# Summary of Studies Supporting USDA Product Licensure

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| Establishment Name | Intervet Inc. |
| USDA Vet Biologics Establishment Number | 165A |
| Product Code | 9790.02 |
| True Name | Gilvetmab |
| Tradename(s) / Distributor or Subsidiary (if different from manufacturer) | |
| Date of Compilation Summary | December 06, 2022 |

**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.**

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| **Study Type** | Safety |
| **Pertaining to** | ALL |
| **Study Purpose** | Demonstrate safety of product under typical use conditions |
| **Product Administration** | Administered by IV infusion at either 14 or 28-day intervals for 10 total treatments. |
| **Study Animals** | 51 dogs meeting enrollment criteria; 26 dogs with mast cell tumor, 25 dogs with melanoma. |
| **Challenge Description** | NA |
| **Interval observed after challenge** | Dogs were monitored for 6 hours post-treatment. Dogs were pretreated with diphenhydramine 2 mg/kg either orally within 4 hours of treatment of IM within 15-30 minutes or treatment. |
| **Results** | See next page for data summary. |
| **USDA Approval Date** | August 29, 2019 |

## Table 1: Summary of Adverse Events for Mast Cell Tumor per Veterinary Cooperative Oncology Group (VCOG) on Common Terminology

| Adverse event | Any grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|---|
| Lethargy/fatigue/general performance | 15 (57.7%) | 12 (46.2%) | 1 ( 3.8%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 |
| Weight loss | 12 (46.2%) | 10 (38.5%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 | 0 |
| Reduced Appetite | 12 (46.2%) | 11 (42.3%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Vomiting | 11 (42.3%) | 9 (34.6%) | 2 ( 7.7%) | 0 | 0 | 0 |
| Diarrhea | 9 (34.6%) | 9 (34.6%) | 0 | 0 | 0 | 0 |
| Erythema | 7 (26.9%) | 5 (19.2%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 | 0 |
| Bacteriuria* | 6 (23.1%) | 6 (23.1%) | 0 | 0 | 0 | 0 |
| Nausea/ptyalism | 6 (23.1%) | 5 (19.2%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (including cysts and polyps) | 6 (23.1%) | 6 (23.1%) | 0 | 0 | 0 | 0 |
| Muscle weakness, generalized or specific area | 5 (19.2%) | 2 ( 7.7%) | 0 | 3 (11.5%) | 0 | 0 |
| Neutrophilia | 5 (19.2%) | 5 (19.2%) | 0 | 0 | 0 | 0 |
| Pain | 5 (19.2%) | 5 (19.2%) | 0 | 0 | 0 | 0 |
| Skin ulceration | 4 (15.4%) | 2 ( 7.7%) | 0 | 2 ( 7.7%) | 0 | 0 |
| ALT | 4 (15.4%) | 2 ( 7.7%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 | 0 |
| Alkaline phosphatase | 4 (15.4%) | 3 (11.5%) | 0 | 1 ( 3.8%) | 0 | 0 |
| AST | 4 (15.4%) | 4 (15.4%) | 0 | 0 | 0 | 0 |
| Cystitis (hematuria/pyuria included) | 4 (15.4%) | 4 (15.4%) | 0 | 0 | 0 | 0 |
| Dermatitis and eczema* | 4 (15.4%) | 4 (15.4%) | 0 | 0 | 0 | 0 |
| Extremity (gait/ambulation) lameness | 4 (15.4%) | 3 (11.5%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Fever | 4 (15.4%) | 4 (15.4%) | 0 | 0 | 0 | 0 |
| Leukocytosis* | 4 (15.4%) | 4 (15.4%) | 0 | 0 | 0 | 0 |
| Proteinuria | 4 (15.4%) | 3 (11.5%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Alopecia | 3 (11.5%) | 3 (11.5%) | 0 | 0 | 0 | 0 |
| Pruritus | 3 (11.5%) | 2 ( 7.7%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Tremor | 3 (11.5%) | 3 (11.5%) | 0 | 0 | 0 | 0 |
| Tumor hemorrhage* | 2 ( 7.7%) | 0 | 1 ( 3.8%) | 0 | 0 | 1 ( 3.8%) |
| Adrenomegaly* | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Anemia* | 2 ( 7.7%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Digestive tract hemorrhage* | 2 ( 7.7%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 | 0 | 0 |
| Grooming disorder* | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Hepatopathy* | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Hypotension | 2 ( 7.7%) | 0 | 2 ( 7.7%) | 0 | 0 | 0 |
| Lymphadenopathy* | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Edema limbs* | 2 ( 7.7%) | 1 ( 3.8%) | 1 ( 3.8%) | 0 | 0 | 0 |

***NOTE: Only the worst grade of an adverse event in any given dog is included in the occurrence calculation.***
***Adverse events that occur in >= 5% of all the dogs in the study or any grade 3 to 5 AE that occurred at any frequency are included.***
**** Adverse event reflects the 'specify' per VCOG 'Other (specify)' under the body system category***

*using the most appropriate AE term from other coding dictionaries. (Veterinary Cooperative Oncology Group, 2016, 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, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product, such as pre-existing disease.

