



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Merial, Inc.
USDA Vet Biologics Establishment Number	298
Product Code	9240.D0
True Name	Canine Melanoma Vaccine, DNA
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Oncept - No distributor specified
Date of Compilation Summary	January 13, 2020

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy														
Pertaining to	Treatment for oral melanoma														
Study Purpose	Demonstrate efficacy in treatment of oral melanoma														
Product Administration	Intramuscularly in rear leg via transdermal route. Four (4) doses at 2-week intervals followed by boosters at 6 month intervals.														
Study Animals	53 client-owned dogs of different breeds ranging in age from 5-16 years with oral melanoma, WHO stage II or III with local disease control. Local disease control is defined as no gross disease of the oral cavity and the absence of regional lymph node involvement and/or pulmonary metastasis. Removal/irradiation of regional lymph nodes or irradiation of the surgical scar may have been performed before the first vaccination to achieve local control.														
Challenge Description	Not applicable														
Interval observed after challenge	Study period was 2 years, 5 months. Following the initial vaccine series, dogs were evaluated monthly. Survival time was calculated from the date of surgery (or histological sample submission) to death or last date of follow-up.														
Results	<p>Survival time of vaccinates.</p> <p>Summary of Outcomes in Melanoma Study Dogs</p> <table border="1"> <thead> <tr> <th>Outcome</th> <th>Vaccine</th> </tr> </thead> <tbody> <tr> <td>Death due to disease</td> <td>13</td> </tr> <tr> <td>Death due to unrelated causes</td> <td>9</td> </tr> <tr> <td>Lost to follow up</td> <td>5</td> </tr> <tr> <td>Removed from study</td> <td>7</td> </tr> <tr> <td>Alive at the end of the study</td> <td>19</td> </tr> <tr> <td>Total</td> <td>53</td> </tr> </tbody> </table> <p>Raw data on attached page.</p>	Outcome	Vaccine	Death due to disease	13	Death due to unrelated causes	9	Lost to follow up	5	Removed from study	7	Alive at the end of the study	19	Total	53
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Death due to disease	13														
Death due to unrelated causes	9														
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Removed from study	7														
Alive at the end of the study	19														
Total	53														
USDA Approval Date	October 26, 2009														

Survival times and outcomes of vaccinated dogs

Outcome	Survival Time (days)
Death due to disease	52
	90
	100
	165
	177
	181
	199
	235
	290
	293
	464
	475
	583
Death due to unrelated causes	62
	87
	267
	274
	293
	304
	307
	470
	550
Lost to follow up	62
	139
	200
	245
	557
Removed from study*	57
	84
	178
	280
	411
	510
525	

Outcome	Survival Time (days)
Alive at end of study	267
	314
	332
	380
	426
	435
	437
	442
	455
	475
	476
	481
	528
	625
	633
	679
	685
723	
736	

*Vaccinated dogs removed from the study:

- Six (6) dogs were removed by owner/veterinarian to pursue an alternative treatment option for melanoma.
- One (1) dog was removed by owner/veterinarian due to a primary lung nodule.

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
Product Administration	Intramuscularly into rear leg via transdermal route Four (4) doses at 2-week intervals
Study Animals	60 dogs with oral melanoma
Challenge Description	Not applicable
Interval observed after challenge	Animals were monitored for at least 30 minutes after vaccination by a veterinarian. Vaccination sites were examined 2 weeks after vaccination by a veterinarian. Owners observed dogs and recorded observations daily for 2 weeks after each vaccination.
Results	Four dogs received at least two vaccinations but did not complete the series. See next page for data summary.
USDA Approval Date	March 18, 2009

Table 1: Number of Acute Local Reactions or any Bruising/Hematoma in 234 vaccinations of 60 dogs.

Injection Site Pain		Injection Site Wheal		Injection Site Leakage		Injection Site Bleeding ^a	
Mild	Moderate	Acute ^b	Subacute ^b	Droplet ^c	Wet ^c	Bruising alone	Hematoma ^d
73	12	3	5	117	11	13	3

^aAll but one case of bruising resolved within 2 weeks.

^bAcute: arose and resolved within 30 minutes; Subacute: still present after 30 minutes. Wheals typically resolved within 1 hour.

^cDroplet: a drop of fluid or blood at entry site. Wet: flow of fluid or blood from entry site. Occurred and resolved at time of injection.

^dReports of hematoma could also include bruising. Hematomas resolved within the first few days after vaccination.

Table 2: Post – vaccination veterinarian reported events.

Clinical Sign	Number of events in 234 vaccinations of 60 dogs
Anemia	1
Anorexia	2
Anxiety	1
Diarrhea	1
Injection site crust	2
Injection site itching	3
Injection site pain	5
Injection site rash	1
Injection site swelling	1
Fever	1
Lethargy	2
Limb weakness	1
Pyoderma	1
Sneezing	1
Vomiting	3

Table 3: Post- vaccination owner reported observations. Events are only reported once per vaccination, even if they were reported on multiple days. Events duplicated in the veterinarian reports are reported in Table 2.

Clinical Sign	Number of events in 234 vaccinations of 60 dogs
Abdominal pain	1
Aggression	1
Anxiety	2
Behavioral disorder Non-specific	2
Bloodshot eye	5
Confusion	1
Cough	4
Decreased activity	2
Decreased appetite/Not eating	21
Depression	33
Diarrhea	8
Difficulty breathing	1
Difficulty standing	6
Difficulty walking	4
Disoriented	1
Enlarged lymph node	1
Erythema	1
Erythematous rash	1
Eye discharge	5
Fever	4
Glazed eye	3
Groaning	1
Hair loss	1
Hiccup	1
Hypersalivation	1
Increased appetite	13
Increased drinking	4
Increased temperature	4
Increased thirst	3
Injection site lump	1
Injection site pain	12
Injection site reddening	12
Injection site self-trauma	1
Injection site swelling ^a	13
Injection site warmth	14
Itchy	6
Jaw disorder	1
Lameness	7
Lethargy	3

Clinical Sign	Number of events in 234 vaccinations of 60 dogs
Loose stool	2
Lump	2
Malaise	2
Nasal bleeding	1
Neurological abnormality Non-specific	1
Not eating	2
Oral bleeding	3
Oral pain	1
Others ^b	18
Pacing	1
Pain	1
Pain on palpation	14
Red eye	1
Reddening of the skin	1
Retching	2
Scratching	5
Self-trauma	1
Skin disorder	1
Skin infection	1
Sleep disorder Non-specific	2
Sneezing	5
Stiffness	4
Swollen eye	1
Tiredness	19
Tongue protrusion	1
Vocalization	1
Vomiting	8
Weight loss	1

^aSwelling typically reported for 1-3 days.

^bIncludes arthritis, deaths (heart mass, metastatic melanoma, anaplastic sarcoma), ear infection, forgetful, gastric dilatation/volvulus, inappropriate defecation, incontinence, licking, lipoma, paw tumor, pica, primary lung tumor, surgical site self-trauma, voice alteration, whipworms