

press release

## **NOBIVAC® CANINE FLU VACCINE GRANTED LICENSE BY USDA**

Roseland, N.J., June 9, 2010 – The first vaccine against canine influenza virus (CIV), Nobivac® Canine Flu H3N8, has been granted a full license by the United States Department of Agriculture (USDA), according to the USDA's Animal and Plant Health Inspection Service through its Center for Veterinary Biologics. Licensure follows evaluation of use of the vaccine by veterinarians since May 27, 2009, when a conditional license was awarded. Intervet/Schering-Plough Animal Health, the global leader in veterinary biologicals and developer of the novel vaccine, announced the full approval today.

Nearly one million doses of the vaccine have been sold to veterinary clinics and shelters throughout the U.S. during the past year. The USDA approval confirms the safety and effectiveness of Nobivac Canine Flu H3N8, which has been shown to significantly decrease the signs, severity and spread of CIV infection. The vaccine has also been shown to reduce the incidence and severity of lung lesions. The Company has submitted data to the USDA on field experience that shows the vaccine is well-tolerated. Adverse events reported since the 2009 approval are comparable to those seen for other canine vaccines.

Steve Shell, Companion Animal Business Unit Head, said, "We are pleased the USDA has confirmed the value of this important vaccine for canine health. Animal care practitioners have welcomed its availability. More than 9,000 small animal practices across the U.S. have the vaccine in clinic. Though not considered a core vaccine, Nobivac Canine Flu is commonly recommended by veterinarians for at-risk social dogs, i.e., those regularly receiving *Bordetella* vaccination because they are frequently in contact with other dogs."

CIV is a highly contagious respiratory disease in dogs caused by an influenza A virus, H3N8. In 2004, Cynda Crawford, D.V.M., Ph.D., University of Florida, Clinical Assistant Professor of Shelter Medicine, and Edward J. Dubovi, Ph.D., Professor of Virology, Cornell University College of Veterinary Medicine, along with their colleagues, were the first to discover that the spread of the respiratory disease in the general dog population was caused by CIV.

“Like influenza vaccines used in other species,” said Dr. Crawford, “the canine influenza vaccine does not prevent infection; however, it significantly reduces clinical disease and the risk for pneumonia, and vaccinated dogs shed much less virus so they are less contagious to other dogs. Vaccine-induced protection is not only important to the health and welfare of individual dogs, but also decreases the likelihood of an influenza outbreak in a population if most of the dogs are vaccinated.”

According to Terri Wasmoen, Ph.D., an immunologist and senior director of Biological Research for Intervet/Schering-Plough Animal Health, “The vaccine is useful not only against CIV but also in helping control a complex of potentially serious canine infectious respiratory diseases that may be secondary to CIV.”

Dr. Ronald D. Schultz, Professor and Chair, Department of Pathobiological Sciences, School of Veterinary Medicine, University of Wisconsin-Madison, recommends vaccination for dogs at risk: “In general, any dog that is in a closed room with other dogs for at least six hours or more can be considered at risk, particularly those that are boarded frequently, go to dog shows, dog day-care and training classes or are in shelters.”

“Other dogs that may be at risk include those in rescue groups and those that travel with families, particularly to endemic areas, are housed in breeder facilities or belong to animal healthcare personnel,” said Dr. Crawford.

Cases of canine influenza have been identified in 33 states and the District of Columbia. During 2009-2010, outbreaks occurred in shelters, kennels, dog day-care centers, veterinary clinics and other facilities in Pennsylvania, New York, New Jersey, Colorado, Connecticut and Virginia.

Dr. Dubovi, an expert on CIV diagnostic testing, cited the cost of treatment, the potential for serious secondary infection and the increasing overuse of antibiotics as reasons for vaccination. “I would much prefer to prevent viral infections with the vaccine than treat a secondary infection with antibiotics,” he said.

The vaccine was developed in response to the growing threat posed by the virus as well as to the American Veterinary Medical Association’s (AVMA) 2006 call for the development of a vaccine against the spread of the disease. The AVMA stated: “There is urgent need for an effective canine influenza vaccine to improve the health and welfare of animals and reduce the financial impacts of canine influenza.”

Nobivac Canine Flu H3N8, made from inactivated virus, is intended as an aid in the control of disease associated with canine influenza virus infection and is administered by subcutaneous injection in two doses, two to four weeks apart. It may be given to dogs six weeks of age or

older and can be given annually as a component of existing respiratory disease vaccine protocols to ensure more comprehensive protection.

**About Intervet/Schering-Plough Animal Health**

Intervet/Schering-Plough Animal Health, based in Boxmeer, the Netherlands, is focused on the research, development, manufacturing and marketing of animal health products. The company offers customers one of the broadest, most innovative animal health portfolios, spanning products to support performance and to prevent, treat and control disease in all major farm and companion animal species. Intervet/Schering-Plough Animal Health; subsidiaries of Merck & Co. Inc., Whitehouse Station NJ, USA. For more information, visit [www.intervet.com](http://www.intervet.com).

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