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## **Human Trials Begin for Army-Developed Zika Purified Inactivated Virus (ZPIV) Vaccine**

SILVER SPRING, Md. – The Walter Reed Army Institute of Research (WRAIR) began vaccinations today in a Phase 1 human clinical trial to test the safety and immunogenicity of the Zika purified inactivated virus (ZPIV) vaccine.

Seventy-five healthy adults will be recruited to participate in the trial at WRAIR's Clinical Trial Center in Silver Spring, Md. Given the concerns for immune enhancement with other similar flaviviruses, like yellow fever and Japanese encephalitis, ZPIV will be tested in some volunteers who will first be vaccinated against one of these other flaviviruses. This is of particular military relevance, as service members are often vaccinated against these diseases and then deployed to areas where Zika is increasingly becoming endemic.

WRAIR scientists developed the ZPIV vaccine candidate earlier this year. The inactivated flavivirus vaccine platform was the same technology the Institute used to create its Japanese encephalitis vaccine, which was licensed in 2009. An earlier preclinical study found that rhesus monkeys that were vaccinated with ZPIV developed a strong immune response and were protected against two strains of Zika virus.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), helped identify the viral strain used in the ZPIV vaccine, supported the preclinical safety testing, and is sponsoring the conduct of this trial. WRAIR, NIAID, and the Biomedical Advanced Research and Development Authority (BARDA) have established a joint research collaboration agreement to support the development of this vaccine.

In addition to concerns about infection during deployment and travel, most military installations in the continental U.S. are concentrated in the southern states, where climate conditions and mosquito populations are favorable for Zika transmission.

Col. Nelson Michael, director of WRAIR's Military HIV Research Program (MHRP) and Zika program co-lead noted that, "The Army has moved efficiently from recognizing Zika virus as a threat, producing ZPIV for use in animals and demonstrating its effectiveness

in mice and monkeys, producing ZPIV for human testing, and now initiating clinical trials to establish its safety and build the case for subsequent efficacy trials. All of this was done in 10 months.”

This study is part of the U.S. Department of Defense response to the ongoing outbreak of Zika virus in North and South America and Southeast Asia. As of November 2, there were 149 confirmed cases of Zika virus within the military health system, including four pregnant service members and one pregnant family member.

"Asymptomatic Zika infections can lead to severe birth defects and neurological complications. A safe and effective Zika vaccine that prevents infection in those at risk is a global public health priority," said Maj. Leyi Lin, principal investigator of the study. The Pilot Bioproduction Facility at WRAIR manufactured the ZPIV vaccine being used in Phase 1 clinical studies, and the Army recently signed a cooperative research and development agreement to transfer the ZPIV technology to Sanofi Pasteur to explore larger scale manufacturing and advanced development. BARDA recently awarded a six-year contract to Sanofi Pasteur to further develop this vaccine to licensure.

“The Army was able to move so quickly in developing, manufacturing and testing a Zika vaccine because of its extensive experience with this vaccine platform and long standing investments in the understanding and mitigation of flaviviruses, like yellow fever, dating back to the founding of WRAIR,” said Dr. Kayvon Modjarrad, Zika program co-lead and associate director for Emerging Infectious Disease Threats at WRAIR’s MHRP.

WRAIR’s ZPIV candidate will also be included as a part of a NIH trial that began in August. That study will test ZPIV in a group of people who first receive the DNA vaccine and then are boosted with the ZPIV vaccine. Three additional Phase 1 trials using ZPIV are scheduled to begin this year:

- St. Louis University researchers, through the NIAID-funded Vaccine and Treatment Evaluation Units network, will examine the optimal dose of the vaccine to be used in larger studies.
- Beth Israel Deaconess Medical Center and Harvard Medical School researchers will evaluate the safety and immune response from a compressed vaccine schedule.
- The clinical research center CAIMED, part of Ponce Health Sciences University in Puerto Rico, will examine the vaccine’s safety and immunogenicity in participants who have already been naturally exposed to Zika or dengue viruses

The WRAIR trial that began today is sponsored by NIAID and funded by the Departments of the Army and Defense.

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**About the Walter Reed Army Institute of Research**

Headquartered in Silver Spring, Maryland, the Walter Reed Army Institute of Research (WRAIR) is the oldest and most mission diverse biomedical research laboratory in the Department of Defense. WRAIR provides unique research capabilities and innovative solutions to a range of force health and readiness challenges currently facing U.S. Service Members, along with threats anticipated during future operations. With comprehensive research units in Africa, Asia, and the Caucasus region, WRAIR is comprised of two Centers of Excellence, the Center for Infectious Disease Research and the Center for Military Psychiatry and Neuroscience.