Summary Report

Study Title	24 Week Toxicity Study of Vector A and Vector B Following a Single Intravenous Injection in Adult Cynomolgus Macaques
Study Director	Redacted Name A
Test Facility	TESTING FACILITY
TESTING FACILITY Study Number	VECTORSTUDYU1
Sponsor	Redacted Sponsor
Sponsor Reference Number	VECTORSTUDYU1
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COMPLIANCE STATEMENT

This study was a non-regulatory study for which a claim of Good Laboratory Practices (GLP) compliance was not made. However, laboratory procedures used were fully commensurate with international standards of GLPs.

TEST SITE INFORMATION

Test Site for VECTOR A and VECTOR B Neutralizing Antibody (NAb) Screening, PROTEIN Expression, and Biodistribution (Tissue)

Company	Redacted Lab B UNITED STATES OF AMERICA
Test Site Reference No.	VECTORSTUDYU1

Test Site for Microscopic Evaluation

Company	TESTING FACILITY. UNITED STATES OF AMERICA
Test Site Reference No.	VECTORSTUDYU1

RESPONSIBLE PERSONNEL

Study Director	Redacted Name A
Responsible Scientist for VECTOR A and VECTOR B Neutralizing (NAb) Antibody, PROTEIN Expression, and Biodistribution (Tissue) Analysis	Redacted Name B Redacted Lab B

RESPONSIBLE PERSONNEL (Continued)

Contributing Scientist for Clinical Pathology	Redacted Name C
Contributing Scientist for Anatomic Pathology	Redacted Name D

1. SUMMARY

The purpose of this study was to evaluate the efficacy and tolerability of AAV VECTOR A and VECTOR B when administered as a single dose via intravenous (IV) injection to cynomolgus monkeys.

Male cynomolgus monkeys were assigned to TWO groups, and doses of the test article were administered as indicated in the following table. Animals were dosed once via intravenous injection via a saphenous vein at a volume of 0.8 mL/kg.

Group[a,b]	No. of Animals Males	Dose Level (GC/kg)	Dose Concentration (GC/mL)
1 (VECTOR A)	3	$1.024x10^{13}$	$1.28x10^{13}$
5 (VECTOR B)	3	$1.024x10^{13}$	$1.28x10^{13}$

GC = Genome copies.
a All groups were administered test article via intravenous (bolus) injection on Day 1.
b Animals were dosed at a volume of 0.8 mL/kg.

Assessment of toxicity was based on mortality, clinical observations, body weights, and clinical and anatomic pathology. Blood samples were collected for VECTOR A and VECTOR B neutralizing antibody and PROTEIN EXPRESSION evaluations. Liver was collected for tissue biodistribution.

No test article-related deaths occurred. No test article-related clinical observations or alterations in body weight or body weight gain were noted. No test article-related hematology, coagulation, or clinical chemistry test results or macroscopic or microscopic findings were noted.

PROTEIN EXPRESSION Analysis Report Pending

Neutralizing Antibody Analysis Report Pending

No prominent clinical pathology findings were observed in animals administered VECTOR A or VECTOR B.

Microscopic findings were observed in animals administered VECTOR A and VECTOR B. Affected organs included the kidney (tubule degeneration and basophilia) and cecum, colon, increased severity of mononuclear cell infiltrates, and ulceration at the mucocutaneous junction of the rectum).

In conclusion, male cynomolgus monkeys were administered VECTOR A and VECTOR B(gene therapy) as a single dose via intravenous (IV) injection. No adverse test article-related findings were noted; the test article was considered to be tolerated.

2. GENERAL STUDY INFORMATION

2.1 Objective

The objective of this study was to evaluate the efficacy and tolerability VECTOR A and VECTOR B when administered as a single dose via intravenous (IV) injection to cynomolgus monkeys.

2.2 Study Timetable

Study Initiation Date	Redacted
Experimental Starting Date	Redacted
Inlife Start Date	Redacted
Inlife End Date	Redacted
Experimental Completion Date	Redacted

2.3 Regulatory Test Guidelines

The study design was not based on a specific regulatory test guideline.

2.4 Protocol Adherence

The study was conducted in accordance with the Protocol and Protocol Amendments, with the exception of the Protocol Deviations. None of the deviations affected the integrity or interpretability of the results of the study. Only the last issued Protocol Amendment is presented in this report; this is because it is a comprehensive version containing all directives for study conduct.

2.5 Animal Welfare, Care, and Use Statement

TESTING FACILITY is fully accredited by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC). All procedures in the Protocol were in compliance with applicable animal welfare acts and were approved by the local Institutional Animal Care and Use Committee (IACUC).

2.6 Major Computer Systems

Application Name[a]	Application Function
LIMS1	Captures direct online inlife toxicology, pharmacy, and clinical and anatomic pathology data and study maintenance information and randomizes animals; transfers data and uploads data from external sources for translation
Statistical Analysis Software (SAS)	Performs statistical analysis

a All version numbers of the applications are maintained by TESTING FACILITY.

2.7 Archive Statement

The raw data, documentation, specimens (excluding wet specimens obtained from blood, urine, feces, and biological fluids), Protocol, study correspondence, and Final Report for

this study will be stored in the TESTING FACILITY archives for at least 1 year, as detailed in the Protocol.

The raw data generated from phases performed by Redacted Lab B and TESTING FACILITY will be archived according to test site standard operating procedures (SOPs).

3. METHODS

3.1 Test System and Study Design

3.1.1 Species Selection and Dose Administration Rationale

Monkeys historically have been used in safety evaluation studies and are recommended by appropriate regulatory agencies. The macaque has been selected for this study based on anatomical, physiological, immunological, and biochemical similarities to humans, which may facilitate extrapolation of observed immunological properties to humans. The number of animals is the minimum number of animals necessary for assessment of inter-animal variability. The intravenous route of administration was selected because it is the intended route of administration in humans.

Vector dose was selected based on human clinical dose in Hemophilia A patients. Doses were selected to mimic immunosuppressive regimens prescribed in clinical renal transplantation subjects. Duration of immunosuppressive dosing was based on data from previous studies conducted in monkeys.

3.1.2 Animal Specifications and Acclimation

Six male cynomolgus monkeys (*Macaca fascicularis*) of Chinese origin were received from TEST SUPPLIER. Animals were acclimated to the test facility for 54 days prior to initiation.

One hundred males were prescreened for anti-VECTOR A and VECTOR B neutralizing antibodies (NAbs) prior to animal shipment to TESTING FACILITY. Only animals with VECTOR A and VECTOR B NAb titers of ≤1:5 were enrolled in the study.

At initiation of dosing, animals were 33 to 56 months old, and body weights ranged from 2.6 to 3.2 kg. Animals not used on study were placed in the stock colony.

3.1.3 Environmental Conditions, Diet, and Water

3.1.3.1 Housing

Animals were housed in stainless steel cages (see Protocol Deviations). When possible, animals were socially housed by sex: up to three animals/cage. Animals were individually housed during acclimation or for study-related procedures.

3.1.3.2 Water

Water was provided *ad libitum* (see Protocol Deviations).

3.1.3.3 Diet

Animals were offered Certified Primate Diet #5L4L (PMI Nutrition International Certified LabDiet®) one to two times daily, unless fasted for study procedures (see Protocol Deviations).

3.1.3.4 Environment

Environmental controls were set to maintain a temperature range of 20 to 26°C, a relative humidity range of 30 to 70%, eight or greater air changes/hour, and a 12-hour light/12-hour dark cycle. Any variations to these conditions are maintained in the raw data and had no effect on the study outcome.

3.1.3.5 Dietary and Environmental Enrichment

Animals were given various cage-enrichment devices and fruit, vegetable, or dietary enrichment (that do not require analyses). Animals were commingled in accordance with TESTING FACILITY SOPs.

3.1.4 Animal Identification and Assignment to Study

Animals were identified using an implantable microchip identification device, tattoo, and/or cage card.

Animals were assigned to the study using a computerized procedure designed to achieve body weight balance with respect to group assignment. Prior to group assignment, animals were excluded from the selection pool to produce minimal variation. After group assignment, the mean body weight for each group was not statistically different at the 5.0% probability level, as indicated by analysis of variance *F* probability.

3.1.5 Study Design - Test Article

Group[a,b]	No. of Animals Males	Dose Level (GC/kg)	Dose Concentration (GC/mL)
1 (VECTOR A)	3	$1.024x10^{13}$	$1.28x10^{13}$
5 (VECTOR B)	3	$1.024x10^{13}$	$1.28x10^{13}$

GC = Genome copies.

a All groups were administered test article via intravenous (bolus) injection on Day 1.

b Animals were dosed at a volume of 0.8 mL/kg.

3.2 Test Article, Immunosuppressants, Vehicle, and Control Article

Information on synthesis methods, stability, purity, composition, or other characteristics defining the test article, immunosuppressants, vehicle, and control article is on file with the Sponsor or the respective manufacturer (see Certificates of Analysis).

3.2.1 Test Article

Test Article	Storage	Lot No.	Retest Date	Titer
VECTOR A	In a freezer, set to maintain -60 to -80°C	VectorLotA	Redacted	$1.28x10^{13}$ GC/mL
VECTOR B	In a freezer, set to maintain -60 to -80°C	VectorLotB	Redacted	$1.28x10^{13}$ GC/mL

3.2.2 Test Article Formulation

Test article formulations were prepared once on the day of dosing. All dose formulations were prepared by TESTING FACILITY according to the mixing procedure. Test article formulations were dispensed according to a dispensing procedure.

The test article was removed from the ultra-freezer on the day of use and thawed at room temperature.

Test article formulations were stored protected from light in a refrigerator, set to maintain 2 to 8°C. Test article formulations were maintained on wet ice (or equivalent) from the time of removal from refrigerator until the time of dosing.

3.3 VECTOR A and VECTOR B Neutralizing Antibody, PROTEIN Expression Analyses

3.3.1 VECTOR A and VECTOR B Neutralizing Antibody Screening Sample Collection and Handling

Blood samples (approximately 2.0 mL) were collected via the femoral vein once during the predose phase and on Day 1 of the dosing phase. Day 1 samples were collected prior to test article and IS administration (as applicable). Animals were not fasted for sample collections, unless fasted for other study procedures.

Blood was collected into serum separator tubes (without anticoagulant), allowed to clot at room temperature, and centrifuged within 1 hour of collection. Serum was harvested into tubes and place on 96-cluster racks. Serum samples were placed on dry ice prior to being placed in a freezer, set to maintain -60 to -80°C, until shipped on dry ice to the Redacted Lab B for analysis.

