

## NMRC Set to Begin Phase 1 Dengue DNA Vaccine Trial

Researchers from the Naval Medical Research Center's (NMRC) Infectious Diseases Directorate will begin a Phase 1 dengue vaccine trial in December at the Walter Reed Army Institute of Research (WRAIR) Clinical Trials Center in Silver Spring, Md. Transmitted by the *Aedes aegypti* mosquito, dengue is one of the most common viral infections deployed personnel can acquire when stationed in tropical areas of the world. Dengue infection can be incapacitating and harmful to Department of Defense missions and no treatment is available to prevent infection; a vaccine is critically needed.

"The increase in dengue endemicity worldwide raises the likelihood of multiple exposures for deployed U.S. military personnel, potentially increasing their risk for developing the more severe forms of the disease – dengue hemorrhagic fever and dengue shock syndrome," said Lt. Cmdr. Janine R. Danko, principal investigator on the study and an internist and infectious diseases subspecialist. "The goal of our dengue vaccine program is to develop a safe and effective vaccine that protects against dengue."

The NMRC team has been preparing for this study for the past two years. The core team incorporates NMRC scientists and physicians, three physicians from the Walter Reed Army Institute of Research, and industry partners.

A Food and Drug Administration (FDA) phase 1 trial is the first clinical study in a small number of volunteers that evaluates the safety of the new vaccine. This 12-month study includes forty volunteers who will be assigned to three dose groups and followed through several visits and laboratory assessments with the study team physicians. The research team intends to compare the immune responses among the three groups.

The FDA's positive review of



NMRC team, back row: Thomas Luke, MD, Lt. Cmdr. Tad Kochel, Capt. Kevin Porter. Front row: Peifang Sun, Ph.D, Lt. Cmdr. Janine Danko, Seema Mirje. Not pictured: Cmdr. Teneza-Mora, Dr. Kankatte Raviprakash, Maj. James Moon, Lt. Col. Stephen Thomas, Maj. Luis Martinez, Cmdr. Timothy Burgess. Photo by Phil Collins.

NMRC's Investigational New Drug application for the vaccine this fall permits the research team to move forward to the next stage in the vaccine development process. This approval is the result of a successful preclinical development program and a sound, practical and safe clinical trial design as described in the clinical trial protocol. The FDA will provide oversight, ensuring the study will produce useful information to assess the safety and efficacy of the vaccine.

"Our vaccine is DNA-based and was created and patented by several scientists in our department. The advantages of DNA-based vaccines include their simplicity of construction and modification, their relatively low cost of production, stability at room temperature, and their safety based on published data," said Danko. "We're

excited to start this clinical trial and are hopeful for promising data to lead us to a larger and dose-finding Phase II trial."

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