long process; it takes decades to find out the effect of the vaccine in these kinds of situations because we're talking about places like Africa [where] you not only have this disease, but you have so many others," Siddiqui said. "You see those kids with bulging bellies; they are carrying not only one, but several parasites. We are trying to fix one, but there are others, so unless you fix all of the other parasites with vaccines or some other approach, we wouldn't know the real impact. But we are getting into this process where, little by little, we're trying to eliminate these diseases as we get more resources to gain more knowledge."

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