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FDA Approves First Canine Cancer Therapy

Tuesday, June 02, 2009 - 08:06pm

Pfizer Animal Health Receives Approval for PALLADIATM

(BUSINESS WIRE)--Pfizer Animal Health today announced that the U.S. Food and Drug Administration (FDA) has approved the first canine cancer therapy in the U.S. – PALLADIA^{TM} (toceranib phosphate) – which was developed by Pfizer to treat mast cell tumors in dogs. Pfizer made the announcement to veterinarians attending the 2009 American College of Veterinary Internal Medicine (ACVIM) Forum and Canadian Veterinary Medical Association Convention.

“Pfizer Animal Health is proud to bring the first canine cancer therapy approved by the FDA to U.S. specialists, their patients and caregivers,” said George Fennell, vice president, Companion Animal Division, Pfizer Animal Health. “In the weeks and months ahead, Pfizer will introduce PALLADIA to boarded specialists to expand the body of clinical experience with this new therapy. The experience gained during this time will enable us to support veterinarians more effectively when we make the product available for purchase in early 2010,” Fennell said.

Pet caregivers should continue to consult with their local veterinarians about options for their dogs with cancer, who may then refer appropriate cases to specialists for treatment with PALLADIA.

A new option to treat canine mast cell tumors

According to the Morris Animal Foundation, cancer is a leading cause of death in dogs. [1]

Pfizer Animal Health estimates 1.2 million new canine cancer cases are reported in the U.S. every year. [2] Mast cell tumors are the second most common tumor type and are often seen as lumps in the skin. These tumors are classified as grade I, II or III, with grade III being the most severe. If not treated, they can spread to other parts of the body including lymph nodes.

Prescription-only PALLADIA is an oral therapy indicated to treat Patnaik grade II or III recurrent cutaneous mast cell tumors with or without regional lymph node involvement. PALLADIA belongs to the tyrosine kinase inhibitor (TKI) class of compounds. It works by blocking the activity of key receptors important for the development of blood vessels that supply tumors, as well as receptors critical for tumor survival.

“PALLADIA is an exciting, new treatment option for dogs with mast cell tumors,” said Cheryl London, DVM, PhD, board certified medical oncologist and associate professor at The Ohio State University College of Veterinary Medicine.

“At the completion of a PALLADIA clinical study, approximately 60% of dogs had their tumors disappear, shrink or stop growing. Also, we determined that dogs whose tumors responded to PALLADIA experienced an improved quality of life,”[3] said Dr. London, who has helped Pfizer Animal Health’s Veterinary Medicine Research & Development to develop PALLADIA since 2000.

Further Information about PALLADIA

PALLADIA can be administered in a veterinary clinic or in the home by a dog's caregiver. PALLADIA is not for human use and is only available in the U.S. Adverse events with PALLADIA can be serious but most are mild to moderate and are generally manageable. The most common side effects of PALLADIA involve the gastrointestinal tract and signs include diarrhea, decreased appetite, lethargy and vomiting. Life-threatening adverse events are rare but possible and early recognition is critical. Children should not come in contact with PALLADIA. In addition, all individuals, including children and pregnant women, should avoid direct contact with broken or partially-dissolved PALLADIA tablets or biological waste from dogs treated with PALLADIA. For specific dosing and prescribing information, visit www.palladia-pi.com.

About Pfizer Animal Health

Pfizer Animal Health, one of six business units of Pfizer Inc (NYSE: PFE), is a world leader in discovering and developing innovative animal prescription medicines and vaccines, investing an estimated $300 million annually. In 2007, Pfizer Animal Health began to expand its focus on pet oncology through a $1.1 million grant to the Morris Animal Foundation in support of an ongoing national canine tumor biospecimen bank. For more information on how Pfizer helps companion animals to live longer, healthier lives, or how Pfizer works to ensure a safe, sustainable global food supply with healthy livestock, visit www.PfizerAH.com.

About the American College of Veterinary Internal Medicine (ACVIM)

The ACVIM is the national certifying organization for veterinary specialists in large and small animal internal medicine, cardiology, neurology and oncology. The mission of the ACVIM is to enhance animal and human health by advancing veterinary internal medicine through training, education and discovery. For more information, please visit www.ACVIM.org.

[1] www.CureCanineCancer.org

[2] Pfizer Animal Health Market Research, New York, New York, data on file

[3] London CA, Malpas PB, Wood-Follis SL, et al. Multi-center, placebo-controlled, double-blind, randomized study of oral toceranib phosphate (SU11654), a receptor tyrosine kinase inhibitor, for the treatment of dogs with recurrent (either local or distant) mast cell tumor following surgical excision. *Clinical Cancer Research*. Published online May 26, 2009 as 10.1158/1078-0432.CCR-08-1860.

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