3.3.2 PROTEIN Expression Sample Collection and Handling

Blood samples (approximately 1.8 mL) were collected via the femoral vein on Days 1, 15, 29, 43, 57, 71, 85, 113, 141, and 169 of the dosing phase. Day 1 samples were collected prior to test article and IS administration (as applicable). All other samples were collected prior to IS administration (as applicable). Animals were not fasted for sample collections, unless fasted for other study procedures.

Blood was collected into tubes containing sodium citrate as the anticoagulant. Samples were maintained on chilled cryoracks prior to and after centrifugation and were centrifuged within 1 hour of collection. Plasma samples were inspected, and any abnormalities in color were documented. Samples that appeared hemolyzed were re-drawn (when possible). Plasma was harvested into two approximately equal aliquots. Samples were stored in appropriately labeled polypropylene tubes. Plasma was stored on dry ice until placed in a freezer, set to maintain -60 to -80°C, until shipped on dry ice to Redacted Lab B for analysis.

3.3.3 Control Blood Sample Banking for PROTEIN Expression Sample Collection and Handling

Blood samples (approximately 9.0 mL) were collected via the femoral vein twice during the predose phase (7 days apart). Animals were not fasted for sample collections.

Blood was collected into tubes containing sodium citrate as the anticoagulant. Samples were maintained on chilled cryoracks prior to and after centrifugation and were centrifuged within 1 hour of collection. Following centrifugation, plasma was harvested into nine approximately equal aliquots. Samples were stored in appropriately labeled polypropylene tubes. Plasma was placed on dry ice prior to being stored in a freezer, set to maintain -60 to -80°C, until shipped on dry ice to the Redacted Lab B for analysis.

3.3.4 VECTOR A AND VECTOR B Neutralizing Antibodies Sample Collection and Handling

Blood samples (approximately 2.0 mL) were collected via the femoral vein on Days 1, 15, 29, 43, 57, 71, 85, 113, 141, and 169 of the dosing phase. Day 1 samples were collected prior to test article and IS administration (as applicable). All other samples were collected prior to IS administration (as applicable). Animals were not fasted for sample collections, unless fasted for other study procedures.

Blood was collected into serum separator tubes (without anticoagulant), allowed to clot at room temperature, and centrifuged within 1 hour of collection. Following centrifugation, serum was harvested into two approximately equal aliquots. Samples were stored in appropriately labeled (*VECTOR A and VECTOR B NAb*) polypropylene tubes. Samples were placed on dry ice prior to being stored in a freezer, set to maintain -60 to -80°C, until shipped on dry ice to the Redacted Lab B for analysis.

3.3.5 VECTOR A and VECTOR B Neutralizing Antibody Screening Analysis

Serum samples were analyzed by the Redacted Lab B for AAV-neutralizing antibodies using a transduction inhibition NAb assay in CELL LINE cells using REPORTER.

Antibody screening samples that required storage at Redacted Lab B were handled in accordance with internal policies and procedures.

3.3.6 PROTEIN Expression Analysis

Plasma samples were analyzed by Redacted Lab B for PROTEIN expression using ELISA.

PROTEIN expression samples requiring storage at Redacted Lab B were handled in accordance with internal policies and procedures.

3.3.7 Control Blood Sample Banking for PROTEIN Expression Analysis

Plasma samples were banked at Redacted Lab B and used as control samples for PROTEIN Expression Analysis.

3.3.8 VECTOR A AND VECTOR B Neutralizing Antibodies Analysis

Serum samples were analyzed by Redacted Lab B for VECTOR A and VECTOR B NAbs using a transduction inhibition NAb assay (VECTOR A and VECTOR B NAbs.

Antibody analysis samples requiring storage at Redacted Lab B were handled in accordance with internal policies and procedures.

3.4 Inlife Procedures

3.4.1 Dose Administration - Test Article

Dose formulations were administered once on Day 1 of the dosing phase by intravenous injection via a saphenous vein at a dose volume of 0.8 mL/kg. Doses were based on the most recently recorded scheduled body weight.

The injection sites were marked and maintained for collection at necropsy (see Protocol Deviations). Dose sites were wiped with ethanol prior to injection.

Test article formulations were maintained on wet ice when removed from storage and during dosing.

After dosing, any remaining test article formulations were stored in a freezer, set to maintain -60 to -80°C. At least 7 days following the Day 1 dose, remaining dose formulations were shipped on dry ice to SPONSOR.

Dose formulations were allowed to equilibrate to approximately room temperature (as applicable) and were stirred using a magnetic stir plate and stir bar for at least 30 minutes prior to and throughout dosing (see Protocol Deviations).

3.4.2 Clinical Observations

3.4.2.1 Health Monitoring

Animals were checked twice daily (a.m. and p.m.) for mortality, abnormalities, and signs of pain or distress (see Protocol Deviations). Abnormal findings were recorded.

3.4.2.2 Clinical Examinations

Cageside observations were conducted for each animal once daily during the predose and dosing phases, except on days when detailed observations were conducted (see Protocol Deviations). Abnormal findings were recorded.

Detailed observations were conducted for each animal eight times during the predose phase and prior to dosing on Day 1 and weekly (based on Day 1) throughout the dosing phase. Detailed observations were also collected for each animal on the day of scheduled sacrifice (all surviving animals). Abnormal findings or an indication of normal was recorded.

Unscheduled observations were recorded.

3.4.3 Body Weights

Body weights were recorded eight times during the predose phase and before dosing on Day 1 and weekly thereafter (based on Day 1) to Week 24 of the dosing phase (see Protocol Deviations).

3.4.4 Food Consumption

Qualitative food consumption was recorded once daily (except on day of animal arrival or unless fasted for other study procedures, if appropriate) during the dosing phase (see Protocol Deviations). Abnormal findings were recorded.

3.5 Clinical Laboratory Procedures

3.5.1 Clinical Pathology

3.5.1.1 Sample Collection and Handling

Blood samples for hematology, coagulation, and clinical chemistry were collected from fasted animals via a femoral vein. Blood samples were collected twice during the predose phase and on Days 1, 15, 29, 57, 85, 113, 141, and 169 of the dosing phase. Blood samples for hematology were collected on Day 41 of the predose phase (Day -14 of the dosing phase). Blood for clinical chemistry and coagulation was collected on Days 43 and 71 of the dosing phase.

The anticoagulants were sodium citrate for coagulation tests and potassium EDTA for hematology tests. Samples for clinical chemistry were collected without anticoagulant.

3.5.1.2 Hematology Tests

red blood cell (erythrocyte) count
hemoglobin
hematocrit
mean corpuscular volume
mean corpuscular hemoglobin
mean corpuscular hemoglobin concentration
red cell distribution width
absolute reticulocyte count
platelet count
white blood cell (leukocyte) count
absolute neutrophil count
absolute lymphocyte count
absolute monocyte count
absolute eosinophil count
absolute basophil count
absolute large unstained cell count
blood smear

3.5.1.3 Coagulation Tests

prothrombin time
fibrinogen
activated partial thromboplastin time

3.5.1.4 Clinical Chemistry Tests

glucose	aspartate aminotransferase
urea nitrogen	alanine aminotransferase
creatinine	alkaline phosphatase
total protein	gamma glutamyltransferase
albumin	creatine kinase
globulin	calcium
albumin:globulin ratio	inorganic phosphorus
total cholesterol	sodium
triglycerides	potassium
total bilirubin	chloride

3.6 Terminal Procedures

3.6.1 Necropsy and Macroscopic Observations

With the exception of fasting, these procedures were also followed for unscheduled sacrifices.

On Day 169 of the dosing phase, all animals, having been fasted overnight, were anesthetized with sodium pentobarbital, exsanguinated, and necropsied.

Terminal body weights were recorded for sacrificed animals. A macroscopic examination of the external features of the carcass; external body orifices; abdominal, thoracic, and cranial cavities; organs; and tissues was performed. A Pathologist was available for consultation during necropsies.

The following tissues (when present) from each animal were preserved in 10% neutral-buffered formalin, unless otherwise indicated.

Organ/Tissue		Organ/Tissue	
adrenal (2)	P	lymph node (mandibular)	P
animal identification		lymph node (mesenteric)	P
aorta	P	muscle, biceps femoris	P
bone, femur with bone marrow (articular surface of the distal end)	P	optic nerve (2)[a]	P
bone, sternum with bone marrow	P	pancreas	P,E
brain	P	pituitary gland	P
cecum	P,E	prostate	P
colon	P,E	rectum	P,E
duodenum	P,E	salivary gland (mandibular [2])	P
epididymis (2)	P	sciatic nerve	P
esophagus	P	seminal vesicle	P
eye (2)[a]	P	skin/subcutis	P
gall bladder (drained)	P,E	spinal cord (cervical, thoracic, and lumbar)	P

gut-associated lymphoid tissue (GALT)/Peyer's patch	P	spleen	P
heart	P	stomach	P,E
ileum	P,E	testis (2)[a]	P
injection sites	P	thymus	P
jejunum	P,E	thyroid (2 lobes) with parathyroid	P
kidney (2)	P,E	tongue	P
lesions	P,E	trachea	P
liver	P,E	urinary bladder	P
lungs with large bronchi	P		

E = Examined microscopically; P = Processed.

a Collected in modified Davidson's fixative and stored in 10% neutral-buffered formalin.

3.6.2 Histology

As indicated in the previous table (Necropsy and Macroscopic Observations section), tissues from each animal (to include both injection sites collected from animals) were embedded in paraffin and sectioned, and slides were prepared and stained with hematoxylin and eosin.

3.6.3 Microscopic Observations

Tissues indicated in the previous table (Necropsy and Macroscopic Observations section) from all animals were examined microscopically by the Contributing Scientist for Anatomic Pathology.

3.6.4 Frozen Tissue Collection for Biodistribution (Tissue) Analysis

At scheduled sacrifices, samples from the liver (eight sites for each lobe [four pieces removed from hilus and four from edge locations on each lobe]), spleen, bicep femoris muscle, lung (from each lobe), and right and left testes were collected from all animals.

The tissues were collected using clean procedures according to TESTING FACILITY SOP. Day 169 of the dosing phase, tissues were collected using ultraclean procedures according to TESTING FACILITY SOP into 2-mL cryovials (nuclease free) - (see Protocol Deviations). Approximately two 10 x 10 x 10 mm samples (actual size was not documented), unless otherwise indicated previously, for polymerase chain reaction (PCR) biodistribution analysis were flash-frozen in liquid nitrogen and stored on dry ice until transferred to a freezer, set to maintain -60 to -80°C. Samples were maintained in the freezer until shipped to the Redacted Lab B.

Tissues were analyzed for biodistribution by the Redacted Lab B using PCR.

Frozen tissue samples requiring storage at Redacted Lab B were handled in accordance with internal policies and procedures.

