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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,"