



## **NovaDigm Therapeutics Presents Positive Phase 1 Safety and Immunogenicity Data for NDV-3 Vaccine**

**--NDV-3 is the First “Cross-Kingdom” Vaccine Being Developed for *Candida* and *Staph* Infections--**

**GRAND FORKS, ND – September 19, 2011** – [NovaDigm Therapeutics](#), a company developing innovative vaccines for fungal and bacterial infections, today announced the presentation of positive Phase 1 data for its [NDV-3 vaccine program](#) at the 51st Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC). NDV-3 is a prophylactic vaccine being developed for the prevention of diseases caused by *Candida* and *Staphylococcus aureus* (including methicillin-resistant *S. aureus*, or MRSA). NDV-3 is the first vaccine to demonstrate preclinical “cross-kingdom” protective efficacy against both fungal and bacterial pathogens. Results from the trial demonstrated that a single dose of the vaccine was safe, well-tolerated and induced strong antibody and T-cell immune responses in healthy adults, thus meeting the endpoints of the study.

“The Phase 1 data shows that those receiving NDV-3 demonstrated rapid and robust immune responses, which adds promising initial human safety and immune response data to the extensive preclinical profile for this program,” said Timothy Cooke, Ph.D., NovaDigm’s Chief Executive Officer. “NDV-3 is an innovative vaccine with significant clinical and commercial potential to protect against diseases caused by these fungal and bacterial pathogens. NovaDigm continues to advance this program into additional clinical and preclinical studies.”

“*Staph aureus* and *Candida* are leading causes of healthcare-associated infections and account for over 40,000 deaths per year in the U.S., demonstrating the need for a prophylactic vaccine approach despite the availability of antibiotics,” said John E. Edwards, Jr., M.D., Professor of Medicine at the David Geffen School of Medicine at UCLA and Chief of the Division of Infectious Diseases, Department of Medicine at Harbor-UCLA Medical Center and a founder of NovaDigm. “NDV-3 represents a potential breakthrough for protecting against diseases caused by either *Staph* or *Candida* infections, for which there are currently no vaccines available despite the significant need.”

The Phase 1 trial was a double-blind, placebo-controlled study evaluating the safety, tolerability and immunogenicity of a single dose of the vaccine at two dose levels (30 and 300 µg per dose) out to six months post-vaccination. The immunogenicity endpoints were a greater than four-fold rise in antibody titers and an increase in cytokine production levels in a high percentage of subjects.

Results from the study demonstrated the safety and tolerability of NDV-3 at both dose levels. Additionally, both dose levels resulted in 100% seroconversion for both serum immunoglobulin G (IgG) and serum immunoglobulin A1 (IgA1) antibodies by day 14, with greater than 75% seroconversion by day seven in the higher dose group. The geometric fold rise in IgG and IgA1 antibody titers for both dose levels was 17- to 59-fold by day 14 post-vaccination. Geometric IgG and IgA1 titers over the course of 28 days were significantly greater in the 300 µg dose level compared to the 30 µg dose level. Preliminary data show that the majority of subjects that received NDV-3 demonstrated significant Als3-stimulated production of the cytokines IL-17A and IFN-γ between seven and 28 days post-vaccination relative to subjects receiving placebo. Als3 is the antigen contained in the NDV-3 vaccine.

The Phase 1 data were presented in a poster titled, *First-in-Human Clinical Evaluation of NDV-3: Safety & Immunogenicity of a Vaccine to Prevent Disease Caused by Candida spp. and Staphylococcus aureus* (Poster G1-759), by Dr. John Hennessey, Vice President of R&D for NovaDigm, on Sunday, September 18, 2011 in poster session 097: Vaccines and Immunomodulators.

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

NDV-3 is a prophylactic vaccine candidate containing a recombinant *Candida* surface protein, Als3, and the widely used adjuvant Alhydrogel<sup>®</sup>. 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](http://www.novadigmtherapeutics.com)

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