3.7 Data Evaluation and Statistical Analysis

Various models of calculators, computers, and computer programs were used to analyze data in this study. Values in some tables (e.g., means, standard deviations, or individual values) may differ slightly from those in other tables, from individually calculated data, or from statistical analysis data, because different models round off or truncate numbers differently. Neither the integrity nor the interpretation of the data was affected by these differences.

Only data collected on or after the first day of dosing were analyzed statistically. Analysis of variance (ANOVA) and pairwise comparisons were used to analyze the following.

- Absolute body weight
- Body weight change
- Continuous clinical pathology values

Levene's test was done to test for equality of variances between groups.

- Where Levene's test was significant ($P \leq 0.05$), a rank transformation (to stabilize the variances) was applied before ANOVA was conducted (note: Levene's test was not applied to the rank-transformed data).
- Where Levene's test was not significant ($P > 0.05$), ANOVA was conducted.

One-way ANOVA was used (if applicable) to analyze the data types listed previously.

- If the group effect of the ANOVA was significant ($P \leq 0.05$), Dunnett's t-test was used for pairwise comparisons between each test article-treated and control group. Group comparisons (Groups 2 through 4 versus Group 1) were evaluated at the 5.0%, two-tailed probability level.
- If the ANOVA was not significant ($P > 0.05$), no further analyses were conducted.

Due to system limitations, additional statistical analyses may have been run but were not reported or used to interpret study data. A sex/group may have been omitted from hypothesis testing when the number of data points for a given interval and data type from that sex/group fell below three.

4. RESULTS

4.1 VECTOR A and VECTOR B Neutralizing Antibody Analysis

VECTOR A and VECTOR B Neutralizing Antibody Titers are presented in Text Table 4.1.

Test article treated animals assigned to a study group had neutralizing antibody titers to VECTOR A and VECTOR B between <5 and 10 during the predose phase.

Text Table 4.1: Capsid Neutralizing Antibody Titer by Study Day

		NAb Titer									
Treatment	**Animal ID**	**Day 1**	**Day 15**	**Day 29**	**Day 43**	**Day 57**	**Day 71**	**Day 85**	**Day 113**	**Day 141**	**Day 169**
VECTOR A	P0001	10	320	80	160	80	80	160	80	80	80
VECTOR A	P0002	<5	40	20	40	160	160	320	160	160	160
VECTOR A	P0003	10	160	40	10	5	<5	5	<5	<5	<5
VECTOR B	P0401	<5	320	80	160	160	160	160	160	160	160
VECTOR B	P0402	<5	40	20	5	5	5	10	5	5	5
VECTOR B	P0403	<5	160	40	80	40	20	10	5	20	80

4.2 PROTEIN Expression Analysis

Results of the PROTEIN expression analysis are presented in Text Table 4.2.

Text Table 4.2: Protein-Expression, as % over Day 1 Baseline Measurement

		% Protein Expression of Normal									
Treatment	**Animal ID**	**Day 1**	**Day 15**	**Day 29**	**Day 43**	**Day 57**	**Day 71**	**Day 85**	**Day 113**	**Day 141**	**Day 169**
VECTOR A	P0001	0	11.23	11.01	15.32	9.66	10	9.57	14.74	9.25	9.96
VECTOR A	P0002	0	15.87	23.54	17.56	14.67	13.51	8.97	9.49	13.5	16.19
VECTOR A	P0003	0	10.87	16.94	14.67	15.35	10.83	13.39	18.29	14.47	12.11
VECTOR B	P0401	0	17.27	18.19	31.9	27.93	19.22	18.21	23.02	10.2	11.61
VECTOR B	P0402	0	22.94	26.73	33.85	30.18	27.22	21.96	10.02	11.05	12.4
VECTOR B	P0403	0	22.68	21.71	23.54	24.21	24.39	19.08	14.76	10.24	18.7

4.3 Biodistribution (Tissue) Analysis

Results of the biodistribution analysis, Vector DNA and RNA transcription in Liver Tissue, are presented in Text Table 4.3 and Text Table 4.4, respectively.

Text Table 4.3: Vector Genome Copies, as DNA copies per ug of Liver Tissue on Day 169

Treatment	Animal ID	Vector Genome Copies (DNA copies/ug)
VECTOR A	P0001	940495
VECTOR A	P0002	2531790
VECTOR A	P0003	1257333
VECTOR B	P0401	1901575
VECTOR B	P0402	3321024
VECTOR B	P0403	1301982

Text Table 4.4: Transgene Expression, as RNA copies per ug of Liver Tissue on Day 169

Treatment	Animal ID	Transgene Expression (transcript copies/ug)
VECTOR A	P0001	8537
VECTOR A	P0002	28453
VECTOR A	P0003	16534
VECTOR B	P0401	29816
VECTOR B	P0402	26702
VECTOR B	P0403	21588

4.4 Inlife Evaluations

4.4.1 Animal Fate

Animal fate data are presented in Table 8.1.

No test article-related deaths occurred.

All animals survived until their intended sacrifice.

4.4.2 Clinical Observations

Clinical observations data are summarized in Table 7.1; individual data are presented in Table 8.2.

The only clinical observation attributed to the test article was red discoloration of the dose site, which was observed on Day 8 of the dosing phase for a few animals (Animals P0401 and P0402). This observation was considered resolved as it was not noted after Day 8 of the dosing phase.

Abnormal fecal observations were noted across all dose groups.

Emesis and vomitus were observed on multiple days beginning Day 5 of the dosing phase. Other clinical observations included vomitus, scab or sores, broken skin (tail), and thinning hair. These appeared rather infrequently, were transient, were with comparable

incidences commonly occurring in this species; therefore, they were considered not test article related.

4.4.3 Veterinary Treatments

In addition to the veterinary treatments mentioned in the Survival/Mortality section, the following animals were monitored and/or treated by the Veterinarian for various conditions.

One control animal (Animal P0001) was monitored for body weight loss and/or liquid feces over the course of the predose and dosing phases and was treated with Enrofloxacin, Pepto-Bismol, and/or Tylosin on multiple occasions.

4.4.4 Body Weights

Body weight data are summarized in Table 7.2; individual data are presented in Table 8.4. Body weight change data are summarized in Table 7.3; individual data are presented in Table 8.5.

No test article-related alterations in body weight or body weight gain were noted.

Body weight losses of magnitude 0.1 to 0.5 kg were noted for animals across all dose groups, which occasionally correlated with nonformed/liquid feces and were considered incidental.

4.5 Qualitative Food Consumption

No test article-related alterations in qualitative food consumption were noted..

4.6 Clinical Laboratory Evaluations

4.6.1 Clinical Pathology

Data are presented and findings are discussed in the Clinical Pathology Report.

4.7 Scheduled Sacrifice

No prominent clinical pathology findings were observed in animals administered VECTOR A or VECTOR B.

4.8 Terminal Evaluations

Organ weight data and macroscopic and microscopic observations and findings are presented in the Anatomic Pathology Report.

4.8.1 Mortality

All animals survived to their scheduled sacrifice.

4.8.2 Macroscopic Observations

No test article-related macroscopic findings were noted. All macroscopic findings were considered spontaneous and/or incidental because they occurred at a low incidence, were randomly distributed across groups (including concurrent controls), and/or were as expected for cynomolgus monkeys of this age; therefore, they were considered not test article related.

4.8.3 Microscopic Observations

Test article-related microscopic findings were observed in the kidney, cecum, and colon (see Text Table 4.5).

Kidney effects consisted of minimal tubule basophilia. Effects in the cecum and colon consisted of minimal mononuclear cell infiltrates in the mucosa.

Text Table 4.5: Incidence and Severity of Test Article-Related Microscopic Findings

Sex	Male	
Test article(s)	VECTOR A	VECTOR B
Number examined/group	3	3
Kidney		
Basophilic tubule		
Minimal	0	1
Slight	0	0
Moderate	0	0
Cecum		
Infiltrate, mononuclear cell		
Minimal	2	2
Slight	0	0
Moderate	0	0
Colon		
Infiltrate, mononuclear cell		
Minimal	2	3
Slight	0	0
Moderate	0	0

All other microscopic findings were considered spontaneous and/or incidental because they occurred at a low incidence, were randomly distributed across groups (including concurrent controls), and/or their severity was as expected for cynomolgus monkeys of this age; therefore, they were considered not test article related.

4.9 Frozen Tissue Biodistribution Analysis

Results of the frozen tissue biodistribution analysis are presented in the Biodistribution Report.

Pending

5. CONCLUSION

Male cynomolgus monkeys were administered VECTOR A and VECTOR B) as a single dose via intravenous (IV) injection. No adverse test article-related findings were noted; the test article was considered to be tolerated. Microscopic changes observed in animals included findings in the kidney, cecum, and colon.

6. ASSOCIATED STUDY INFORMATION

6.1 Abbreviations

The following lists of abbreviations are used by TESTING FACILITY. Some, but not necessarily all, of this information may be needed for this report.

General Abbreviations

-	Dead animal; no value
#, N, No.	Number
% RSD	Relative standard deviation
%-Diff	Percent difference
·	No value calculated for mean and standard deviation
a.m.	Ante meridian
BID, bid	Twice a day
BODYTEMP; Btemp	Body temperature
C	Comment found at the end of each group for each sex
CAM	Covariate-adjusted mean
CANFDAS	Canned food assessment
CO	Clinical observation
CTLS, ctls	Controls
CV	Coefficient of variation
DIA	Diastolic pressure
DESQUAM	Desquamation
DSNG	Dosing phase
DSNG X.X	Dosing Phase Week X. Day X
DT TY	Data type
EP	European Pharmacopeia
F	Female
FECBOL	Number of fecal boli
FGSA	Forelimb grip strength average (2 trials)
FISSUR	Fissuring
FOOT1	Foot splay 1
FOOT2	Foot splay 2
FORE1	Forelimb grip strength 1
FORE2	Forelimb grip strength 2
FSA2	Foot splay average (2 trials)
GROOM	Number of Grooms
HGSA2	Hindlimb grip strength average (2 trials)
HIND1	Hindlimb grip strength 1
HIND2	Hindlimb grip strength 2
ID	Identification
IM	Intramuscular
int	Interval
IPD	Immediate postdose
LAT	Latency
LOQ	Limit of quantitation

General Abbreviations (Continued)

