



## **NovaDigm Therapeutics Announces Initiation of Phase 2a Clinical Trial of NDV-3A in *Staphylococcus aureus***

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

**BOSTON, MA – April 19, 2018** – [NovaDigm Therapeutics](#), a company developing innovative immunotherapeutics and preventative vaccines for fungal and bacterial infections, today announced the initiation of a Phase 2a study evaluating NDV-3A for the reduction of *Staphylococcus aureus* (*S. aureus*) colonization in a high-risk population of military trainees. The study is being conducted with the Uniformed Services University of the Health Sciences (USU) and is enrolling U.S. Army Infantry trainees at Fort Benning, GA. NDV-3A is the company's lead development candidate to potentially treat antimicrobial resistant fungal and bacterial pathogens.

"Military recruits who are colonized with *Staph aureus* are at increased risk for skin infections, which can manifest in various ways including benign boils, cellulitis or more severe, invasive soft-tissue infections. The goal of this study is to reduce colonization during basic training with the NDV-3A vaccine," said Timothy Cooke, CEO of NovaDigm. "Following on the results of this trial, a larger study would be conducted to demonstrate a reduction in skin infections. We look forward to continuing our collaboration with the Department of Defense, which plays a critical role in the support of innovative approaches to address antimicrobial-resistant pathogens."

Military recruits are known to be at increased risk for *S. aureus* colonization and infection, attributable to a number of factors in the military training environment that may enhance the acquisition and transmission of *S. aureus* (e.g. limited access to hygiene during field training, crowding, etc.). The development of countermeasures to treat and prevent infections affecting medical readiness, such as those caused by *S. aureus* and MRSA (methicillin-resistant *S. aureus*), are an important focus for the military. NDV-3A has been demonstrated to be both safe and highly immunogenic in healthy human volunteers. Preclinical studies of NDV-3A have demonstrated its effectiveness in reducing the impact of bloodstream and skin infections caused by *S. aureus*.

The investigative team has initiated enrollment for the 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*. With a target enrollment of approximately 400 participants, infantry trainees from four classes will be recruited for the study, with receipt of NDV-3A occurring shortly after arrival at Fort Benning. Follow-up visits will occur throughout the 14-week training cycle to assess *S. aureus* colonization status of study participants.

### **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*, multidrug-resistant *Candida auris* 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 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](http://www.usuhs.edu).

#### **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](http://www.novadigmtherapeutics.com)

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#### **Contact:**

Timothy Cooke  
NovaDigm Therapeutics  
701.757.5161

#### **Media:**

Stefanie Tuck  
MacDougall Biomedical Communications  
781.235.3060  
[stuck@macbiocom.com](mailto:stuck@macbiocom.com)