Inviragen and PharmaJet Receive $15.5 Million NIAID Contract to Develop a Needle-free Dengue Vaccine

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Fort Collins, Colorado and Golden, Colorado

Inviragen and PharmaJet announced the award of a five year, $15.5 million dollar contract from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to advance the development of a needle-free, easy to administer dengue vaccine. The award will fund preclinical studies, regulatory filings, manufacturing and clinical testing of Inviragen's tetravalent dengue vaccine, DENVax™ delivered with PharmaJet's convenient needle-free injection device.

"This NIAID contract will allow Inviragen and PharmaJet to continue our pioneering development of a needleless dengue vaccine," commented Dr. Dan Stinchcomb, Inviragen's Chief Executive Officer. "The PharmaJet injector has many properties that make it ideal for administering a dengue vaccine worldwide, potentially saving lives in affected countries and reducing the spread of the disease to new regions."

Over 3.5 billion people live in countries that have frequent dengue outbreaks. The four dengue viruses are spread amongst humans by mosquitoes and cause an estimated 30 to 50 million cases of debilitating dengue fever and 0.5 to 2 million cases of life-threatening dengue hemorrhagic fever every year. A recent dengue outbreak in Florida highlights the continuing global spread of the disease.

"People of all ages fear needles and safe disposal of needle waste is a constant problem for health care providers. A needle-free dengue vaccine would be welcomed by patients in endemic countries and by travelers worldwide and could protect them from this

devastating disease," said Dr. Linda McAllister, PharmaJet's interim Chief Executive Officer. "In this collaboration, PharmaJet will develop 'needle-free' syringes compatible with our jet injection technology for pre-filling with Inviragen's novel dengue vaccine."

Inviragen's DENVax vaccine, developed by researchers at the CDC's Division of Vector-Borne Diseases, is based on an attenuated DEN-2 virus that generates long-lasting anti-dengue immune responses. CDC scientists engineered this clinically tested, weakened DEN-2 virus to express DEN-1, DEN-3 or DEN-4 structural genes. DENVax is a four-way mixture of the three engineered viruses and the original DEN-2 strain. Inviragen has completed preclinical testing, formulation, and manufacturing of DENVax. Phase 1 clinical safety testing of DENVax, delivered by traditional needle and syringe, began earlier this year. Other dengue vaccine technologies in clinical testing require multiple injections with long intervals between doses. The goal of the Inviragen/PharmaJet collaboration is to develop a needle-free dengue vaccine delivery platform that can rapidly induce neutralizing antibody response after one or two easily administered doses.

PharmaJet's jet injector creates a fine stream of pressurized liquid that penetrates the skin, quickly and effectively delivering doses of medicines and vaccines into different tissues. Jet injection eliminates needles from the process of administering vaccines and eliminates the costs and dangers associated with sharp needle waste. PharmaJet's technology is FDA-cleared for delivery into the muscle (intramuscular) and under the skin (subcutaneous). PharmaJet is developing jet injectors for delivery between the skin layers (intradermal). For some vaccines, intradermal delivery has the potential to reduce the amount of vaccine required, leading to cost savings and expanded coverage for vaccines in limited supply.

"In preliminary animal model studies, we used PharmaJet technology to deliver DENVax intradermally. The combination was safe, induced neutralizing antibodies to all four dengue serotypes and protected against dengue infection," noted Dr. Jorge Osorio, Inviragen's Chief Scientific Officer. "Our ongoing Phase 1 clinical trial is assessing the safety and immune responses after both subcutaneous and intradermal delivery of DENVax by needle. Under this NIAID contract, we aim to test DENVax delivery with the PharmaJet device in children and adults in South America and Southeast Asia, regions that are significantly impacted by dengue disease."

About Inviragen, Inc.

Inviragen is focused on developing vaccines to protect against infectious diseases worldwide. Inviragen's lead product candidate is a vaccine to protect against dengue fever. Inviragen is also developing vaccines to protect against hand, foot and mouth disease and Japanese encephalitis, both of which affect millions of children in Asia. Vaccines in preclinical research stages include a chikungunya vaccine, a low-cost human papilloma virus vaccine, vaccines to protect against new forms of influenza, a vaccine to protect against West Nile and a combination plague/smallpox vaccine for biodefense. Inviragen has offices in Colorado, Wisconsin and Singapore. Please see www.inviragen.com for more details.

About PharmaJet, Inc.

PharmaJet, Inc. is a privately held company located in Denver, Colorado, with offices and representatives also in San Francisco, California, Baltimore, Maryland, Chicago, Illinois, and Sao Paulo, Brazil. PharmaJet develops, manufactures and markets vaccine and drug delivery products based on its proprietary needle free jet injection technology. PharmaJet's US FDA 510(k) clearance relates to its 0.5 ml volume syringe, cleared for use with any liquid medicine. This technology is also cleared for use in the EU (CE Mark) and Brazil. The company meets GMP and ISO compliant standards for sterile single use products: 10993, 11737, 11607, and 11137. It is compliant with the ISO Quality Management System of 13485:2003, and the Needle Free Worldwide Standard of ISO 21649:2006. Please see http://www.pharmajet.com for more details.

Editor's note: for more information dengue fever, please the WHO website at www.who.int/topics/dengue/en or the Pediatric Dengue Vaccine Initiative (PDVI) website at www.pdvi.org/about_dengue/DF.asp.

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