M	Male
MAP	Mean arterial pressure
Mean; MEAN	Arithmetic mean
N	Number of measurements in a group
NA	No value; not applicable; not present
ND	None detected
NF	National Formulary
NVL	No visible lesions
Obs	Observations
OD	Right eye
OS	Left eye
OU	Both eyes
OXSA	Blood oxygen saturation
P	Present
P(DR)	P value (dose response)
P(overall)	Overall P value for all groups
P(v1)	P value (versus group 1)
p.m.	Post meridian
PD	Postdose
PRED	Predose phase
PRED X.X	Predose Phase Week X. Day X
REAR	Number of rears
RECO	Recovery phase
RECO X.X	Recovery Phase Week X. Day X
RESP	Respiration rate
S.E.M./SEM	Standard error mean
SD; S.D.; STAND DEV; STANDARD DEV; sd; STD.DEV	Standard deviation (when used in numerical data tables)
SE; STDERR	Standard error
SYS	Systolic pressure
TBW	Terminal body weight
TK	Toxicokinetic
Typ	Type
UNSCHED or SCHED	Unscheduled or scheduled
URIPOL	Number of urine pools
USP	United States Pharmacopeia
WK	Week
WT	Weight

General Abbreviations (Continued)

Units of Measure

amol	Attomole
BPM	Beats per minute
ºC	Degrees Celsius
cm	Centimeter
DL, dl, dL	Deciliter
EU	Ehrlich unit
FL, fl	Femtoliter
fmol	Femtomole
G, g	Gram
H, h	Hours
IU	International unit
KG, kg	Kilogram
L	Liter
MCG, UG, µg, ug	Microgram
MEQ	Milliequivalent
MG, mg	Milligram
MI	Million
ML, mL, ml	Milliliter
mm	Millimeter
mmHG/mmHg	Millimeter of mercury
MMOL, mmol	Millimole
MN, min	Minute
MOS	Milliosmole
Msec, msec	Millisecond
mU	Milliunit
ng	Nanogram
PG, pg	Picogram
pmol	Picomole
PPM, ppm	Parts per million
S, s, sec	Seconds
TH	Thousand
U	Units
UL, µL, uL	Microliter
UMOL, µmol	Micromole
um, µm	Micrometer

Veterinary Abbreviations

A	Assessment
AU	Auris utraque (both ears)
AWCM	Animal Welfare and Comparative Medicine
BAR	Bright, alert, and responsive
BCS	Body condition score
BW	Body weight
CRT	Capillary refill time
DLAM	Department of Laboratory Animal Medicine
FC	Food consumption
HC	Hydrocortisone
IM	Intramuscular
IV	Intravenous
NHP	Nonhuman primate
NSAID	Nonsteroidal anti-inflammatory drug
MM	Mucous membranes
P	Plan
QAR	Quiet, alert, and responsive
QFC	Qualitative food consumption
RR	Respiration rate
SC	Subcutaneous
SD	Study Director (when used in textual data tables)
S/O	Subjective/objective observations
SOAP	Subjective/objective observations, assessment, plan
TA	Test article
TM	Test article/material
TX	Treatment
VS	Veterinary Services
WNL	Within normal limits

6.2 Comments on the Data

The following comments on the data are used by TESTING FACILITY. Some, but not necessarily all, of this information may be needed for this report.

The number of animals listed in the heading of the summary tables reflects the number of animals assigned to each group at the start of each respective phase, with the exception of the anatomic pathology tables, which indicate the number of animals assigned to each respective necropsy interval. The summary table for observations indicates the number of animals for which a condition was observed, without regard to the specific nature, severity, reversibility, number of incidences/animal, or the length of time the condition persisted.

6.3 Study Deviations

6.3.1 Protocol Deviations

Procedure	Protocol Deviations
Inlife Procedures	
Dose Administration - Test Article	On Day 169 of the dosing phase, at the terminal sacrifice, it could not be verified which injection site was used for administration of the test article; therefore, both sites were marked and maintained at the time of necropsy.
Clinical Observations	On Day 14 of the predose phase, a.m. general daily observations were not performed. On Day 14 of the predose phase and Day 53 of the dosing phase, p.m. general daily observations were not performed. On Day 51 of the predose phase and Days 1, 43, 64, and 162 of the dosing phase, cageside observations were performed although not required.
Body Weights	It could not be verified that body weights were collected on Day 168 of the dosing phase, although required.
Food Consumption	On Day 48 of the predose phase, qualitative food consumption was performed, although not required.
Terminal Procedures	

These study deviations neither affected the overall interpretation of study findings nor compromised the integrity of the study.

7. SUMMARY TABLES

Table 7.1: Summary of Clinical Observations

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Phase: Dosing		
Category	Group/Sex:	1/M 5/M
Observation	Number in Group:	3 3
NORMAL		
No remarkable observations		3 3
Appearance		
swollen, penis		1 0

VECTORSTUDYU1

Table
Summary of Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Phase: Dosing

Category Observation	Group/Sex: Number in Group:	1/M 3	5/M 3
Excretion			
feces, liquid, group observation		3	0
feces, liquid, individual observation		1	0
feces, nonformed, group observation		3	3
feces, nonformed, individual observation		1	0

VECTORSTUDYU1

Table
Summary of Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Phase: Dosing

Category Observation	Group/Sex: Number in Group:	1/M 3	5/M 3
Skin and pelage			
broken skin, tail distal		2	0
discolored skin, dose site, red		0	2
discolored skin, right inguinal, red		0	1
scab, periorbital		0	1
scab, tail distal		1	0
scab, tail mid		0	1
scar, tail distal		1	1

Table 7.2: Summary of Body Weight

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Phase	DSNG					
	Day	1	8	15	22	29	36
1/M	Mean	2.8	3.0	2.8	2.9	2.8	3.0
	SD	0.21	0.31	0.30	0.29	0.31	0.38
	N	3	3	3	3	3	3
5/M	Mean	2.8	2.8	2.8	2.9	2.9	2.9
	SD	0.15	0.17	0.17	0.21	0.23	0.29
	N	3	3	3	3	3	3
	Statistics	AT	A	A	A	A	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Phase	DSNG					
	Day	43	50	57	64	71	78
1/M	Mean	2.8	2.9	2.8	3.0	2.8	3.0
	SD	0.29	0.29	0.25	0.38	0.23	0.47
	N	3	3	3	3	3	3
5/M	Mean	2.9	3.0	2.9	3.1	2.9	3.0
	SD	0.25	0.26	0.26	0.32	0.29	0.26
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Phase	DSNG					
	Day	85	92	99	106	113	120
1/M	Mean	2.8	2.9	2.9	2.9	2.8	3.1
	SD	0.35	0.53	0.53	0.44	0.32	0.35
	N	3	3	3	3	3	3
5/M	Mean	2.9	3.1	3.1	3.0	3.0	3.1
	SD	0.29	0.32	0.32	0.26	0.32	0.23
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Phase	DSNG					
	Day	127	134	141	148	155	162
1/M	Mean	3.1	3.1	3.3	3.0	3.1	3.0
	SD	0.38	0.31	0.53	0.35	0.38	0.42
	N	3	3	3	3	3	3
5/M	Mean	3.3	3.2	3.1	3.1	3.1	3.1
	SD	0.23	0.26	0.23	0.23	0.23	0.23
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

Table 7.3: Summary of Body Weight Change

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X

Group/ Sex	Phase / Day	1 - 8	8 - 15	15 - 22	22 - 29	29 - 36	36 - 43
		DSNG					
1/M	Mean	0.1	-0.2	0.1	-0.1	0.2	-0.2
	SD	0.15	0.06	0.15	0.10	0.10	0.10
	N	3	3	3	3	3	3
5/M	Mean	0.0	0.0	0.1	-0.1	0.1	-0.1
	SD	0.06	0.00	0.06	0.06	0.06	0.12
	N	3	3	3	3	3	3
	Statistics	X2	AT	A	A	A	A

X2 = Not analyzed (too few distinct values)
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Body Weight Change

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X
DSNG

Group/ Sex	Phase / Day	43 - 50	50 - 57	57 - 64	64 - 71	71 - 78	78 - 85
1/M	Mean	0.1	0.0	0.1	-0.1	0.1	-0.2
	SD	0.00	0.12	0.21	0.15	0.25	0.15
	N	3	3	3	3	3	3
5/M	Mean	0.1	-0.1	0.2	-0.1	0.1	-0.1
	SD	0.15	0.00	0.06	0.06	0.06	0.06
	N	3	3	3	3	3	3
	Statistics	X2	X2	AT	X2	A	X2

X2 = Not analyzed (too few distinct values)
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Body Weight Change

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X DSNG

Group/ Sex	Phase / Day	85 - 92	92 - 99	99 - 106	106 - 113	113 - 120	120 - 127
1/M	Mean	0.1	0.0	0.0	-0.1	0.3	0.0
	SD	0.20	0.00	0.10	0.15	0.06	0.06
	N	3	3	3	3	3	3
5/M	Mean	0.1	0.0	-0.1	0.0	0.1	0.2
	SD	0.06	0.00	0.06	0.06	0.10	0.00
	N	3	3	3	3	3	3
	Statistics	A	X2	X2	X2	X2	X2

A = ANOVA and Dunnett's
X2 = Not analyzed (too few distinct values)

VECTORSTUDYU1

Table
Summary of Body Weight Change

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X DSNG

Group/ Sex	Phase / Day	127 - 134	134 - 141	141 - 148	148 - 155	155 - 162	1 - 162
1/M	Mean	0.0	0.2	-0.3	0.0	0.0	0.2
	SD	0.10	0.31	0.32	0.12	0.06	0.26
	N	3	3	3	3	3	3
5/M	Mean	-0.1	-0.1	0.0	0.0	0.0	0.3
	SD	0.06	0.06	0.00	0.00	0.00	0.10
	N	3	3	3	3	3	3
	Statistics	X2	AT	X2	X2	X2	A

X2 = Not analyzed (too few distinct values)
A = ANOVA and Dunnett's
T = Rank-transformed data

8. INDIVIDUAL ANIMAL DATA TABLES

Table 8.1: Individual Animal Fate

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Date	Phase of Fate	Phase Week	Phase Day	Fate Status	Terminal Body Weight (kg)
1/M	P0001	14/JAN/19	Dosing	25	169	Terminal Sacrifice	2.9
	P0002	14/JAN/19	Dosing	25	169	Terminal Sacrifice	2.6
	P0003	14/JAN/19	Dosing	25	169	Terminal Sacrifice	3.4
5/M	P0401	14/JAN/19	Dosing	25	169	Terminal Sacrifice	3.2
	P0402	14/JAN/19	Dosing	25	169	Terminal Sacrifice	3.0
	P0403	14/JAN/19	Dosing	25	169	Terminal Sacrifice	2.7

Table 8.2: Individual Clinical Observations

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
1/M	P0001	NORMAL		
		No remarkable observations	PRED	9,16,23,30,44
			DSNG	29,36,43,64,78,85,92,99,106, 113,141,155,162,169

