



August 30, 2010 08:00 AM Eastern Daylight Time

Nanotherapeutics Submits Investigational New Drug Application to FDA for Clinical Testing of Oral Drug to Treat Radiation Exposure

Also Begins Clinical Trial of New Nasal Formulation of H5N1 Flu Vaccine

ALACHUA, Fla.--([BUSINESS WIRE](#))--Nanotherapeutics, Inc., announced that it has filed an Investigational New Drug (IND) Application with the Food and Drug Administration (FDA) for NanoDTPA™ an orally administered capsule that is a less invasive treatment alternative to the FDA approved injectable Zn-DTPA (diethylenetriamine pentacetic acid). DTPA is used to remove radioactive compounds from the body to help eliminate the contamination. The NanoDTPA™ capsule is a unique orally -bioavailable fine particle formulation that allows DTPA to be absorbed into the body from the gastrointestinal tract.

Nanotherapeutics began development of NanoDTPA™ with funding from the National Institutes of Health (NIH) and the Biomedical Advanced Research and Development Authority (BARDA) under a competitive program, *Development of Improved DTPA for Radionuclide Chelation*. While DTPA can be used for exposure to radioactive nuclear materials from a spill or “dirty bomb” attack, as an intravenous formulation, it is not practical for treating a widespread population. The NIH contracted with the company to develop a more practical easier-to-administer alternative.

Preclinical studies of NanoDTPA™ Zn-DTPA capsule demonstrated strong pharmacokinetic and safety profiles. The IND will allow the company to begin clinical trials of the capsule to determine dosing, safety, and efficacy of this alternative formulation. There is also potential for use of NanoDTPA™ for iron chelation to treat iron overload.
(http://www.nanotherapeutics.com/products_pipeline.php)

Clinical Trial Underway for GelVac™ H5N1 Flu Vaccine

Nanotherapeutics has also announced that patient enrollment is underway in a Phase I safety and immunogenicity study for its GelVac™ H5N1 Influenza Vaccine. GelVac™ is a nasal dry-powder formulation of the inactivated vaccine. The new formulation represents a novel approach to vaccine stabilization and delivery, which offers distinct advantages in meeting the critical needs of pandemic preparedness. The nasal dry-powder formulation has the potential to increase efficacy with reduced dosing, improve immune response, and provide higher shelf-life stability.

GelVac™ is based on the company's GelSite® polymer platform, a distinct and inert ionic polysaccharide (polygalacturonic acid) that enhances the immune response through prolonged nasal residence and sustained antigen release by an *in situ* gelation mechanism. The GelVac™ platform combines the advantages of powder formulation and nasal delivery and is potentially well suited to meet the critical needs of influenza pandemic preparedness and epidemic control.
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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 GMP 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.

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