

*Introducing  
the first  
**DNA-based**  
vaccine for  
canine cancer.\**

Canine Melanoma Vaccine



\*Canine oral melanoma.

# An innovative adjunct for treatment and prolonging survival

A USDA conditional license has been granted to Merial for a therapeutic DNA vaccine. This vaccine is for dogs with stage II or stage III oral melanoma and for which local disease control has been achieved.<sup>1</sup>

When combined with surgery and/or radiation in the treatment of canine oral melanoma, this type of vaccine has resulted in:

- **Remarkably prolonged survival times**<sup>2</sup>
- Both T-cell and humoral immune responses<sup>2,3</sup>
- Minimal local toxicity and a lack of systemic toxicity<sup>2</sup>

## Canine melanoma is aggressive and deadly.

- Canine melanoma is an aggressive neoplasm, usually of the oral cavity, nail bed, footpad and mucocutaneous junction.<sup>2,4</sup>
- Melanoma of the oral cavity should always be considered malignant regardless of the histology.<sup>5</sup>
- Canine melanoma is traditionally treated with surgery and/or radiation therapy with possible adjunct chemotherapy for distant (metastatic) cancer cells.<sup>2,4</sup>

## Traditional therapy leaves room for improvement.

- In canine patients with melanoma, metastatic disease is common and chemoresistant.<sup>2,4,5</sup>
- Dogs with advanced melanoma (stage II through stage IV) have reported median survival times of less than five months when treated with standard therapies (surgery, radiation and/or chemotherapy).<sup>2</sup>
- Response rates to chemotherapy have historically been poor, with little evidence that treatment prolongs survival.<sup>2,4</sup>

**Canine Melanoma Vaccine is a promising adjunct to traditional therapies — and may prolong survival time.**<sup>2,4,5,6</sup>

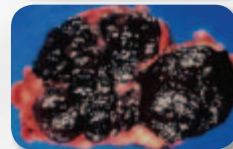
### Clinical Staging of Canine Oral Melanoma<sup>2</sup>



**Stage I tumor:**  
<2 cm diameter,  
negative nodes



**Stage II tumor:**  
2 to 4 cm diameter,  
negative nodes



**Stage III tumor:**  
>4 cm and/or  
positive nodes



**Stage IV tumor:**  
any size with  
distant metastatic  
disease

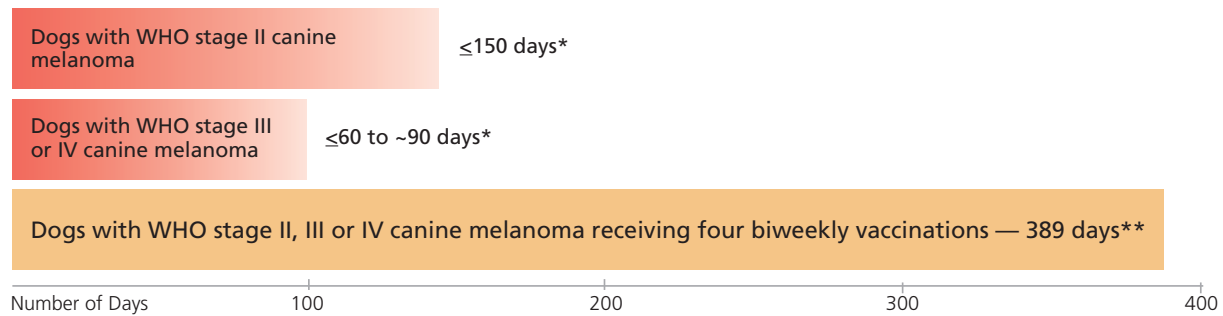
*NOTE: All oral tumors, regardless of stage, should be considered malignant and potentially fatal. Contact a specialist practicing veterinary oncology for more information about canine melanoma and possible treatments.*

# ating canine melanoma — survival time.

## How the new DNA therapeutic vaccine works.

- Canine Melanoma Vaccine alerts the immune system to the presence of the melanoma tumor protein tyrosinase.<sup>2,4</sup>
- Innovative vaccine technology uses a gene for human tyrosinase inserted into a DNA plasmid. The tyrosinase that is produced is different enough from the canine tyrosinase protein that it will stimulate an immune response, yet similar enough to the canine tyrosinase that the immune response is directed against melanoma cells.<sup>2,4</sup>
- The immune system recognizes the tyrosinase on the dog's melanoma cells as "foreign" rather than "self," and an immune response is generated against the cells.<sup>6</sup>
- As an adjunct to surgery and/or radiation therapy to remove the initial tumor, this immune response may help extend the survival time of the dog with oral melanoma.<sup>2,4</sup>

Table 1: Median Survival Time Comparison



Patients in all groups received surgery and/or radiation for local tumor control.

\*Historical Kaplan-Meier median. \*\*Documented Kaplan-Meier survival curve for dogs in a human tyrosinase trial.<sup>2</sup>

## Vaccine trials demonstrate safety and prolonged survival.

- From April 2000 to present, more than 100 dogs with melanoma have been treated with xenogeneic DNA vaccines (vaccine utilizing DNA from species other than the patient).<sup>4</sup>
- Canine Melanoma Vaccine is administered via a needle-free transdermal device, which ensures distribution of antigen in target tissue.
- Xenogeneic human tyrosinase vaccines have demonstrated effectiveness based on clinical antitumor responses and remarkably prolonged median survival times.<sup>2</sup>

# Canine Melanoma Vaccine is a promising adjunct to traditional therapies — and may prolong survival time.<sup>2,4,5,6</sup>

**NOTICE:** The USDA has issued a conditional U.S. Veterinary Biological Product License for this therapeutic vaccine. This conditional license is a response to an application and assurance of safety and purity, and a reasonable expectation of efficacy based on initial trials.<sup>2,4</sup>

During the period of the conditional license, additional research will be conducted to further support the safety and efficacy of the vaccine. Production under this license is in compliance with all regulations and standards applicable to such products.



## Canine Melanoma Vaccine

- Four single-dose vials for initial series of biweekly vaccination
- Booster doses recommended at six-month intervals

Canine Melanoma Vaccine is manufactured by Merial, a world leader in recombinant canarypox-vectored vaccine technology and developers of advanced vaccines, including PUREVAX® Recombinant Leukemia, PUREVAX Feline Rabies and RECOMBITEK® distemper vaccines.

For the name of a cancer specialist in your area, visit [www.acvim.org](http://www.acvim.org) or [www.vetcancersociety.org](http://www.vetcancersociety.org).  
For additional information about Canine Melanoma Vaccine, please contact Merial Technical Solutions at 1-888-MERIAL-1, Option 3.

<sup>1</sup>Vaccine product label.

<sup>2</sup>Bergman PJ, et al. Long-Term Survival of Dogs with Advanced Malignant Melanoma after DNA Vaccination with Xenogeneic Human Tyrosinase: A Phase I Trial. *Clinical Cancer Research* 2003;9:1284-1290.

<sup>3</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>4</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>5</sup>Cronin K. Canine and feline oral tumors: Earlier is better. *DVM* 2006;37(7):65-115.

<sup>6</sup>Tremayne J. Researcher eyes vaccines to treat canine skin cancer. *DVM* 2005;36(8):22.