VECTORSTUDYU1

Table
Individual Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
1/M	P0001	Excretion		
		feces, discolored, group observation, black	PRED	18,19
		feces, liquid, group observation	PRED	10,17,18,29,33,37,41
			DSNG	15,39,54,71,75,81,93,103, 120,132,137,142,145-147,152, 153
		feces, liquid, individual observation	PRED	2,52
			DSNG	50,132,134,147,148
		feces, nonformed, group observation	PRED	26,27,35,36,51-53
			DSNG	1,2,7,8,11,18,22,57,73,95, 98,100,115,127,130,143
		feces, nonformed, individual observation	DSNG	142

VECTORSTUDYU1

Table
Individual Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
1/M	P0002	NORMAL		
		No remarkable observations	PRED	2,9,16,23,30,37,44
			DSNG	15,29,36,43,50,64,78,85,92, 99,106,141,148,155,162
		Excretion		
		feces, liquid, group		
		observation	PRED	41
			DSNG	15,39,54,71,75,81,93,103, 120,132,134,137,142,145-147, 152,153
		feces, nonformed, group		
		observation	PRED	51-53
			DSNG	1,2,7,8,11,18,22,57,73,95, 98,100,115,127,130,143
		Skin and pelage		
		broken skin, tail distal	DSNG	111,113,115,120,127
		scab, tail distal	DSNG	169

VECTORSTUDYU1

Table
Individual Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
1/M	P0003	NORMAL		
		No remarkable observations	PRED	2,16,23,30,37,44
			DSNG	15,29,36,43,50,64,78,92,99, 106,113,141,148,155,162,169
		Appearance		
		swollen, penis	DSNG	103
		Excretion		
		feces, liquid, group		
		observation	PRED	41
			DSNG	15,39,54,71,75,81,93,103, 120,132,134,137,142,145-147, 152,153
		feces, nonformed, group		
		observation	PRED	10,17,51-53
			DSNG	1,2,7,8,11,18,22,57,73,95, 98,100,115,127,130,143
		feces, nonformed,		
		individual observation	PRED	9

VECTORSTUDYU1

Table
Individual Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
1/M	P0003	Skin and pelage		
		broken skin, tail distal	DSNG	72
		scar, tail distal	DSNG	85

VECTORSTUDYU1

Table
Test Article (dosage) 1M 5M

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
5/M	P0401	NORMAL		
		No remarkable observations	PRED	2,9,16,23,30,44,51
			DSNG	1,15,22,29,36,43,50,57,64, 71,78,85,92,99,106,113,120, 127,134,141
		Excretion		
		feces, discolored, group		
		observation, black	PRED	18,19
		feces, liquid, group		
		observation	PRED	10,17,18,29,33
		feces, nonformed, group		
		observation	PRED	26,27,35-37
			DSNG	111
		Skin and pelage		
		discolored skin, dose site,		
		red	DSNG	8
		scab, periorbital	DSNG	148
		scar, tail distal	DSNG	148,155,162,169

VECTORSTUDYU1

Table

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
5/M	P0402	NORMAL		
		No remarkable observations	PRED	2,9,16,23,30,37,44,51
			DSNG	1,15,22,29,36,50,57,64,71, 78,85,92,99,106,113,120,127, 134,141,148,155,162,169
		Excretion		
		feces, nonformed, group		
		observation	DSNG	111
		Skin and pelage		
		discolored skin, dose site,		
		red	DSNG	8
		discolored skin, right		
		inguinal, red	DSNG	43

VECTORSTUDYU1

Table
Individual Clinical Observations

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Group/ Sex	Animal Number	Observation	Phase	Day(s)
5/M	P0403	NORMAL		
		No remarkable observations	PRED	2,9,16,23,30,37,44,51
			DSNG	1,8,22,29,36,43,50,57,64,71, 78,85,92,99,106,113,120,127, 134,141,148,155,162,169
		Excretion		
		feces, nonformed, group observation	DSNG	111
		Skin and pelage		
		scab, tail mid	DSNG	15

Table 8.4: Individual Body Weight

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Animal Number	Phase Day	PRED 2	PRED 9	PRED 16	PRED 23	PRED 30	PRED 37
1/M	P0001		2.7	2.5	2.3	2.7	2.9	3.0
	P0002		2.6	2.6	2.6	2.7	2.6	2.6
	P0003		3.0	2.9	3.2	3.0	2.9	3.0
5/M	P0401		2.9	2.9	3.1	3.0	3.0	3.1
	P0402		2.8	2.8	2.9	2.8	2.8	2.9
	P0403		2.8	2.7	2.8	2.7	2.6	2.6

VECTORSTUDYU1

Table
Individual Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Animal Number	Phase Day	PRED 44	PRED 51	DSNG 1	DSNG 8	DSNG 15	DSNG 22
1/M	P0001		2.9	2.9	2.9	2.9	2.8	2.7
	P0002		2.5	2.5	2.6	2.7	2.5	2.7
	P0003		3.1	3.1	3.0	3.3	3.1	3.2
5/M	P0401		2.9	2.9	2.8	2.9	2.9	3.1
	P0402		2.9	2.8	2.9	2.9	2.9	3.0
	P0403		2.7	2.7	2.6	2.6	2.6	2.7

VECTORSTUDYU1

Table
Individual Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Animal Number	Phase Day	DSNG 29	DSNG 36	DSNG 43	DSNG 50	DSNG 57	DSNG 64
1/M	P0001		2.7	2.8	2.6	2.7	2.8	2.7
	P0002		2.5	2.7	2.6	2.7	2.6	2.8
	P0003		3.1	3.4	3.1	3.2	3.1	3.4
5/M	P0401		3.0	3.1	3.1	3.1	3.0	3.2
	P0402		3.0	3.1	2.9	3.2	3.1	3.3
	P0403		2.6	2.6	2.6	2.7	2.6	2.7

VECTORSTUDYU1

Table
Individual Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Animal Number	Phase Day	DSNG U66	DSNG 71	DSNG 78	DSNG 85	DSNG 92	DSNG 99
1/M	P0001	-		2.7	2.6	2.6	2.5	2.5
	P0002	-		2.7	2.8	2.6	2.7	2.7
	P0003	-		3.1	3.5	3.2	3.5	3.5
5/M	P0401	-		3.1	3.1	3.1	3.2	3.2
	P0402	-		3.1	3.2	3.1	3.3	3.3
	P0403	-		2.6	2.7	2.6	2.7	2.7

VECTORSTUDYU1

Table
Individual Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Animal Number	Phase Day	DSNG 106	DSNG 113	DSNG 120	DSNG 127	DSNG 134	DSNG 141
1/M	P0001		2.6	2.7	2.9	2.9	3.0	2.9
	P0002		2.7	2.6	2.9	2.8	2.8	3.1
	P0003		3.4	3.2	3.5	3.5	3.4	3.9
5/M	P0401		3.1	3.1	3.2	3.4	3.3	3.2
	P0402		3.2	3.2	3.2	3.4	3.4	3.2
	P0403		2.7	2.6	2.8	3.0	2.9	2.8

VECTORSTUDYU1

Table
Individual Body Weight

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg"

Group/ Sex	Animal Number	Phase Day	DSNG 148	DSNG 155	DSNG 162
1/M	P0001		3.0	2.9	2.9
	P0002		2.7	2.8	2.7
	P0003		3.4	3.5	3.5
5/M	P0401		3.2	3.2	3.2
	P0402		3.2	3.2	3.2
	P0403		2.8	2.8	2.8

Table 8.5: Individual Body Weight Change

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X

Group/ Sex	Animal Number	Phase Day	DSNG 1 - 8	8 - 15	15 - 22	22 - 29	29 - 36	36 - 43
1/M	P0001		0.0	-0.1	-0.1	0.0	0.1	-0.2
	P0002		0.1	-0.2	0.2	-0.2	0.2	-0.1
	P0003		0.3	-0.2	0.1	-0.1	0.3	-0.3
5/M	P0401		0.1	0.0	0.2	-0.1	0.1	0.0
	P0402		0.0	0.0	0.1	0.0	0.1	-0.2
	P0403		0.0	0.0	0.1	-0.1	0.0	0.0

VECTORSTUDYU1

Table
Individual Body Weight Change

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X

Group/ Sex	Animal Number	Phase Day	DSNG 43 - 50	50 - 57	57 - 64	64 - 71	71 - 78	78 - 85
1/M	P0001		0.1	0.1	-0.1	0.0	-0.1	0.0
	P0002		0.1	-0.1	0.2	-0.1	0.1	-0.2
	P0003		0.1	-0.1	0.3	-0.3	0.4	-0.3
5/M	P0401		0.0	-0.1	0.2	-0.1	0.0	0.0
	P0402		0.3	-0.1	0.2	-0.2	0.1	-0.1
	P0403		0.1	-0.1	0.1	-0.1	0.1	-0.1

VECTORSTUDYU1

Table
Individual Body Weight Change

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X

Group/ Sex	Animal Number	Phase Day	DSNG 85 - 92	92 - 99	99 - 106	106 - 113	113 - 120	120 - 127
1/M	P0001		-0.1	0.0	0.1	0.1	0.2	0.0
	P0002		0.1	0.0	0.0	-0.1	0.3	-0.1
	P0003		0.3	0.0	-0.1	-0.2	0.3	0.0
5/M	P0401		0.1	0.0	-0.1	0.0	0.1	0.2
	P0402		0.2	0.0	-0.1	0.0	0.0	0.2
	P0403		0.1	0.0	0.0	-0.1	0.2	0.2

VECTORSTUDYU1

Table
Individual Body Weight Change

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Data Presented in "kg" Interval X through X

Group/ Sex	Animal Number	Phase Day	DSNG 127 - 134	134 - 141	141 - 148	148 - 155	155 - 162	1 - 162
1/M	P0001		0.1	-0.1	0.1	-0.1	0.0	0.0
	P0002		0.0	0.3	-0.4	0.1	-0.1	0.1
	P0003		-0.1	0.5	-0.5	0.1	0.0	0.5
5/M	P0401		-0.1	-0.1	0.0	0.0	0.0	0.4
	P0402		0.0	-0.2	0.0	0.0	0.0	0.3
	P0403		-0.1	-0.1	0.0	0.0	0.0	0.2

9. APPENDICES

9.7 Clinical Pathology Report

Draft Clinical Pathology Report

Study Title	24 Week Toxicity Study of Vector A and Vector B Following a Single Intravenous Injection in Adult Cynomolgus Macaques
TESTING FACILITY Study Number	VECTORSTUDYU1

TABLE OF CONTENTS

1. SUMMARY

This report describes clinical pathology findings for TESTING FACILITY Study VECTORSTUDYU1. The purpose of this study was to evaluate the efficacy and tolerability VECTOR A and VECTOR B when administered as a single dose via intravenous (IV) injection to cynomolgus monkeys. Animals were administered $1.024x10^{13}$ genome copies/kg VECTOR A and VECTOR B via IV injection.

No prominent clinical pathology findings were observed in animals administered VECTOR A and VECTOR B.

