FDA Grants First Full Approval for Treatment of Lymphoma in Dogs

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Today, the U.S. Food and Drug Administration fully approved Tanovea (rabacfosadine injection) to treat lymphoma in dogs. Lymphoma, also called lymphosarcoma, is a type of cancer that can affect many species, including dogs. Tanovea is the first conditionally approved new animal drug for dogs to achieve the FDA's full approval.

Tanovea was approved using the new animal drug approval process after initially receiving conditional approval under statutory provisions related to drugs intended for uncommon diseases or conditions in major animal species (minor uses) or for use in the minor species of animals under the FDA's Minor Use and Minor Species (MUMS) program (i.e., MUMS drugs).

"The FDA is dedicated to making treatment options available for all patients – including animals suffering from rare conditions. Today's first ever full approval of a new animal drug for treating lymphoma in dogs demonstrates the positive impact that the FDA's Minor Use and Minor Species program can have on the availability of novel animal treatments," said Acting

FDA Commissioner Janet Woodcock, M.D. "We're committed to continue using all our authorities to help make limited-demand treatment options available to our animal companions."

The FDA's MUMS program is intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species and uncommon diseases in the major animal species. This program provides innovative ways to bring products to market for these small populations and is designed to help pharmaceutical companies overcome the financial roadblocks they face in providing limited-demand animal drugs. Before the passage of legislation establishing the program in 2004, pharmaceutical companies would rarely attempt to bring MUMS drugs to market, because the markets were too small to generate an adequate financial return.

"Today's approval shows that drugs to treat rare animal diseases, like canine lymphoma, can go through the FDA's conditional approval pathway to reach full approval. This gives veterinarians another important tool to help extend the quality of life for dogs with lymphoma, and potentially give them and their owners more time together," said Steven M. Solomon, M.P.H., D.V.M., director of the FDA's Center for Veterinary Medicine. "While canine lymphoma affects fewer than 70,000

dogs in the U.S. annually, it accounts for up to 24 percent of all cancers in dogs, making it one of the most significant canine cancers. For the first time, dog owners have the assurance of a treatment that has fully met the FDA's standards for effectiveness in dogs."

Lymphoma originates from white blood cells called lymphocytes. These cells are a normal part of the immune system and protect the body from infection, but they grow abnormally if impacted by lymphoma. Although lymphoma can affect virtually any organ in the body, it most commonly starts in organs that function as part of the immune system, such as the lymph nodes, spleen, and bone marrow. The signs of lymphoma in dogs vary depending on which organs are affected. The cause of canine lymphoma is unknown.

Chemotherapy drugs often have potential side effects, but, unlike in human medicine in which patients may be willing to tolerate uncomfortable side effects in exchange for a potential cure, the primary purpose of chemotherapy in pets is to extend survival, with an emphasis on the pet's quality of life and comfort. The active ingredient in Tanovea is rabacfosadine, a substance that kills rapidly growing cancer cells. Tanovea must be prescribed by a licensed veterinarian because professional expertise is needed to correctly diagnose lymphoma in dogs, determine the best treatment, and manage potential side effects. Tanovea comes in a concentrated form and, once diluted, is injected into a vein over a period of 30 minutes. The treatment is repeated every three weeks for up to a total of five administrations. Because Tanovea is a chemotherapeutic drug, owners should take extra care when handling and cleaning up after their dogs for a period of five days following each treatment. Veterinarians should discuss these precautions with dog owners.

Tanovea received conditional approvalExternal Link Disclaimer under the MUMS program in December 2016, meaning that the agency had found the drug was safe for the intended purpose and had a "reasonable expectation of effectiveness" for treating lymphoma in dogs. Conditional approvalExternal Link Disclaimer allowed the drug manufacturer to market Tanovea for a period of time while collecting additional study data to meet the "substantial evidence" standard of effectiveness for full approval. These additional studies have now been reviewed as the basis for the full approval.

The effectiveness and safety of Tanovea was demonstrated in a well-controlled clinical field study involving a total of 158 dogs that had been diagnosed with multicentric lymphoma with at least one enlarged peripheral lymph node. The study was open to dogs of any breed, except West Highland White Terriers. West Highland White Terriers were not enrolled due to the breed's tendency to develop pulmonary fibrosis, which is a known potential side effect of Tanovea that was identified prior to conditional approval. All 158 dogs were evaluated for safety (120 in the Tanovea group and 38 in the placebo group), and 148 dogs were evaluated for effectiveness (112 in the Tanovea group and 36 in the placebo group). Dogs ranged from one to 15 years in age in the Tanovea group and from three to 16 years in age in the placebo group.

The study found that Tanovea extended the median survival rate by 61 days and for dogs with a complete response to the drug, the median progression-free survival was extended to 168 days. The most common side effects seen in dogs treated with Tanovea included diarrhea, decreased

appetite, vomiting, lethargy, weight loss and neutropenia, a decrease in a type of white blood cell. The most serious adverse events included pulmonary fibrosis and skin issues, including infection, ulceration and skin peeling in some cases. Veterinarians should advise owners about the possible adverse events and side effects before using the drug and share the client information sheet developed for the product. The FDA encourages dog owners to work with their veterinary team to report any adverse events or side effects potentially related to the use of any drug, including Tanovea.

The FDA granted approval for Tanovea to VetDC Inc.

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