NovaDigm Therapeutics Presents Positive Safety and Immunogenicity Data in a Second Phase 1 Study for NDV-3 Vaccine

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

GRAND FORKS, ND – May 7, 2012 – NovaDigm Therapeutics, a company developing innovative vaccines for fungal and bacterial infections, today announced the presentation of positive data for its NDV-3 vaccine program in a second Phase 1 study. The presentation was made at the 15th Annual Conference on Vaccine Research, sponsored by the National Foundation for Infectious Diseases and held in Baltimore, MD. NDV-3 is a vaccine being developed for the prevention and treatment of diseases caused by *Candida* and *Staphylococcus aureus* (including methicillin-resistant *S. aureus*, or MRSA). NDV-3 contains recombinant Als3, a surface adhesin/invasin from *Candida albicans*, which is the first vaccine antigen to demonstrate preclinical "cross-kingdom" protective efficacy against both fungal and bacterial pathogens. Results from the new study demonstrated that a single dose of NDV-3 with or without alum adjuvant was safe, well-tolerated and induced strong antibody and T-cell immune responses.

"The data from our second Phase 1 study confirms positive results from our initial Phase 1 study and shows that those receiving adjuvant-free NDV-3 had robust immune responses, as did those receiving NDV-3 with alum adjuvant," said Timothy Cooke, Ph.D., NovaDigm's Chief Executive Officer. "These results position us to begin Phase 2 efficacy studies with an optimized vaccine formulation and a Phase 1 safety database of 200 adults."

The second Phase 1 trial was a double-blind, placebo-controlled study in 160 healthy adults evaluating the safety, tolerability and immunogenicity of a single dose of three different formulations and two routes of administration. A dose of the vaccine containing 300 µg of Als3 was administered intramuscularly with and without alum adjuvant to assess the impact of the adjuvant. In the third vaccinated group, a dose of NDV-3 containing 30 µg of Als3 was administered intradermally without alum adjuvant.

Results from the study demonstrated the safety and tolerability of NDV-3 in all three vaccinated groups compared to the saline placebo group. All three vaccinated groups showed rapid increases in serum and vaginal immunoglobulin G (IgG) and immunoglobulin A1 (IgA1) antibodies by day 7 following vaccination, which peaked at day 14. The demonstration of vaginal antibody responses to NDV-3 may be important in preventing vaginal yeast infections caused by *Candida albicans*, which is the objective of a planned Phase 2 efficacy study. The majority of subjects that received NDV-3 also

demonstrated significant Als3-stimulated production of the T-cell cytokines IL-17A and IFN-γ between 7 and 14 days post-vaccination relative to subjects receiving placebo.

The Phase 1 data were presented in an oral presentation titled, *NDV-3, a Recombinant Vaccine for Candida and Staphylococcus aureus is Safe and Immunogenic in Healthy Adults*, by John Hennessey, Ph.D., Vice President of R&D for NovaDigm, on Monday, May 7, 2012 at 3:30pm in a session entitled "Vaccine Candidates: Preclinical and Clinical Studies."

NDV-3 Development Program

NDV-3 is a prophylactic vaccine candidate containing a recombinant form of the *Candida* 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 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 *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 *S. 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

Contact:
Timothy Cooke
NovaDigm Therapeutics
701.757.5161

Media
Kari Watson or Jennifer Conrad
MacDougall Biomedical Communications
781.235.3060
kwatson@macbiocom.com
jconrad@macbiocom.com