NovaDigm Therapeutics Announces Positive Results from First-ever Antifungal Immunotherapy in a Phase 2a Study in Women with Recurrent Vulvovaginal Candidiasis (RVVC)

Single dose increased recurrence-free rate out to one year in patients under 40

BOSTON, MA –August 15, 2016 – NovaDigm Therapeutics, a company developing innovative immunotherapeutics and preventative vaccines for fungal and bacterial infections, today announced positive data from the Company's Phase 2a clinical trial evaluating its NDV-3A immunotherapeutic vaccine in women with recurrent vulvovaginal candidiasis (RVVC). Initial results were presented at the Annual Meeting of the Infectious Diseases Society for Obstetrics and Gynecology in Annapolis, Maryland on August 13, 2016 by Paul Nyirjesy, MD, Professor of Obstetrics and Gynecology and of Medicine at Drexel University College of Medicine.

The study of 188 patients at 20 clinical sites met its primary endpoint of safety and tolerability. There were no significant differences between NDV-3A and placebo for injection site reactions and systemic reactions of grade 3 or greater. A single dose of NDV-3A generated very rapid and robust immune responses. Exploratory efficacy measures based on patient-reported symptom scores showed a trend toward significance at the 12-month follow-up period ($p=0.10$). Younger patients showed higher efficacy rates. In patients under 40 years of age (80% of the study population), NDV-3A recipients were about 50% more likely to be recurrence free at the end of the study compared to placebo recipients ($p<0.05$). Full results of the study will be published at a later date.

"Women who have recurrent vulvovaginal candidiasis have limited options to maintain control of this chronic condition, which can have a significant impact on their health and overall quality of life," said Dr. Nyirjesy, who was a principal investigator in the Phase 2a study. "The results of this trial demonstrate increases in recurrence-free time out to 12 months for younger women based on patient symptom scores following a single dose of NDV-3A. This finding represents a potential breakthrough for an immunotherapeutic approach to treating these patients."

Nine million women in the United States (11%) report having recurrent yeast infections, with approximately seven million (9%) experiencing RVVC, which has been defined as having three or more episodes per year. Approximately 90% of patients report onset of RVVC prior to the age of 40 years.[1] Many of these women experience frequent episodes of pain and discomfort, high rates of depression and a reduced overall quality of life.[2] While current therapies are effective at controlling acute infections, they do not control recurrences without chronic antifungal suppression, which is not widely used due to potential adverse events.

"These results show the first demonstration of efficacy for any immunotherapeutic or preventative vaccine against a fungal pathogen," said Timothy Cooke, CEO of NovaDigm. "The ability to reduce recurrences in RVVC patients out to at least one year with a single dose of NDV-3A shows the power of harnessing the patient's own immune system to control their recurrent symptoms. The positive results

of this trial are encouraging for continued development of NDV-3A as an immunotherapy for RVVC and the continued exploration of our vaccines in other infectious disease indications."

The Phase 2a trial was a multi-center, double-blind, randomized, placebo-controlled study evaluating the safety, tolerability, immunogenicity and efficacy of NDV-3A. The study enrolled 188 patients over 20 US study sites. Patients were assigned one dose of either 300µg NDV-3A immunotherapy or a placebo. The primary objective of the study was to assess the safety and tolerability of a single, intramuscular dose of NDV-3A, as compared to placebo, in patients with at least three episodes of VVC in the past 12 months. Secondary objectives included assessments of humoral and cellular immune responses and various measures of efficacy in reducing the frequency and/or severity of recurrences over a 12-month period. A summary of the study can be found on the United States National Institutes of Health clinicaltrials.gov website.

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 methicillin-resistant *Staphylococcus aureus*, or 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. NDV-3A is the first vaccine candidate to demonstrate "cross-kingdom" protective efficacy against both fungal and bacterial pathogens in preclinical studies. This vaccine was developed as a result of research in the laboratories of NovaDigm's scientific founders at the Los Angeles BioMedical Research Institute at Harbor-UCLA Medical Center, demonstrating that several members of the Als family of proteins induce protective immunity in preclinical models. Preclinical studies have shown that the vaccine confers a high efficacy rate compared to placebo 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 the vaccine 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).

Vulvovaginal Candidiasis

Vulvovaginal candidiasis (VVC), also called vaginal yeast infections, is a mucosal fungal infection that affects approximately 75% of the female population between puberty and menopause. Approximately seven million women in the U.S. suffer from recurrent vulvovaginal candidiasis (RVVC), which has been defined as three or more episodes of VVC in a year.

About NovaDigm

NovaDigm is developing innovative immunotherapeutics 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-3, is the first vaccine to demonstrate preclinical efficacy in reducing the severity of disease caused by both fungal and bacterial pathogens. NDV-3 is in Phase 2 clinical development for recurrent vulvovaginal candidiasis (RVVC) with follow-on indications planned for *Candida*, a fungal pathogen, and *Staphylococcus aureus*, including MRSA.
www.novadigmtherapeutics.com

References

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