First-in-class DNA-encoded monoclonal antibody therapy rapidly advances into the clinic

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The Wistar Institute, along with partners Penn Medicine and Inovio Pharmaceuticals, Inc., announce that the FDA has approved the initiation of a first-in-human clinical trial investigating the safety and tolerability of a novel synthetic DNA-encoded monoclonal antibody (DMAb) therapeutic technology for the prevention of Zika virus infection.

DMAb therapeutic technology is unlike all known conventional therapeutic antibodies in that DMAbs are made inside of people, not manufacturing plants. Patients are administered DNA instructions to equip their bodies with the necessary tools to make their own highly specific antibodies against pathogenic targets such as bacteria, virus-infected cells and cancer cells.

David B. Weiner, Ph.D., executive vice president, director of the Vaccine Center, and the W.W. Smith Charitable Trust Professor in Cancer Research at Wistar, has been leading the research and development of the DMAb technology.

"DMAb technology is changing the clinical story as we know it. In just the last few years we've conducted detailed preclinical studies developing this new platform and have demonstrated in vivo production of DMAbs using the CELLECTRA delivery system," said Weiner. "This approach represents the potential for major advancement over traditional monoclonal antibody approaches and may broaden therapeutic strategies opening new patient markets to the benefits of antibody-based therapies for disease prevention or treatment."

In 2016, The Bill & Melinda Gates Foundation awarded funding to The Wistar Institute to move DMAb technology from prototype into a clinical candidate for eradicating an emerging infectious disease.

Within two short years, a phase 1 clinical trial for Zika DMAbs is now enrolling participants. The trial will be led by Pablo Tebas, M.D., professor of infectious diseases at the Perelman School of Medicine at the University of Pennsylvania. It is a single center, open-label, dose escalation trial that will enroll up to 24 healthy volunteers who will receive up to four doses of Inovio vaccine/product INO-A002.

"This is a completely novel technology that could change the way we deliver antibodies as therapeutic agents and may have the potential to be fast-tracked into clinical trials. While there are still questions to be answered, this could be useful not only for Zika, but for other emerging infections as well," said Tebas.

"While this trial targets Zika virus infection, we will gain important data from this study towards development of a broad range of our DMAb programs targeting infectious diseases, cancer, inflammation, as well as cardiovascular disease," said J. Joseph Kim, Ph.D., president and CEO, Inovio Pharmaceuticals, Inc. "Our collective goal is to develop this new and unique approach to monoclonal antibody technology that would allow for a new pipeline of high-impact DMAb products, which can be developed with corporate partnerships, external funding and collaborations."

Provided by The Wistar Institute