2. METHODS

Male cynomolgus monkeys were administered test article, VECTOR A and VECTOR B, via a single intravenous injection as indicated in the following table.

Group Designation and Dose Levels - Test Article

Group[a,b]	No. of Animals Males	Dose Level (GC/kg)	Dose Concentration (GC/mL)
1 (VECTOR A)	3	$1.024x10^{13}$	$1.28x10^{13}$
5 (VECTOR B)	3	$1.024x10^{13}$	$1.28x10^{13}$

GC = Genome copies.

a All groups were administered test article via intravenous (bolus) injection on Day 1.

b Animals were dosed at a volume of 0.8 mL/kg.

Blood was collected for hematology, coagulation, and clinical chemistry tests twice during the predose phase (three collections for hematology) and on Days 1, 15, 29, 43 (clinical chemistry only), 57, 71 (clinical chemistry only), 85, 113, 141, and 169 of the dosing phase.

Test article-related clinical pathology findings were primarily determined by comparing predose phase values with dosing phase values for each respective group/individual.

3. RESULTS AND DISCUSSION

3.1 Scheduled Sacrifice

Hematology and coagulation data are summarized in Table 5.1; individual data are listed in Table 6.1.Clinical chemistry data are summarized in Table 5.2; individual data are listed in Table 6.2.

No prominent clinical pathology findings were observed in animals administered VECTOR A or VECTOR B.

4. ASSOCIATED STUDY INFORMATION

4.1 Abbreviations

The following lists of abbreviations are used by TESTING FACILITY. Some, but not necessarily all, of this information may be needed for this report.

Abbreviations for Hematology

Abbreviation	*Test*
ANISO	Anisocytosis
BASO	Absolute basophils
BASO%	Percent basophils
CFWB	White blood cell count cerebral spinal fluid
CHCMr	Reticulocyte hemoglobin concentration mean
CHr	Concentration of hemoglobin in reticulocytes
DDimerOS	D-dimer
EOS	Absolute eosinophils
EOS%	Percent eosinophils
ESR	Erythrocyte sedimentation rate
FNBC	Cell poor fluid nucleated cell count
FRBC	Cell poor fluid red blood cell count
FWBC	Cell poor fluid white blood cell count
Hct	Hematocrit
HDW	Hemoglobin distribution width
HGB	Hemoglobin
HRTC	High absorbance reticulocytes
HRTC%	Percent high absorbance reticulocytes
HYPO	Hypochromasia
LRTC	Low absorbance reticulocytes
LRTC%	Percent low absorbance reticulocytes
LUC	Absolute large unstained cells
LUC%	Percent large unstained cells
LYM	Absolute lymphocytes
LYM%	Percent lymphocytes
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MCVr	Reticulocyte MCV
MONO	Absolute monocytes
MONO%	Percent monocytes
MPC	Mean platelet component
MPV	Mean platelet volume
MRTC	Mid absorbance reticulocytes
MRTC%	Percent mid absorbance reticulocytes
NEUT	Absolute neutrophils
NEUT%	Percent neutrophils

Abbreviations for Hematology (Continued)

Abbreviation	*Test*
PCT	Platelet crit
PDW	Platelet distribution width
PLT	Platelet count
POIK	Poikilocytosis
POLY	Polychromasia
RBC	Red blood cell count
RDW	Red blood cell distribution width
RDWr	Reticulocyte distribution width
RETIC	Reticulocyte count
RETIC%	Percent reticulocyte
TOXIC	Toxic granulation
WBC	White blood cell count

Abbreviations for Blood Cell Morphology

Red Blood Cell Morphology	
NORM	Normal; estimated 0 to 3% cells/100x field
MIN	Minimal; estimated 4 to 9% cells/100x field
MILD	Mild; estimated 10 to 29% cells/100x field
MOD	Moderate; estimated 30-49% cells/100x field
MARK	Marked; estimated >50% cells/100x field
White Blood Cell Morphology	
Normal	No abnormal cells/observations/100x field
OCC	Occasional; 1-2 abnormal cells/observations in several to every 100x field
Few	Moderate increase in abnormal cells/observations (3-4 cells/100x field) but normal cells still present
Many	Marked increase in abnormal cells/observations (>5 cells/100x field); extreme cases of abnormality

Abbreviations for Manual Differential

Abbreviation	*Test*
BAND	Absolute band neutrophils
BAND%	Percent band neutrophils
BANDC	Band neutrophil count
BASO	Absolute basophils
BASO%	Percent basophils
BASOC	Basophil count
BASOMY%	Percent basophilic Myelocytes/Metamyelocytes/Bands/Segmenters
BASOMYC	Basophilic Myelocytes/Metamyelocytes/Bands/Segmenters
BLAST	Absolute blast cells
BLAST%	Percent blasts
BLASTC	Blast cell count
EOS	Absolute eosinophils
EOS%	Percent eosinophils
EOSC	Eosinophil count
EOSMY%	Percent eosinophilic Myelocytes/Metamyelocytes/Bands/Segmenters
EOSMYC	Eosinophilic Myelocytes/Metamyelocytes/Bands/Segmenters
LYM	Absolute lymphocytes
LYM%	Percent lymphocytes
LYMPS%	Percent lymphocytes
LYMC	Lymphocyte count
MACROP%	Percent macrophage count
MACROPC	Macrophage count
MEGACT	Megakaryocyte count
MEGAS%	Percent megakaryocytes
META	Absolute metamyelocytes
META%	Percent metamyelocytes
METAC	Metamyelocyte count
MONO	Absolute monocytes
MONO%	Percent monocytes
MONOC	Monocyte count
MYE,PRO	Absolute promyelocytes/myelocytes
MYE,PRO%	Percent promyelocytes/myelocytes
MYE,PROC	Promyelocytes/myelocytes count
MYPCERPC	Myeloid/erythroid ratio
MYPROC	Myeloblast/Progranulocytes
MYPROC%	Percent myeloblast/Progranulocytes
NEUC	Neutrophil count

Abbreviations for Manual Differential (Continued)

Abbreviation	*Test*
NEUT	Absolute neutrophils
NEUT%	Percent neutrophils
NRBC	Nucleated red blood cell count
NEUMY%	Percent neutrophilic Myelocytes/Metamyelocytes/Bands/Segmenters
NEUMYC	Neutrophilic Myelocytes/Metamyelocytes/Bands/Segmenters
PLACT	Plasma cell count
PLSMS%	Percent plasma cells
RBPR%	Percent rubriblasts/prorubricytes
RBPRC	Rubriblasts/Prorubricytes
RUBMR%	Percent rubricytes/metarubricytes
RUBMRC	Rubricytes/Metarubricytes
TLCC	Total cells counted
TotERY%	Percent total erythroid cells
TotERYC	Total erythroid cells count
TotMYE%	Percent total granulocytic (myeloid) cells
TotMYEC	Total granulocytic (myeloid) cell count

Abbreviations for Bone Marrow Cytology Data

Abbreviation	*Test*
A	Adequate
D	Decreased
ErCL	Erythroid cell line
I	Increased
Inter	Interpretation
Megak	Megakaryocytes
MER	M:E ratio estimate
MyCL	Myeloid cell line
N	Normal
NCA	No cytologic abnormalities
OComm	Other comments
SA Cell	Sample Cellularity/Quality

Abbreviations for Bone Marrow Full Myelogram Data

Abbreviation	*Test*
BLSTMBC cells	Myeloblast count
BLSTMBCE %	Percent myeloblasts
PROMYCNT cells	Promyelocyte count
PROMYCE %	Percent promyelocytes
MYELOCNT cells	Myelocyte count
MYCYCE %	Percent myelocytes
METAMCNT cells	Metamyelocyte count
METAMYCE %	Percent metamyelocytes
GBANDCNT cells	Granulocyte (band) count
GRANBAND %	Percent granulocytes (band)
GRANSEGC cells	Granulocyte (segmented) count
GRANSEG %	Percent granulocytes (segmented)
MYELTOT %	Percent myeloid cells
MYELCNT cells	Myeloid cell count
RUBBLCNT cells	Rubriblast count
RUBLAST %	Percent rubriblasts
PRORUBC cells	Prorubricyte count
PRORUB %	Percent prorubricytes
RUBCNT cells	Rubricyte count
RUBICYTE %	Percent rubricytes
METRUBCT cells	Metarubricyte count
METUBCTC%	Percent metarubricytes
ERYTOT %	Percent erythroid cells
ERYCNT cells	Erythroid cell count
M:E Ratio	Myeloid:Erythroid ratio
LYBMC cells	Lymphocyte count
LYMBM %	Percent lymphocytes
BMOTHERC cells	Other cell type count
BMOTHER %	Percent other cell types
MEGAKRY cells	Megakaryocyte cellularity
SLIDQUAL	Quality/Cellularity of slide preparation
TLCC	Total Cells Counted
A	Adequate
D	Decreased
I	Increased
N	Normal
NCA	No cytologic abnormalities
NC	Not counted
NSR	No sample received
SUFA	Sample unsuitable for analysis

Abbreviations for Bone Marrow Modified Myelogram Data

Abbreviation	*Test*
MYPRC cells	Proliferating myeloid count
MYPRTC %	Percent proliferating myeloid/total cells
MMAC cells	Maturing myeloid count
MMTC %	Percent maturing myeloid/total cells
MYELCNT cells	Myeloid cell count
MYELTOT %	Percent myeloid total
EYPRC cells	Proliferating erythroid count
EYPR %	Percent proliferating erythroid/total cells
EMATC cells	Maturing erythroid count
EMAT %	Percent maturing erythroid/total cells
ERYCNT cells	Erythroid cell count
ERYTOT %	Percent erythroid total
LYBMC cells	Lymphocytes bone marrow count
LYMBM %	Lymphocyte bone marrow/total cells
M:E Ratio	Myeloid:Erythroid ratio
TLCC	Total cells counted
BMOTHERC cells	Bone marrow other cells
BMOTHER %	Bone marrow other cells/total cells
MEGAKRY cells	Megakaryocyte cellularity
SLIDQUAL	Quality/Cellularity of slide preparation
NSR	No sample received
SUFA	Sample unsuitable for analysis

Abbreviations for Coagulation

Abbreviation	*Test*
APTT	Activated partial thromboplastin time
DDIM	D-dimer
FDP	Fibrin/fibrinogen degradation products
FIB	Fibrinogen
PAGA	Platelet aggregation - adenosine diphosphate
PAGC	Platelet aggregation - collagen
PAGR	Platelet aggregation - ristocetin
PT	Prothrombin time
TT	Thrombin time

