



NovaDigm Therapeutics Presents Positive Preclinical Data in Vulvovaginal Candidiasis for NDV-3 Vaccine

--Study Demonstrates Potent Protective Immunity--

GRAND FORKS, ND – September 19, 2011 – [NovaDigm Therapeutics](#), a company developing innovative vaccines for fungal and bacterial infections, today announced the presentation of positive data from a preclinical study evaluating the efficacy its [NDV-3 vaccine](#) in a model of vulvovaginal candidiasis (VVC), which is primarily caused by *Candida albicans*. The results were presented at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). NDV-3 is a prophylactic vaccine being developed for *Candida* and *Staphylococcus aureus* (including methicillin-resistant *S. aureus*, or MRSA), and recently completed a Phase 1 trial evaluating its safety and immunogenicity. NDV-3 is the first vaccine to demonstrate preclinical “cross-kingdom” protective efficacy against both fungal and bacterial pathogens.

The study concluded that vaccination with NDV-3 induced potent, protective immune responses against VVC that were characterized by high anti-NDV-3 antibodies. These immune responses led to decreases in vaginal fungal burden. The study found that the mechanism of protection elicited by NDV-3 against VVC was mediated by both T-cells and B-cells.

“This preclinical efficacy data for NDV-3 in a specific fungal disease indication further supports prior preclinical data, and also complements the positive immune response activity that NovaDigm recently reported from the Phase 1 trial for this vaccine,” said Timothy Cooke, Ph.D., NovaDigm’s Chief Executive Officer. “NDV-3 holds significant promise as a vaccine against VVC, which is one of the potential indications that NovaDigm is pursuing for this program.”

The data were presented in a poster titled, *NDV-3 Protects Mice From Vulvovaginal Candidiasis Through T- and B-Cell Immune Response (G1-768/251)*, by Dr. Ashraf Ibrahim, Professor of Medicine at the David Geffen School of Medicine at UCLA and Division of Infectious Diseases, Department of Medicine, Harbor-UCLA Medical Center and a founder of NovaDigm, on Sunday, September 18, 2011 in poster session 097: Vaccines and Immunomodulators.

NDV3 Development Program

NDV-3 is a prophylactic vaccine candidate containing a recombinant *Candida* surface protein, Als3, and the widely used adjuvant Alhydrogel[®]. This vaccine was developed as a result of research in the labs of NovaDigm’s scientific founders at the LA 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 one of several species of *Candida* or against one of several strains of *Staphylococcus aureus* (*S. aureus*), including methicillin-resistant *S. aureus* (MRSA).

Medical Need

Candida is the third most common cause of nosocomial bloodstream infections. The incidence of candidiasis in the United States is at least 20 per 100,000 people, or over 60,000 infections per year, of which approximately 40% (24,000) are lethal despite antifungal treatment. *Candida* is also the fungus responsible for vaginal yeast infections and the oral infection known as thrush. Historically, *S. aureus* was predominantly the cause of invasive infections occurring among individuals with immune deficiencies, or those in hospital settings. However, an urgent concern is the recent explosion of drug-resistant *S. aureus* infections among young and otherwise healthy individuals in the community. *S. aureus* is now a common cause of skin infections and the CDC estimates that 12 million physician visits annually are due to suspected *S. aureus* or MRSA skin infections. In 2008, there were an estimated 90,000 cases of invasive MRSA in the U.S., leading to 15,000 deaths (17% mortality).

About NovaDigm

NovaDigm is developing innovative vaccines to protect patients from fungal and bacterial infections, which can be life-threatening and drug-resistant. The Company's founding scientists from the LA 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." NovaDigm's lead product candidate, NDV-3, targets *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

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