



## **NovaDigm Therapeutics Initiates Phase 1b/2a Clinical Trial with NDV-3 Vaccine in Recurrent Vulvovaginal Candidiasis (RVVC)**

### **Immunotherapy Could Offer Long-Term Control of Chronic *Candida* Infections**

**GRAND FORKS, N.D. – September 26, 2013** – [NovaDigm Therapeutics](#), a company developing innovative vaccines for fungal and bacterial infections, today announced the initiation of a Phase 1b/2a clinical trial to evaluate its NDV-3 vaccine in preventing episodes of vulvovaginal candidiasis (VVC) in patients with recurrent VVC (RVVC). The trial is a multi-center, double-blind, randomized, placebo-controlled study to evaluate the safety, tolerability, immunogenicity and efficacy of NDV-3.

NDV-3 is a vaccine being developed for the treatment and prevention of infections caused by the fungus *Candida* and the bacterium *Staphylococcus aureus* (including methicillin-resistant *Staphylococcus aureus*, or MRSA). NDV-3 is the first vaccine to demonstrate preclinical “cross-kingdom” protective efficacy against both fungal and bacterial pathogens.

“An active immunotherapy approach such as NDV-3 has unique potential to address the significant need for improved long-term control of RVVC, the market for which could reach over \$1 billion worldwide,” said Timothy Cooke, Ph.D., NovaDigm’s Chief Executive Officer. “The initiation of this trial follows a preclinical study in a model of VVC, which demonstrated that NDV-3 induced potent and protective immune responses, as well as two successful Phase 1 studies, which demonstrated that NDV-3 was safe, well-tolerated and induced strong antibody and T-cell immune responses in healthy adults. In addition to RVVC, NovaDigm is also continuing to advance NDV-3 for other infectious disease indications, such as skin and soft tissue infections caused by drug-resistant *Staphylococcus aureus* and nosocomial infections caused by drug-resistant *Staphylococcus aureus* and *Candida*.”

“RVVC symptoms cause severe negative impact on an affected woman’s quality of life, and continuously treating the condition has a financial impact, as well,” said Professor Jack D. Sobel, M.D., Chief of the Division of Infectious Diseases at the Wayne State University School of Medicine and renowned international expert on vulvovaginal candidiasis. “Currently available over-the-counter and prescription anti-fungal medications can be fairly effective at controlling existing infections, but they do not prevent future infections without chronic use. NDV-3 has the potential to provide better long-term control of symptoms for patients suffering from RVVC and an improved quality of life.”

The Phase 1b/2a trial will enroll 189 patients at multiple centers in the United States. The objectives of the study are to estimate the effect of a single, intramuscularly-administered dose of NDV-3, as compared to placebo, by evaluating safety and tolerability, as well as humoral and cellular immune responses, over a 12-month period. In addition to these objectives, the study will summarize recurrence of VVC over both a six- and 12-month period, time-to-onset of first VVC episode and severity of

subsequent VVC episodes. A summary of the study can be found on the United States National Institutes of Health [clinicaltrials.gov](https://clinicaltrials.gov) website, identifier number NCT01926028.

### **Vulvovaginal Candidiasis**

Vulvovaginal candidiasis (VVC), also called vaginal thrush or vaginal yeast infection, is a mucosal fungal infection that affects approximately 75% of the female population between puberty and menopause. Approximately five million women in the U.S. suffer from recurrent VVC (RVVC), which refers to chronic, recurring cases of VVC infection. Women who have at least four episodes of VVC within a year are defined as suffering from RVVC. An additional two million women in the U.S. have three infections a year, and may also be candidates for a vaccine.

### **NDV-3 Development Program**

NDV-3 is a vaccine candidate containing a recombinant form of the *Candida albicans* surface protein Als3, which facilitates *Candida* adherence to and invasion of human endothelial cells. This vaccine was developed as a result of research in the labs of NovaDigm's scientific founders at the Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center, demonstrating that several members of the agglutinin-like sequence (Als) family of proteins induce protective immunity in preclinical models. NDV-3 is the first vaccine to demonstrate protective efficacy against both fungal and bacterial pathogens. Preclinical studies have shown that NDV-3 confers a high survival rate following a challenge with highly virulent doses of *Candida albicans* or against one of several strains of *Staphylococcus aureus*, including methicillin-resistant *Staphylococcus aureus* (MRSA). Two Phase 1 studies involving 200 healthy adults have indicated that NDV-3 is safe, well-tolerated and induces rapid antibody and T-cell responses after a single dose, with or without alum adjuvant. This 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 and W81XWH-11-1-0686).

### **About NovaDigm**

NovaDigm is developing innovative vaccines to protect patients from fungal and bacterial infections, which can be recurrent, drug-resistant and in some cases, life-threatening. The Company's founding scientists from the Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center (LA BioMed) are recognized leaders in the field of infectious disease and the emerging threat of "superbugs". Their work has been largely funded by the National Institutes of Health's National Institute of Allergy and Infectious Diseases (NIH NIAID). NovaDigm's lead product candidates target *Candida*, a fungal pathogen, and *Staphylococcus aureus*, including MRSA. Based in North Dakota with additional research activities at LA BioMed, NovaDigm has received funding from Domain Associates, a leading health care venture capital firm, and collaborates with multiple government agencies.

[www.novadigmtherapeutics.com](http://www.novadigmtherapeutics.com)

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