## Table 1: Summary of Adverse Events for Mast Cell Tumor per Veterinary Cooperative Oncology Group (VCOG) on Common Terminology - continued

| Adverse Event | Any grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|---|
| Panting* | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Somnolence/depressed level of consciousness/dullness | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Urinary tract infection* | 2 ( 7.7%) | 2 ( 7.7%) | 0 | 0 | 0 | 0 |
| Anaphylaxis | 1 ( 3.8%) | 0 | 0 | 1 ( 3.8%) | 0 | 0 |
| Hemoglobin | 1 ( 3.8%) | 0 | 0 | 1 ( 3.8%) | 0 | 0 |
| Recumbency* | 1 ( 3.8%) | 0 | 0 | 1 ( 3.8%) | 0 | 0 |
| Regurgitation* | 1 ( 3.8%) | 0 | 0 | 1 ( 3.8%) | 0 | 0 |

***NOTE: Only the worst grade of an adverse event in any given dog is included in the occurrence calculation.***
***Adverse events that occur in >= 5% of all the dogs in the study or any grade 3 to 5 AE that occurred at any frequency are included.***
**** Adverse event reflects the 'specify' per VCOG 'Other (specify)' under the body system category***
*using the most appropriate AE term from other coding dictionaries. (Veterinary Cooperative Oncology Group, 2016, 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, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product, such as pre-existing disease.

## Table 2: Summary of Adverse Events for Melanoma per Veterinary Cooperative Oncology Group (VCOG) on Common Terminology

| Adverse event | Any grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|---|
| Lethargy/fatigue/general performance | 18 (72.0%) | 12 (48.0%) | 4 (16.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 |
| Reduced Appetite | 15 (60.0%) | 8 (32.0%) | 5 (20.0%) | 2 ( 8.0%) | 0 | 0 |
| Diarrhea | 12 (48.0%) | 12 (48.0%) | 0 | 0 | 0 | 0 |
| Weight loss | 12 (48.0%) | 11 (44.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Vomiting | 11 (44.0%) | 9 (36.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 |
| Halitosis* | 9 (36.0%) | 8 (32.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Tumor hemorrhage* | 8 (32.0%) | 7 (28.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| BUN | 7 (28.0%) | 2 ( 8.0%) | 4 (16.0%) | 0 | 1 ( 4.0%) | 0 |
| Neutrophilia | 7 (28.0%) | 7 (28.0%) | 0 | 0 | 0 | 0 |
| Leukocytosis* | 6 (24.0%) | 5 (20.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Nausea/ptyalism | 6 (24.0%) | 5 (20.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Tumor infection* | 6 (24.0%) | 3 (12.0%) | 3 (12.0%) | 0 | 0 | 0 |
| Fever | 5 (20.0%) | 2 ( 8.0%) | 3 (12.0%) | 0 | 0 | 0 |
| Neoplasms benign, malignant and unspecified (including cysts and polyps) | 5 (20.0%) | 5 (20.0%) | 0 | 0 | 0 | 0 |
| Polydipsia* | 5 (20.0%) | 5 (20.0%) | 0 | 0 | 0 | 0 |
| Alkaline phosphatase | 4 (16.0%) | 2 ( 8.0%) | 0 | 2 ( 8.0%) | 0 | 0 |
| Muscle weakness, generalized or specific area | 4 (16.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 2 ( 8.0%) | 0 | 0 |
| Pain | 4 (16.0%) | 2 ( 8.0%) | 0 | 1 ( 4.0%) | 1 ( 4.0%) | 0 |
| Monocytosis* | 4 (16.0%) | 3 (12.0%) | 0 | 1 ( 4.0%) | 0 | 0 |
| Pancreatitis | 4 (16.0%) | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 |
| Amylase | 4 (16.0%) | 3 (12.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Anemia* | 4 (16.0%) | 3 (12.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Bacteriuria* | 4 (16.0%) | 3 (12.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Creatinine | 4 (16.0%) | 4 (16.0%) | 0 | 0 | 0 | 0 |
| Cystitis (hematuria/pyuria included) | 4 (16.0%) | 4 (16.0%) | 0 | 0 | 0 | 0 |
| Extremity (gait/ambulation) lameness | 4 (16.0%) | 4 (16.0%) | 0 | 0 | 0 | 0 |
| Somnolence/depressed level of consciousness/dullness | 4 (16.0%) | 3 (12.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Tremor | 4 (16.0%) | 4 (16.0%) | 0 | 0 | 0 | 0 |
| Urinary tract infection* | 4 (16.0%) | 4 (16.0%) | 0 | 0 | 0 | 0 |
| Dysphagia | 3 (12.0%) | 0 | 2 ( 8.0%) | 0 | 0 | 1 ( 4.0%) |
| Lipase | 3 (12.0%) | 2 ( 8.0%) | 0 | 1 ( 4.0%) | 0 | 0 |
| Cough | 3 (12.0%) | 2 ( 8.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Globulin, high* | 3 (12.0%) | 3 (12.0%) | 0 | 0 | 0 | 0 |