Abbreviations for Chemistry

Abbreviation	*Test*
A ALB	Absolute albumin
A Alpha1	Absolute alpha-1 globulin
A Alpha2	Absolute alpha-2 globulin
A BETA	Absolute beta globulin
Adipo	Adiponectin
A GAMMA	Absolute gamma globulin
A:G	Albumin:globulin ratio
A:G-B	Albumin:globulin ratio (rabbit)
A:G-S	Albumin:globulin ratio (mini-pig)
ACTH	Adrenocorticotropic hormone
ALB	Albumin
ALBB	Albumin (rabbit)
ALBS	Albumin (minipig)
ALB%	Percent albumin
ALD	Aldolase
ALP	Alkaline phosphatase
Alpha1%	Percent alpha-1 globulin
Alpha2%	Percent alpha-2 globulin
ALT	Alanine aminotransferase
ALTP5P	Alanine aminotransferase (with pyridoxal-5-phosphate)
AMY	Amylase
AST	Aspartate aminotransferase
ASTP5P	Aspartate aminotransferase (with pyridoxal-5-phosphate)
Bb	Complement factor Bb
BETA%	Percent beta globulin
C3	Complement 3
C4	Complement 4
Ca	Calcium
CFCK	Cerebrospinal fluid chloride creatine kinase
CFCl	Cerebrospinal fluid chloride
CFGL	Cerebrospinal fluid chloride glucose
CFK	Cerebrospinal fluid chloride potassium
CFNa	Cerebrospinal fluid chloride sodium
CFTP	Cerebrospinal fluid chloride total protein
CH50	50% Complement-related hemolysis of erythrocytes
cHCO3	Derived bicarbonate
CHOL	Total cholesterol
CK	Creatine kinase
CKBB	Absolute creatine kinase BB
CKBB%	Percent creatine kinase BB
CKMB	Absolute creatine kinase MB
CKMB%	Percent creatine kinase MB

Abbreviations for Chemistry (Continued)

Abbreviation	*Test*
CKMM	Absolute creatine kinase MM
CKMM%	Percent creatine kinase MM
Cl	Chloride
CORT	Cortisol
C	Complement
CORST	Corticosterone
CREA	Creatinine (Jaffe)
CREAT	Creatinine (enzymatic)
CRP	C-reactive protein
CTLI	Canine trypsin-like immunoreactivity
CTX1	Carboxy (C)-terminal telopeptide fragment of type I collagen
DBIL	Direct bilirubin
DDIMM	D-dimer modular
EPO	Erythropoietin
ESTR	Estradiol
FABPr3	Fatty acid binding protein 3
Fe	Iron
FERR	Ferritin
FeS%	Percent iron saturation
FFA	Free fatty acids
FT3	Free T3
FT4	Free T4
GAMMA%	Percent gamma globulin
GGT	Gamma glutamyl transferase
GLDH	Glutamate Dehydrogenase
GLOB	Globulin
GLOBB	Globulin (rabbit)
GLOBS	Globulin (minipig)
GLP-1	Glucagon-like peptide-1
GLU	Glucose
GGON	Glucagon
HAPT	Haptoglobin
HBA1C	Hemoglobin A1C
HCO3	Bicarbonate
HDL	High density lipoprotein cholesterol
IBIL	Indirect bilirubin
ICA	Ionized calcium
IFNg	Interferon-gamma
IGA	Immunoglobulin A
IGF-1	Insulin-like growth factor-1
IGG	Immunoglobulin G
IGM	Immunoglobulin M

Abbreviations for Chemistry (Continued)

Abbreviation	*Test*
iHct	Ionized calcium hematocrit
IL	Interleukin
IL-2	Interleukin-2
IL-4	Interleukin-4
IL-6	Interleukin-6
IL-10	Interleukin-10
IL-12p70	Interleukin-12p70
IL-13	Interleukin-13
IL-17	Interleukin-17
INS	Insulin
Insu	Insulin
K	Potassium
LACT	Lactate
LDH	Lactate dehydrogenase
LDH1	Absolute Lactate Dehydrogenase 1
LDH1%	Percent Lactate Dehydrogenase 1
LDH2	Absolute Lactate Dehydrogenase 2
LDH2%	Percent Lactate Dehydrogenase 2
LDH3	Absolute Lactate Dehydrogenase 3
LDH3%	Percent Lactate Dehydrogenase 3
LDH4	Absolute Lactate Dehydrogenase 4
LDH4%	Percent Lactate Dehydrogenase 4
LDH5	Absolute Lactate Dehydrogenase 5
LDH5%	Percent Lactate Dehydrogenase 5
LDL	Low density lipoprotein cholesterol
LIP	Lipase
METHGB	Methemoglobin
Mg	Magnesium
MYLCS	Myosin light chain 3
MYO	Myoglobin
Na	Sodium
OSTEO2	Osteocalcin
P1NP	N-terminal propeptide of type 1 collagen
PAMY	P-amylase
P-CHE	Cholinesterase - plasma
pCO2	Partial pressure carbon dioxide
pH	Ionized calcium pH
PHOS	Inorganic phosphorus
PINP	N-terminal propeptide of type 1 collagen
PLIP	Phospholipids
PO2	Partial pressure oxygen
PROG	Progesterone

Abbreviations for Chemistry (Continued)

Abbreviation	*Test*
PROL	Prolactin
PTH	Parathyroid hormone
R-CHE	Cholinesterase - red blood cells
SBA	Total bile acids
S-CHE	Cholinesterase - serum
SDH	Sorbitol dehydrogenase
SHGB	Supernatant hemoglobin
SKET	Serum ketone
SKlTropI	Skeletal troponin I
sO2	Oxygen saturation of hemoglobin
SOSMO	Serum osmolality
SPDOS	Serum surfactant protein D
T3	Triiodothyronine
T4	Thyroxine
T4K9	Canine thyroxine
TBIL	Total bilirubin
TEST	Testosterone
TIBC	Total iron binding capacity
TNF-a	Tumor necrosis factor-alpha
TP	Total protein
TPI	Troponin I
TPTOS	Troponin T
TRAP5b	Tartrate-resistant acid phosphatase 5b
TRIG	Triglyceride
TSH	Thyroid stimulating hormone
TSHK9	Canine thyroid stimulating hormone
UA	Uric acid
UIBC	Unsaturated iron binding capacity
UN	Urea nitrogen
UN:CR	Serum UN:creatinine ratio
Vit. D	Vitamin D
VLDL	Calculated very low density lipoprotein cholesterol

Abbreviations for Synovial/Body Fluid

Abbreviation	*Test*
BFMNC	Mononuclear cells
BFNEUT	Neutrophils
BFRBC	Red blood cells
INTERP	Interpretation
NCA	No cytologic abnormalities
SQUAL	Sample quality

Abbreviations for Urine Analysis Functions

Abbreviation	*Test*
ALBCREAT	Urine albumin:urine creatinine ratio
ALBEX	Urine albumin excretion
B2M:UCRE	Urine beta-2-microglobulin:urine creatinine ratio
B2MICGOS	Urine beta-2-microglobulin
B2MIOS	Urine beta-2-microglobulin
CACREAT	Urine calcium:urine creatinine ratio
CaEX	Urine calcium excretion
CaFCL	Calcium fractional clearance
CASTT	Cast type
CLCREAT	Urine chloride:urine creatinine ratio
ClEX	Urine chloride excretion
ClFCL	Chloride fractional clearance
CRCLEAR	Creatinine clearance
CREATCLR	Creatinine clearance
CREATEXR	Urine creatinine excretion
CREAX	Urine creatinine excretion
FECA	Calcium fractional clearance
FECL	Chloride fraction clearance
FEK	Potassium fractional clearance
FEMAG	Magnesium fractional clearance
FENI	Sodium fractional clearance
FEPI	Phosphorus fractional clearance
FOBL	Fecal occult blood
FOBLN	Fecal occult blood negative control
FOBLP	Fecal occult blood positive control
GGTCREAT	Urine gamma glutamyl transferase:urine creatinine ratio
GLCCRT	Urine glucose:urine creatinine ratio
GLUEX	Urine glucose excretion
ICTO	Ictotest
KCREAT	Urine potassium:urine creatinine ratio
KEX	Urine potassium excretion
KFCL	Potassium fractional clearance
KIM1	Urine kidney injury molecule 1
KIM:UCRE	Urine kidney injury molecule1:urine creatinine ratio
KIM:UCREA	Urine kidney injury molecule1:urine creatinine ratio
MALB	Urine microalbumin
MALBUCRE	Urine microalbumin:urine creatinine ratio
MALBUCREA	Urine microalbumin:urine creatinine ratio
MGCREAT	Urine magnesium:urine creatinine ratio
MgEX	Magnesium excretion
NACREAT	Urine sodium:urine creatinine ratio
NaEX	Urine sodium excretion

Abbreviations for Urine Analysis Functions (Continued)

Abbreviation	*Test*
NaFCL	Sodium fractional clearance
NGAL	Urine neutrophil gelatinase-associated lipocalin
NGAL:UC	Urine neutrophil gelatinase-associated lipocalin:urine creatinine ratio
Osteopon	Urine osteopontin
OST:UCREA	Urine osteopontin:urine creatinine ratio
pHMET	Urine pH by pH meter
PHOSCRT	Urine phosphorus:urine creatinine ratio
PHOSEX	Urine phosphorus excretion
PHOSFCL	Phosphorus fractional clearance
PROTCRT	Urine protein:urine creatinine ratio (enzymatic)
REDS	Reducing substances
SPGR	Urine specific gravity
TPEX	Urine total protein excretion
UALB	Urine albumin
UALT	Urine alanine aminotransferase
UAMY	Urine amylase
UAST	Urine aspartate aminotransferase
UB2:UCR	Urine beta-2-microglobulin:urine creatinine ratio
UBACT	Urine bacteria
UBIL	Urine bilirubin
Uca	Urine calcium
Uca:UCR	Urine calcium:urine creatinine ratio
UCAST	Casts
Ucl	Urine chloride
UCL:UCR	Urine chloride:urine creatinine ratio
UCLA	Urine clarity
UCLUST	Urine clusterin
UCLS:UCR	Urine clusterin:urine creatinine ratio
UCOL	Urine color
UCREA	Urine creatinine (Jaffe)
UCREAT	Urine creatinine (enzymatic)
UCRYS	Abnormal crystals
UCRYST	Abnormal crystal type
UCYC	Urine cystatin C
UCYC:UCR	Urine cystatin C:urine creatinine ratio
UEPI	Epithelial cells
UGGT	Urine gamma glutamyl transferase
UGGT:UCR	Urine gamma glutamyl transferase:urine creatinine ratio
UGL:UCR	Urine glucose:urine creatinine ratio
UGLU	Urine qualitative glucose
UGLUC	Urine qualitative glucose

Abbreviations for Urine Analysis Functions (Continued)

