



## MERIAL Receives Full License Approval for ONCEPT™ Canine Melanoma Vaccine

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### **ONCEPT is the First and Only USDA-Approved, Therapeutic Vaccine for the Treatment of Cancer**

Duluth, GA — Merial, a world-leading animal health company, has gained full-licensure from the U.S. Department of Agriculture for ONCEPT™ Canine Melanoma Vaccine, DNA. ONCEPT is a breakthrough vaccine indicated for aiding in extending survival of dogs with stage II or stage III oral canine melanoma, a common yet deadly form of cancer in dogs.

ONCEPT is the first and only USDA-approved, therapeutic vaccine for the treatment of cancer — in either animals or humans.

Traditionally, dogs with stage II or stage III malignant melanoma survive less than five to six months when treated with surgery alone.<sup>1</sup> Clinical studies of ONCEPT demonstrated significantly longer life spans even in dogs with stage II or stage III of oral melanoma. In fact, median survival time of dogs treated with ONCEPT could not be determined because more than 50 percent of the treated dogs were still living melanoma-free at the conclusion of the study or died of unrelated illness.<sup>2</sup>

Canine oral melanoma is a common type of cancer in dogs and is the most common malignant tumor of the dog's mouth. It can also be seen in the nail and footpad.<sup>3</sup> Canine melanoma may be seen in any breed and is a highly aggressive cancer that frequently spreads throughout the body, including the lymph nodes, liver, lungs and kidneys.<sup>4</sup> To date, the most common treatments for this form of cancer have been radiation and surgery to establish local tumor control. Canine oral melanoma, however, has a high propensity to metastasize to other parts of the body and is often resistant to chemotherapy.<sup>2,3</sup>

"Canine melanoma spreads readily, and, unfortunately, existing treatments have not succeeded in controlling the disease," said Dr. Bob Menardi, a veterinarian and spokesperson for Merial. "ONCEPT is a new adjunct treatment option for dogs that have been diagnosed with this often fatal disease."

The vaccine was developed through a partnership between Merial and Memorial Sloan-Kettering Cancer Center. While Memorial Sloan-Kettering was testing a human melanoma vaccine, they received an inquiry from Dr. Philip Bergman — who at the time was with Animal Medical Center, and currently with Brightheart Veterinary Center — seeking novel treatments for canine melanoma. The discussions resulted in clinical trials of the Memorial Sloan-Kettering melanoma vaccine, and subsequent parallel trials by Dr. Bergman and Memorial Sloan-Kettering refined the dosage and protocol to the current therapeutic regimen for dogs. Dr. Bergman completed the initial clinical work on ONCEPT at Animal Medical Center in New York.

"We're very excited about continuing research into this vaccine to explore the potential implications it has for humans. We hope this will result in improved cancer treatment for all," explained Jedd D. Wolchok, MD, PhD, a medical oncologist who specializes in immunotherapy on the Melanoma and Sarcoma Service at Memorial Sloan-Kettering and also Associate Director of the Ludwig Center for Cancer Immunotherapy.

The USDA issued a conditional U.S. Veterinary Biological Product License for ONCEPT in 2007. During the period of conditional licensure, ONCEPT was available to veterinary oncologists as Merial conducted additional research to further support the safety and efficacy of the vaccine.

The results of that research led to the full licensure of ONCEPT. Merial obtained licensing rights from Memorial Sloan-Kettering and Dr. Philip Bergman, and, using their access to and experience

with DNA vaccine technology licensed from Vical Incorporated (Nasdaq: VICL), completed the industrialization and regulatory requirements for full licensure. The vaccine will be administered via a Canine Transdermal Device, which delivers the vaccine without the use of a needle.<sup>5</sup> The device was developed in conjunction with Bioject, Inc., a Portland-based drug delivery company (OTCBB: BJCT).

"The Canine Transdermal Device makes administration of the vaccine easy and quick for oncologists and their patients, leaving one less worry for dog owners dealing with their pet's cancer treatment" said Dr. Richard Stout, executive vice president and chief medical officer of Bioject. "We are proud to work with Merial in bringing this breakthrough product to market."

"The approval of ONCEPT is a milestone in the cancer vaccine field and a significant advancement for our DNA delivery technology platform," said Vijay B. Samant, Vical's President and Chief Executive Officer. "Therapeutic vaccines — the holy grail of vaccinology — are delivered after disease onset to impede disease progress for the patient's benefit. We believe this achievement is a major step toward the initial approvals of therapeutic vaccines for humans."

ONCEPT is available for use by specialists practicing veterinary oncology, so pet owners will want to ask their veterinarians about how best to access this treatment option.

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<sup>1</sup>Bergman PJ, Wolchok JD. Of Mice and Men (and Dogs): development of a xenogeneic DNA vaccine program for canine malignant melanoma. *Cancer Therapy* 2008;6:817-826.

<sup>2</sup>Data on file at Merial. Study 05-171. 2009.

<sup>3</sup>Bergman PJ, et al. Development of a xenogeneic DNA vaccine program for canine malignant melanoma at the Animal Medical Center. *Vaccine* 2006;24:4582-4585.

<sup>4</sup>Liao JCF, et al. Vaccination with human tyrosinase DNA induces antibody responses in dogs with advanced melanoma. *Cancer Immunity* 2006;6:8-17.

<sup>5</sup>ONCEPT product label.

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Merial is a world-leading, innovation-driven animal health company, providing a comprehensive range of products to enhance the health, well-being and performance of a wide range of animals. Merial employs approximately 5,700 people and operates in more than 150 countries worldwide. Its 2009 sales were \$2.6 billion. Merial is the Animal Health subsidiary of sanofi-aventis. For more information, please see [www.merial.com](http://www.merial.com).

Bioject Medical Technologies Inc., based in Portland, Oregon, is an innovative developer and manufacturer of needle-free injection therapy systems (NFITS). NFITS provide an empowering technology and work by forcing medication at high speed through a tiny orifice held against the skin. This creates a fine stream of high-pressure fluid penetrating the skin and depositing medication in the tissue beneath. The Company is focused on developing mutually beneficial agreements with leading pharmaceutical, biotechnology, and veterinary companies. For more information about Bioject, visit [www.bioject.com](http://www.bioject.com).

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. Additional information on Vical is available at [www.vical.com](http://www.vical.com).

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