



**Contact:** Michele Parisi  
for Vaxart  
925/864-5028  
ir-pr@vaxart.com

## **VAXART DEMONSTRATES EFFICACY OF ORAL AVIAN FLU VACCINE IN PRECLINICAL STUDIES**

-- Using proprietary platform, company develops first orally-administered vaccine to protect against avian influenza in a large-animal model --

**SAN FRANCISCO, CA – October 24, 2008** – Vaxart Inc., a biotechnology company focused on the development of oral vaccines, today announced positive efficacy results from preclinical studies of the company’s oral avian flu vaccine. Sean Tucker, PhD, Vaxart founder and vice president of research, presented data from animal models demonstrating that an orally administered flu vaccine was protective against lethal exposure to H5N1 influenza. Tucker presented the data this morning at the Modern Mucosal Vaccines, Adjuvants & Microbicides (MMVAM) international conference in Porto, Portugal.

Delivery of flu vaccine via a capsule rather than an injection offers critical advantages, particularly in the case of a pandemic. The Vaxart vaccine formulation can withstand ambient temperatures, enabling emergency distribution methods that avoid the transmission risks associated with centralized vaccination clinics. In the developing world, where medical providers and supplies are scarce, oral vaccination will reduce costs, as well as needle reuse and consequent cross-infection.

The data presented today are from studies measuring the effectiveness of an orally-administered avian flu vaccine designed by Vaxart scientists using the company’s proprietary modular platform. The Vaxart vaccine (ND1) comprises a non-replicating chimeric adenovirus-5 vector, or delivery vehicle, engineered to express avian flu hemagglutinin (HA) and a TLR3 ligand as a vaccine adjuvant.

“Injected vector-based vaccines that deliver a target pathogen protein have shown excellent potency in animal models, but their application has been limited in humans because the immune system typically responds to the vector rather than the target,” said Dr. Tucker. “By using oral delivery of a non-replicating vector with a potent adjuvant, we achieve a robust immune response that is focused on the targeted pathogen rather than the delivery vehicle. This approach addresses the problems that have plagued vector-based vaccination and also allows us to create different vaccines simply by switching out the antigen.”

-more-

In the recent study, Vaxart tested the ND1 vaccine using oral administration to ferrets, widely recognized as the most predictive animal model for influenza research. Researchers administered vaccine at the start of the study and at 4 weeks. At 8 weeks, researchers measured antibody responses, then monitored survival following direct nasal exposure of 10 times the median lethal dose of H5N1 avian influenza virus. Seventy-five percent (6 of 8) of oral vaccinated ferrets developed antibody levels of 1:200 or greater, survived the challenge and were healthy as demonstrated by weight gain after challenge, while all 12 control ferrets either died (67 percent) or became very ill (33 percent). These results, if confirmed in human immunogenicity studies, compare well to the approved, injectable avian flu vaccine that achieved protective antibody levels in 45 percent of human subjects.

In a previous study conducted in mice, 6 of 6 mice vaccinated orally with ND1 survived H5N1 avian flu challenge, while 8 of 8 unvaccinated mice died. Based on these results, Vaxart plans to proceed to an investigational new drug application (IND) and begin clinical studies of the avian flu vaccine in 2009. The company is also developing an annual flu vaccine.

“To date, efforts to develop a broadly-applicable oral vaccine platform have not been successful, but the advantages of a modular approach for vaccine development are compelling, particularly for influenza,” said Mark Backer, PhD, Vaxart CEO. “We can provide a vaccine that matches a new outbreak strain months faster than current approaches.”

“These results are encouraging. An oral vaccine for pandemic flu would be a great help in rapid distribution to large numbers of people,” said Dr. Arnold Monto, professor of epidemiology at University of Michigan. “The availability of an oral vaccine for annual influenza would also likely improve vaccination compliance and help reduce the rates of hospitalization and death that are associated with flu every year.”

### **The Vaxart Approach**

Vaxart has developed a proprietary, modular approach to vaccine development that will reduce the time and expense needed to bring new vaccines to market. The key to Vaxart’s efforts is a unique adjuvant (an adjuvant is the vaccine component that enhances immune response to a foreign protein). Vaxart uses an adjuvant that works through a “toll-like receptor” (TLR). Vaxart determined that TLR3 is much more active in the gut than other TLR pathways that have been used for injected vaccines, making this the only TLR adjuvant approach likely to work well for oral vaccines. The company has demonstrated both the induction of mucosal immunity and the stimulation of antigen-specific cell-based immunity following oral administration of its vaccines; these features may provide a performance advantage over injected protein vaccines.

Another key feature of the Vaxart platform is the ability to employ the same vector (delivery vehicle) across all vaccines. Typically an injected vector can only be used once, because antibodies build up against the vector proteins after initial exposure. Subsequent vaccines are less effective, because the body neutralizes the vector before a response can be mounted against the disease target. Vaxart has overcome this

obstacle and demonstrated that strong immune responses can be generated against multiple diseases following a series of different oral vaccines. Vaxart will be able to produce new vaccines through a standardized and low-cost process, and safety data from one vaccine will be supportive for others created through the platform.

**About Vaxart**

Vaxart ([www.vaxart.com](http://www.vaxart.com)) is a privately held biotechnology company focused on the development of oral vaccines. Vaxart's proprietary approach is ideally suited for modular creation of vaccines, enabling the company to reduce development risk. Vaxart intends to apply its platform to develop a first-in-class vaccine for pandemic influenza, as well as creating oral alternatives to current vaccines such as annual influenza and HPV. The company expects to begin clinical testing of its pandemic flu vaccine in 2009.

###