Autoimmune Technologies LLC

Applied Biomedical Science

NIH Awards Contract of up to $10.8 Million to Autoimmune Technologies to Continue Developing Its New Influenza Drug

FOR IMMEDIATE RELEASE

New Orleans, March 6, 2014 - Autoimmune Technologies LLC, a New Orleans biomedical company, announced today that it has been awarded a drug development contract by the National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH). The contract will support the continued development of FF-3, the company's new antiviral influenza drug. If all project milestones are met, the NIAID contract, including its option period, will provide up to $10.8 million in funding over 30 months.

FF-3 is intended for the prevention and treatment of seasonal and pandemic influenza in adults and children. FF-3 works by stopping the flu virus from penetrating and infecting its target cells. FF-3 has successfully completed its FDA Phase 1 first-in-human clinical safety trial in nasal liquid spray form, and a Phase 1 trial of the oral dry powder spray formulation is scheduled to commence in the next several weeks. The NIAID contract will support additional virology studies and the first FDA Phase 2a human safety and efficacy clinical trial.

The FDA has designated the investigation of FF-3 for prophylaxis and/or treatment of Influenza A or Influenza B as a Fast Track development program.

Unlike most drugs, which are based on chemical compounds, the active ingredient in FF-3 is a small protein called a peptide. Researchers at Tulane University's School of Medicine have developed a technique through which a unique peptide can be designed to neutralize a specific virus and prevent the virus from causing infection. In addition to influenza virus, proprietary peptides designed in this way have exhibited high potency against SARS, MERS, West Nile, Hepatitis C, Dengue, Ebola, and other viruses.

FF-3 has been found to be highly effective against multiple seasonal and pandemic influenza viruses and has been shown to block influenza transmission in animal models of flu. In addition, several factors suggest that FF-3 may be less likely than some other drugs to give rise to viral mutations that can lead to the development of drug resistance.

"Peptide inhibitors of viral entry represent a new frontier in the development of effective anti-viral drugs for both human and veterinary use," said Dr. Russell B. Wilson, Autoimmune's president and chief science officer. "Peptides are generally much larger than the chemical ingredients that are used in most other drugs, and their greater size can give peptides a functionality that is beyond the capabilities of those small chemical molecules."

The initial virology work and animal testing for FF-3 was conducted at Tulane and Autoimmune, the formulations were developed at Xavier University of Louisiana's College of Pharmacy, and the

bioinformatics was done at Autoimmune and the Department of Computer Science at the University of New Orleans. Autoimmune's laboratories are located in the Research Institute for Children at Children's Hospital in New Orleans. Autoimmune has assembled a network of collaborators, consultants, and contract research organizations located throughout the United States, and the NIAID contract potentially involves more than a dozen subcontracts with other companies in the United States, Canada, and the United Kingdom.

"The growing depth of the biomedical industry in New Orleans is evident in the fact that three local universities and Children's Hospital have all played key roles in developing the new drug," said Michael D. Charbonnet, the company's CEO. "Also important is Autoimmune's success with implementing the virtual-drug-company model in building our drug development team. This virtual approach has enabled us to take advantage of the wealth of pharmaceutical industry talent and resources that are available throughout the U.S. and abroad."

Nathaniel P. Phillips, Jr., one of Autoimmune's founders and its co-manager, commented on the importance of the contract. "This award will accelerate the development of FF-3 as we continue on the path to FDA approval," he said. "The National Institutes of Health is the world's largest provider of medical research funds, and this contract represents a significant milestone for our company and its platform for developing anti-viral drugs."

Autoimmune Technologies was founded in 1995 to license and commercialize medical technology from Tulane. The company holds an exclusive worldwide license from Tulane to develop drugs and vaccines using the entry-inhibiting-peptide technology. Patents covering FF-3 have issued in many countries and additional patent applications are on file.

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The contract referred to herein is No. HHSN272201400003C. The development of FF-3 has also been supported by NIAID grant awards R41AI68230 and R44AI082778. The information contained herein is solely the responsibility of the authors and does not necessarily represent the official views of NIAID or NIH.

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