Summary of Studies Supporting USDA Product Licensure

Establishment Name	ELIAS Animal Health, LLC
USDA Vet Biologics Establishment Number	691
Product Code	95A7.50
True Name	Autologous Prescription Product
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Not Listed - No distributor specified
Date of Compilation Summary	March 13, 2025

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	Safety
Pertaining to	ALL
Study Purpose	To demonstrate safety under typical use conditions
Product Administration	Product Group: Following amputation surgery, dogs received autologous vaccines administered by intradermal injection at every 7 days for a total of three doses and one autologous T cell infusate administered by IV infusion 21 days after final vaccine. Control Group: Following amputation surgery, dogs received carboplatin (300mg/M^2) by IV infusion every 21 days for a total of four doses.
Study Animals	101 dogs diagnosed with osteosarcoma were evaluated at 11 veterinary practices. 49 of the dogs were administered the product. The remaining 52 dogs were administered carboplatin (Control Group).
Challenge Description	Not applicable
Interval observed after challenge	Product Group: Following vaccination, dogs were released to owner. Following T cell infusate, dogs were monitored for 4-6 hours post-T cell infusion and then were assessed 1 and 10 days later. Control Group: Following the first carboplatin infusion, dogs were released to owner and then were assessed 7 and 14 days later. Following the remaining carboplatin infusions, dogs were released to owner. Following end of treatment, all dogs were assessed at 90-day intervals for the duration of the 18-month study.
Results	See following pages for data summary of adverse events.
USDA Approval Date	January 10, 2024

Adverse Events Observed in Product Group (Product Code 95A7.50):

Table 1: Summary of Adverse Events for Autologous Vaccine per Veterinary Cooperative Oncology Group (VCOG) on Common Terminology (49 dogs administered at least one vaccine)

Adverse Event	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Lethargy/fatigue/ general performance	9 (18.4%)	8 (16.3%)	1 (2.0%)	0	0	0
Anorexia	6 (12.2%)	5 (10.2%)	1 (2.0%)	0	0	0
Diarrhea	6 (12.2%)	4 (8.2%)	2 (4.1%)	0	0	0
Personality/behavior	5 (10.2%)	4 (8.2%)	1 (2.0%)	0	0	0
Vomiting	4 (8.2%)	4 (8.2%)	0	0	0	0
Nausea/ptyalism	3 (6.1%)	3 (6.1%)	0	0	0	0

NOTE: Only the worst grade of an adverse event is included in the occurrence calculation. Adverse events that occurred in ≥ 5% of all dogs or any grade 3 to 5 AE that occurred at any frequency are included.

Adverse Event represents the most appropriate AE term from VCOG-CTCAE v1.1 (Veterinary Cooperative Oncology Group, 2011, Veterinary and Comparative Oncology 4:417-446). The adverse events table data does not indicate the probable cause of the adverse events listed. Any unfavorable and unintended event that occurs after the use of the product constitutes an adverse event, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product. Adverse events due to pre-existing conditions and progression of the disease being treated (osteosarcoma) were excluded.

Table 2: Summary of Adverse Events for Autologous T cell Infusate per Veterinary Cooperative Oncology Group (VCOG) on Common Terminology (45 dogs administered T cell infusate)

Adverse Event	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Lethargy/fatigue/ general performance	9 (20.0%)	4 (8.9%)	5 (11.1%)	0	0	0
Anorexia	8 (17.8%)	4 (8.9%)	4 (8.9%)	0	0	0
Nausea/ptyalism	7 (15.6%)	5 (11.1%)	2 (4.4%)	0	0	0
Diarrhea	6 (13.3%)	6 (13.3%)	0	0	0	0
Vomiting	6 (13.3%)	3 (6.7%)	3 (6.7%)	0	0	0
Fever	5 (11.1%)	3 (6.7%)	2 (4.4%)	0	0	0
Personality/behavior	4 (8.9%)	4 (8.9%)	0	0	0	0
Cough	4 (8.9%)	3 (6.7%)	0	1 (2.2%)	0	0
Pain (unspecified)	3 (6.7%)	0	1 (2.2%)	2 (4.4%)	0	0
Dyspnea	1 (2.2%)	0	0	1 (2.2%)	0	0

NOTE: Only the worst grade of an adverse event is included in the occurrence calculation. Adverse events that occurred in ≥ 5% of all dogs or any grade 3 to 5 AE that occurred at any frequency are included.

Adverse Event represents the most appropriate AE term from VCOG-CTCAE v1.1 (Veterinary Cooperative Oncology Group, 2011, Veterinary and Comparative Oncology 4:417-446). The adverse events table data does not indicate the probable cause of the adverse events listed. Any unfavorable and unintended event that occurs after the use of the product constitutes an adverse event, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product. Adverse events due to pre-existing conditions and progression of the disease being treated (osteosarcoma) were excluded.

Adverse Events Observed in Control Group (Standard of Care Carboplatin Therapy):

Table 3: Summary of Adverse Events for Carboplatin per Veterinary Cooperative Oncology Group (VCOG) on Common Terminology (52 dogs administered at least one dose of carboplatin)

Adverse Event	Any Grade	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Neutropenia	40 (76.9%)	27 (51.9%)	3 (5.8%)	7 (13.5%)	3 (5.8%)	0
Thrombocytopenia	14 (26.9%)	4 (7.7%)	3 (5.8%)	2 (3.8%)	5 (9.6%)	0
Lethargy/fatigue/general performance	11 (21.2%)	8 (15.4%)	3 (5.8%)	0	0	0
Diarrhea	10 (19.2%)	10 (19.2%)	0	0	0	0
Nausea/ptyalism	9 (17.3%)	6 (11.5%)	3 (5.8%)	0	0	0
Vomiting	9 (17.3%)	6 (11.5%)	3 (5.8%)	0	0	0
Anorexia	8 (15.4%)	6 (11.5%)	2 (3.8%)	0	0	0
Cough	8 (15.4%)	6 (11.5%)	1 (1.9%)	0	1 (1.9%)	0
Personality/behavior	7 (13.5%)	4 (7.7%)	3 (5.8%)	0	0	0
Decreased MCHC	3 (5.8%)	3 (5.8%)	0	0	0	0
Arthritis, non-septic	3 (5.8%)	1 (1.9%)	2 (3.8%)	0	0	0
Extremity (gait/ambulation) lameness	3 (5.8%)	1 (1.9%)	2 (3.8%)	0	0	0
Cystitis	3 (5.8%)	3 (5.8%)	0	0	0	0
Fever	2 (3.8%)	1 (1.9%)	0	1 (1.9%)	0	0
Sepsis	1 (1.9%)	0	0	1 (1.9%)	0	0
Constipation	1 (1.9%)	0	0	0	1 (1.9%)	0
Hemoabdomen	1 (1.9%)	0	0	0	0	1 (1.9%)
Pain (hip fracture)	1 (1.9%)	0	0	0	0	1 (1.9%)

NOTE: Only the worst grade of an adverse event is included in the occurrence calculation. Adverse events that occurred in ≥ 5% of all dogs or any grade 3 to 5 AE that occurred at any frequency are included.

Adverse Event represents the most appropriate AE term from VCOG-CTCAE v1.1 (Veterinary Cooperative Oncology Group, 2011, Veterinary and Comparative Oncology 4:417-446). The adverse events table data does not indicate the probable cause of the adverse events listed. Any unfavorable and unintended event that occurs after the use of the product constitutes an adverse event, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product. Adverse events due to pre-existing conditions and progression of the disease being treated (osteosarcoma) were excluded.