***NOTE: Only the worst grade of an adverse event in any given dog is included in the occurrence calculation.***
***Adverse events that occur in >= 5% of all the dogs in the study or any grade 3 to 5 AE that occurred at any frequency are included.***
**** Adverse event reflects the 'specify' per VCOG 'Other (specify)' under the body system category***

*using the most appropriate AE term from other coding dictionaries. (Veterinary Cooperative Oncology Group, 2016, 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, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product, such as pre-existing disease.

## Table 2: Summary of Adverse Events for Melanoma per Veterinary Cooperative Oncology Group on Common Terminology – continued

| Adverse Event | Any grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|---|
| Hemoglobin | 3 (12.0%) | 1 ( 4.0%) | 2 ( 8.0%) | 0 | 0 | 0 |
| Lymphadenopathy* | 3 (12.0%) | 3 (12.0%) | 0 | 0 | 0 | 0 |
| Oral hemorrhage* | 3 (12.0%) | 2 ( 8.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Proteinuria | 3 (12.0%) | 2 ( 8.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Pruritus | 3 (12.0%) | 3 (12.0%) | 0 | 0 | 0 | 0 |
| Pulmonary disorder* | 3 (12.0%) | 2 ( 8.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Tachypnea (not panting) | 3 (12.0%) | 2 ( 8.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Urine specific gravity, low* | 3 (12.0%) | 3 (12.0%) | 0 | 0 | 0 | 0 |
| Dyspnea | 2 ( 8.0%) | 1 ( 4.0%) | 0 | 1 ( 4.0%) | 0 | 0 |
| Glucose, high | 2 ( 8.0%) | 0 | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 |
| AST | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Albumin, low | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Alopecia | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Arthritis, non-septic | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| BUN/Creatinine ratio, high* | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Calcium, low | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Dehydration | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| External ear inflammation | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Grooming disorder* | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Hypotension | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Lymphocytosis* | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Mucositis/stomatitis | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Muscle wasting* | 2 ( 8.0%) | 0 | 2 ( 8.0%) | 0 | 0 | 0 |
| Edema face* | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Edema limbs* | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Pain, oral | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Phosphorous, high | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Polyuria | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Proprioception abnormality* | 2 ( 8.0%) | 1 ( 4.0%) | 1 ( 4.0%) | 0 | 0 | 0 |
| Rhinitis* | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Scar* | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Skin ulceration | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Tumor pain | 2 ( 8.0%) | 2 ( 8.0%) | 0 | 0 | 0 | 0 |
| Glucosuria | 1 ( 4.0%) | 0 | 0 | 1 ( 4.0%) | 0 | 0 |

***NOTE: Only the worst grade of an adverse event in any given dog is included in the occurrence calculation.***
***Adverse events that occur in >= 5% of all the dogs in the study or any grade 3 to 5 AE that occurred at any frequency are included.***
**** Adverse event reflects the 'specify' per VCOG 'Other (specify)' under the body system category*** *using the most appropriate AE term from other coding dictionaries. (Veterinary Cooperative Oncology Group, 2016, 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, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product, such as pre-existing disease.

## Table 2: Summary of Adverse Events for Melanoma per Veterinary Cooperative Oncology Group on Common Terminology – continued

| Adverse Event | Any grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 | Grade 5 |
|---|---|---|---|---|---|---|
| Leukemia* | 1 ( 4.0%) | 0 | 0 | 1 ( 4.0%) | 0 | 0 |
| Potassium, high | 1 ( 4.0%) | 0 | 0 | 0 | 1 ( 4.0%) | 0 |
| Tumor edema* | 1 ( 4.0%) | 0 | 0 | 1 ( 4.0%) | 0 | 0 |

***NOTE: Only the worst grade of an adverse event in any given dog is included in the occurrence calculation.***
***Adverse events that occur in >= 5% of all the dogs in the study or any grade 3 to 5 AE that occurred at any frequency are included.***
**** Adverse event reflects the 'specify' per VCOG 'Other (specify)' under the body system category***
*using the most appropriate AE term from other coding dictionaries. (Veterinary Cooperative Oncology Group, 2016, 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, whether the cause of the adverse event is known to be attributed to the product or is not attributed to the product, such as pre-existing disease.