



NovaDigm Therapeutics Awarded \$6 Million by U.S. Department of Defense to Conduct a Phase 2a *Staphylococcus aureus* Vaccine Trial

Assessing the Impact of NDV-3A Vaccine on *S. aureus* Colonization in a High Risk Population of Military Trainees

BOSTON, MA – June 2, 2017 – [NovaDigm Therapeutics](#), a company developing innovative immunotherapeutics and preventative vaccines for fungal and bacterial infections, today announced awards totaling \$6 million from the U.S. Department of Defense to conduct a clinical study of NDV-3A in military personnel at high risk for skin and soft tissue infections due to *Staphylococcus aureus* ("*S. aureus*"), including methicillin-resistant *S. aureus* (MRSA). NovaDigm will collaborate with the Uniformed Services University of the Health Sciences (USU) on the execution of the Phase 2a study among U.S. Army Infantry trainees at Fort Benning, GA.

Earlier studies have shown that about one-third of trainees are nasally colonized with *S. aureus* at entry and approximately two-thirds are colonized by the completion of the 14-week training period. The military training environment has a number of factors that may enhance transmission and colonization of *S. aureus* (e.g. limited access to hygiene during field training, crowding, etc.). The development of medical countermeasures to prevent infections affecting medical readiness, such as those caused by *S. aureus* and MRSA, are an important focus for USU. NDV-3A has been demonstrated to be safe and highly immunogenic in humans, and preclinical studies have demonstrated its effectiveness in reducing the impact of bloodstream and skin infections caused by *S. aureus*.

The study will enroll 420 trainees in an individually-randomized, double-blind, placebo-controlled clinical trial to assess the safety, immunogenicity and efficacy of NDV-3A in reducing nasal/oral acquisition of *S. aureus*.

"The unique requirements of military training make this population especially susceptible to skin and soft tissue infections. SSTIs cause discomfort and can result in hospitalization impairing the recruits' successful completion of training. This study is an important first step to determine if a vaccine can prevent or reduce infections caused by *S. aureus* and MRSA," said Army Col. Michael Kozar, director of the Military Infectious Diseases Research Program at the U.S. Army Medical Research and Materiel Command, Fort Detrick, Maryland.

"We have had a long and fruitful collaboration with the Department of Defense for the development of NDV-3A to prevent *S. aureus* infections," said Timothy Cooke, CEO of NovaDigm. "This Phase 2a study is the culmination of these efforts and represents a new approach to preventing community infections in high-risk populations."

About the NDV-3A Development Program

NDV-3A is being developed as an immunotherapy and as a preventative vaccine for infections caused by several species of the fungus *Candida*, including *Candida albicans*, and the bacterium *Staphylococcus*

aureus, including MRSA. NDV-3A contains a recombinant form of the *Candida albicans* agglutinin-like sequence 3 (Als3) surface protein, which facilitates *Candida* adherence to and invasion of human endothelial cells. Als3 has been shown to have strong structural homology to surface proteins responsible for adherence of *S. aureus* to human endothelial cells. This finding helps to explain why NDV-3A is the first vaccine candidate to demonstrate “cross-kingdom” protection against both fungal and bacterial pathogens in preclinical studies. These studies showed that NDV-3A confers significant protection compared to placebo following bloodstream or mucocutaneous challenge with highly virulent doses of several species of *Candida* or several strains of *Staphylococcus aureus*, including MRSA strains. Two Phase 1 studies involving 200 healthy adults suggested that the vaccine is well-tolerated, safe, and induces rapid antibody and T-cell responses after a single dose, with or without alum adjuvant. A Phase 2 efficacy study of NDV-3A versus placebo in 188 patients with recurrent vulvovaginal candidiasis (RVVC) demonstrated that a single dose of NDV-3A resulted in an increase in the recurrence-free rate out to 12 months and extended the time to first recurrence for those that had a recurrence. This development program was based on research in the laboratories of NovaDigm’s scientific founders at the Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center. The work was supported in part by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (Grant Numbers AI19990, AI063382 and AI071554) and by the Department of the Army (Award Numbers JW81XWH-10-2-0035, W81XWH-11-1-0686 and W81XWH-16-C-0125).

About NovaDigm

NovaDigm is developing innovative immunotherapeutic and preventative vaccines to protect patients from fungal and bacterial diseases, which can be recurrent, drug-resistant and in some cases, life-threatening. NovaDigm’s lead development candidate, NDV-3A, is the first vaccine to demonstrate preclinical efficacy in reducing the severity of disease caused by both fungal and bacterial pathogens. NDV-3A is in Phase 2 clinical development for recurrent vulvovaginal candidiasis (RVVC) with follow-on indications planned for diseases associated with *Candida* and *Staphylococcus aureus* infections.
www.novadigmtherapeutics.com

About the Uniformed Services University of the Health Sciences:

The Uniformed Services University of the Health Sciences, founded by an act of Congress in 1972, is the nation’s federal health sciences university and the academic heart of the Military Health System. USU students are primarily active duty uniformed officers in the Army, Navy, Air Force and Public Health Service who receive specialized education in tropical and infectious diseases, TBI and PTSD, disaster response and humanitarian assistance, global health, and acute trauma care. A large percentage of the university’s more than 5,800 physician and 1,000 advanced practice nursing alumni are supporting operations around the world, offering their leadership and expertise. USU also has graduate programs in biomedical sciences, public health and oral biology committed to excellence in research. The University’s research program covers a wide range of clinical and other areas important to both the military and public health. For more information about USU and its programs, visit www.usuhs.edu.

###

Contact:

Timothy Cooke
NovaDigm Therapeutics
701.757.5161

Media:

Stefanie Tuck
MacDougall Biomedical Communications
781.235.3060
stuck@macbiocom.com