



## **Nanotherapeutics' GelVac™ Nasal Dry-Powder H5N1 Influenza Vaccine Shown to Be Safe in Early Stage Clinical Trial**

*A novel dry-powder formulation nasal flu vaccine for the H5N1 strain, GelVac™ Nasal Dry-Powder H5N1 Influenza, was proven to be safe in an early stage clinical trial. Other preliminary data is encouraging and support the development of larger scale clinical trials to confirm efficacy and show its distinct advantages in meeting the critical needs of pandemic preparedness.*

Alachua, Florida ([PRWEB](#)) October 03, 2011 -- Nanotherapeutics, Inc. announced the successful completion of a Phase 1 clinical trial of GelVac™ Nasal Dry-Powder H5N1 Influenza Vaccine. The trial assessed the safety of the novel intranasal dry-powder formulation vaccine for the H5N1 flu strain. No safety issues were identified, and no serious adverse events occurred during the trial. The vaccine, which was administered intranasally by a disposable single-use inhaler, was well tolerated by the patients. GelVac™ incorporates the GelSite® polymer, combining it with an H5N1 antigen.

Patients received two intranasal doses given 4 weeks apart. Nasal wash and serum samples were collected at several time points for exploratory endpoints of effectiveness. Although the study was not statistically powered to provide effectiveness data, initial results are encouraging and support the development of larger trials to confirm efficacy and demonstrate distinct advantages in meeting the critical needs of pandemic preparedness. The preliminary data show increased serum and mucosal IgA as well as serum HAI responses to H5N1.

The GelVac™ vaccine possesses distinct potential advantages, including induction of both mucosal and systemic immunity, room temperature stability, prolonged shelf life, cold-chain-free distribution, and needle-free administration that can be particularly valuable in meeting the needs for pandemic preparation and stockpiling.

GelSite® polymer is a novel, naturally occurring, mucoadhesive ionic carbohydrate polymer capable of forming a gel when brought into contact with nasal fluids. Gelling occurs with the powder formulation and provides sustained antigen release within the nasal cavity for enhancement of the immune response.

### **About GelVac™ Nasal Dry-Powder H5N1 Influenza Vaccine**

GelVac™ Nasal Dry-Powder H5N1 Influenza Vaccine is a powder vaccine that has been formulated using an inactivated cell-based influenza H5N1 whole virion antigen in combination with GelSite® polymer, a novel plant polysaccharide with gelling properties to encapsulate vaccine/adjuvant formulation as gel particles. The powder vaccine formulation is filled into a positive pressure nasal delivery device and delivered into the nasal cavity by compressed air.

GelVac™ Nasal Dry-Powder H5N1 Influenza Vaccine with GelSite® Polymer offers distinctive chemical and functional properties. The vaccine provides important advantages for the pandemic preparedness, including room temperature stability, needle-free administration, and induction of both mucosal and systemic immune responses.



## About the GelSite® Polymer Platform

GelSite® Polymer is a chemically and functionally distinct high molecular weight anionic polysaccharide extracted from Aloe vera L., a succulent plant widely cultivated in the tropical and subtropical regions and is general considered as safe (GRAS). GelSite® Polymer has been shown to have an adjuvant-like effect increasing immune response and antigen sparing when administered together with the antigen by intramuscular injection. GelSite® Polymer is inert and the polymer gel does not support cell adhesion. This adjuvant effect can be obtained at a very low polymer concentration, lower than that of the alum adjuvant commonly used in licensed vaccines. GelSite® Polymer has been tested in various vaccine formulations for administration by the nasal route and injection and can serve as a platform technology due to its distinctive chemical and functional properties.

## About Nanotherapeutics

Nanotherapeutics, Inc. is a privately held biopharmaceutical company with a major focus on developing a diversified proprietary pipeline of products having both biodefense and medical applications. Products under development include biodefense, CNS, wound healing, addiction and pain, oncology, anti-infectives and orthopedics. The Company has one FDA-approved injectable biologic NanoFUSE® DBM used by orthopedic surgeons as bone graft filler. Nanotherapeutics has in-house cGMP manufacturing, formulation, and expertise in pre-clinical and clinical product development as well as clinical trial management to support its products. Established ten years ago, the Company employs several proprietary platform technologies to manipulate and enhance the properties of drug candidates. For more information, visit the Company website at [www.nanotherapeutics.com](http://www.nanotherapeutics.com).

## Media contact:

Gary A. Ascani

386-462-9663

Nanotherapeutics, Inc.

VP, Business Development

gascani(at)nanotherapeutics(dot)com

###



**Contact Information**

**Gary Ascani, VP Business Development**

Nanotherapeutics, Inc.

<http://www.nanotherapeutics.com>

386-462-9663

**Online Web 2.0 Version**

You can read the online version of this press release [here](#).