Abbreviation	*Test*
UK	Urine potassium
UKET	Urine ketone
ULDH	Urine lactate dehydrogenase
ULEU	Urine leukocyte
UMA:UCREA	Urine microalbumin:urine creatinine ratio
UMALBOS	Urine microalbumin
UMg	Urine magnesium
UMg:UCR	Urine magnesium:urine creatinine ratio
UNa	Urine sodium
UNa:UCR	Urine sodium:urine creatinine ratio
UNa:UK	Urine sodium:potassium ratio
UNAG	Urine N-acetyl-B-D-glucosaminidase
UNAG:UCR	Urine N-acetyl-b-d-glucosaminidase:urine creatinine ratio
UNEX	Urine urea nitrogen excretion
UNIT	Urine nitrite
UOBL	Urine blood/occult
UOSMO	Urine osmolality
UOTH	Urine other
UPAMY	Urine P-amylase
UpH	Urine pH
UPHO:UCR	Urine phosphorus:urine creatinine ratio
UPHOS	Urine phosphorus
UPRO	Urine qualitative protein
UREANCRT	Urine urea nitrogen:urine creatinine ratio
URBC	Urine red blood cell
UTP	Urine qualitative total protein
UTP:UCR	Urine protein:urine creatinine ratio (Jaffe)
UUA	Urine uric acid
UUBG	Urine urobilinogen
UUN	Urine urea nitrogen
UUN:UCR	Urine urea nitrogen:urine creatinine ratio
UVOL	Urine volume
UWBC	Urine white blood cell

Abbreviations for Urine Analysis Functions (Continued)

MICROSCOPIC EXAMINATION OF URINE

Gradings	
Casts, red and white blood cells, and epithelial cells	Crystals, bacteria
0 None seen	0 Not present
1 1 to 5	1 Occasional, not seen in every field
2 6 to 10	2 Few in all fields
3 11 to 20	3 Moderate in all fields
4 >20	4 Many in all fields, may obscure other elements

Abbreviations for Urine Analysis Functions (Continued)

URINE ANALYSIS

Clinitek® 200+ Analyzer, Multistix® Strip, Clinitek Atlas					
Urine Glucose		Urine Ketones		Urine Blood	
NEGATIVE	Negative	NEGATIVE	Negative	NEGATIVE	Negative
TRACE	100 mg/dL	TRACE	5 mg/dL	TRACE	Trace
1+	250 mg/dL	1+	15 mg/dL	1+	Small
2+	500 mg/dL	2+	40 mg/dL	2+	Moderate
3+	≥1000 mg/dL	3+	≥80 mg/dL	3+	Large

Urine Nitrite		Urine Protein		Urine Bilirubin	
NEGATIVE	Negative	NEGATIVE	Negative	NEGATIVE	Negative
POSITIVE	Positive	TRACE	Trace	1+	Small
		1+	30 mg/dL	2+	Moderate
		2+	100 mg/dL	3+	Large
		3+	≥300 mg/dL		

Urine Cast/Crystals		Leukocyte Esterase		Urine Color	
NT	No Type	NEGATIVE	Negative	DKYELLOW	Dark Yellow
		TRACE	Trace	CO	Pale/Colorless
		1+	Small		
		2+	Moderate		
		3+	Large		

Ictotest® Urine Bilirubin		Clinitest® Urine Reducing Substances	
-	Negative	NEGATIVE	Negative
+	Positive	TRACE	1/4 %
		1+	1/2 %
		2+	3/4 %
		3+	1 %
		4+	2 %

4.2 Comments on the Data

The following comments on the data are used by TESTING FACILITY. Some, but not necessarily all, of this information may be needed for this report.

Various models of calculators, computers, and computer programs were used to analyze data in this study. Values in some tables (e.g., means, standard deviations, or individual values) may differ slightly from those in other tables, from individually calculated data, or from statistical analysis data because different models round off or truncate numbers differently. Neither the integrity nor the interpretation of the data was affected by these differences.

Clinical pathology data for diagnostic health checks (used for veterinary assessment) and/or replaced animals may appear in the clinical pathology data tables. These data were reviewed, but not included in the overall interpretation of clinical pathology test results.

5. SUMMARY TABLES

Table 5.1: Summary of Hematology

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RBC E6/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	6.36	5.28	5.42	5.76	5.70	5.72
	SD	1.166	0.365	0.174	0.171	0.312	0.236
	N	3	3	3	3	3	3
5/M	Mean	6.33	5.45	5.57	5.78	5.65	5.72
	SD	0.312	0.499	0.255	0.417	0.510	0.501
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	AT

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RBC E6/uL

Group/ Sex	Phase / Day	Dosing 57	85	113	141	169
1/M	Mean	5.77	5.76	5.47	5.50	5.45
	SD	0.319	0.319	0.220	0.225	0.287
	N	3	3	3	3	3
5/M	Mean	5.79	5.75	5.65	5.50	5.58
	SD	0.412	0.536	0.631	0.472	0.404
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

HGB g/dL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	14.9	12.3	12.7	13.6	12.9	13.6
	SD	2.51	1.47	0.23	0.64	0.38	0.67
	N	3	3	3	3	3	3
5/M	Mean	14.8	12.9	13.2	13.9	13.2	13.9
	SD	0.57	1.00	0.29	0.50	0.95	0.81
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

HGB g/dL

Group/ Sex	Phase	Dosing Day 57	85	113	141	169
1/M	Mean	13.5	13.3	12.8	13.0	12.8
	SD	0.81	0.38	0.89	0.47	0.40
	N	3	3	3	3	3
5/M	Mean	14.1	14.1	13.8	13.3	13.5
	SD	0.81	0.82	1.21	0.67	0.61
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

Hct %

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	50.7	42.4	43.1	44.4	42.8	44.7
	SD	7.05	4.44	0.71	1.91	1.49	2.20
	N	3	3	3	3	3	3
5/M	Mean	51.5	43.2	43.8	45.3	43.3	44.7
	SD	2.34	2.65	0.87	2.08	2.60	2.71
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Hct %
Dosing

Group/ Sex	Phase / Day	57	85	113	141	169
1/M	Mean	44.1	43.4	42.6	44.2	42.1
	SD	2.50	0.95	2.80	1.91	0.72
	N	3	3	3	3	3
5/M	Mean	45.8	45.6	45.9	46.0	44.9
	SD	3.12	2.97	3.75	2.89	2.77
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCV fL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	80.1	80.2	79.5	77.0	75.2	78.2
	SD	4.26	2.82	3.66	3.36	3.89	2.73
	N	3	3	3	3	3	3
5/M	Mean	81.3	79.5	78.7	78.5	76.7	78.4
	SD	2.95	2.59	2.01	2.30	2.56	3.50
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCV fL

Group/ Sex	Phase / Day	Dosing 57	85	113	141	169
1/M	Mean	76.5	75.7	77.8	80.5	77.3
	SD	4.37	5.05	4.94	5.24	4.69
	N	3	3	3	3	3
5/M	Mean	79.3	79.6	81.3	83.8	80.5
	SD	2.20	2.79	2.71	2.86	1.47
	N	3	3	3	3	3
	Statistics	A	AT	AT	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCH pg

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	23.5	23.2	23.4	23.6	22.7	23.8
	SD	0.83	1.18	1.06	1.36	1.00	1.28
	N	3	3	3	3	3	3
5/M	Mean	23.4	23.6	23.7	24.1	23.4	24.5
	SD	0.26	0.50	0.81	1.01	0.92	1.15
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase	MCH pg Dosing				
	Day	57	85	113	141	169
1/M	Mean	23.3	23.1	23.4	23.7	23.5
	SD	1.42	1.66	1.53	1.45	1.68
	N	3	3	3	3	3
5/M	Mean	24.3	24.6	24.5	24.3	24.2
	SD	0.55	1.18	1.18	1.12	0.78
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

MCHC g/dL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	29.3	29.0	29.4	30.6	30.2	30.4
	SD	0.79	0.46	0.10	0.44	0.32	0.74
	N	3	3	3	3	3	3
5/M	Mean	28.8	29.7	30.1	30.7	30.5	31.2
	SD	0.78	0.59	0.44	0.60	0.55	0.12
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

Group/ Sex	Phase	MCHC g/dL Dosing				
	Day	57	85	113	141	169
1/M	Mean	30.5	30.5	30.1	29.4	30.4
	SD	0.12	0.15	0.12	0.15	0.40
	N	3	3	3	3	3
5/M	Mean	30.7	30.9	30.2	29.0	30.1
	SD	0.38	0.42	0.60	0.36	0.50
	N	3	3	3	3	3
	Statistics	AT	A	A	A	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RDW %

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	12.4	12.7	12.4	12.0	13.2	12.4
	SD	0.23	0.60	0.35	0.36	1.00	0.76
	N	3	3	3	3	3	3
5/M	Mean	11.8	12.1	12.1	11.7	12.9	12.4
	SD	0.72	0.70	0.60	0.50	0.75	0.46
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	AT	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RDW %
Dosing

Group/ Sex	Phase / Day	57	85	113	141	169
1/M	Mean	11.9	12.3	12.3	12.1	12.4
	SD	0.38	0.56	0.17	0.12	0.36
	N	3	3	3	3	3
5/M	Mean	12.0	12.1	11.7	11.8	12.1
	SD	0.42	0.42	0.59	0.52	0.40
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RETIC E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	49.2	147.2	89.1	45.9	124.4	77.4
	SD	10.34	70.52	36.05	21.68	71.05	25.02
	N	3	3	3	3	3	3
5/M	Mean	32.7	90.8	86.6	41.1	117.3	77.2
	SD	12.60	14.52	20.68	4.36	9.92	8.72
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	AT	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RETIC E3/uL

Group/ Sex	Phase	Dosing				
	Day	57	85	113	141	169
1/M	Mean	44.8	59.2	49.2	60.7	37.6
	SD	15.63	23.56	11.71	15.69	17.20
	N	3	3	3	3	3
5/M	Mean	57.7	85.4	43.9	76.4	49.7
	SD	10.83	5.22	11.82	13.71	14.44
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

PLT E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	470	366	361	354	375	363
	SD	198.1	129.6	142.5	146.7	134.6	137.4
	N	3	3	3	3	3	3
5/M	Mean	461	489	481	476	532	448
	SD	30.8	72.3	100.0	105.1	145.8	99.3
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

		PLT E3/uL				
	Phase	Dosing				
Group/ Sex	Day	57	85	113	141	169
1/M	Mean	371	383	360	351	366
	SD	130.1	165.0	173.8	159.7	144.7
	N	3	3	3	3	3
5/M	Mean	491	509	479	462	499
	SD	59.5	71.0	44.1	67.4	89.9
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

WBC E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	11.70	11.59	11.22	10.34	10.83	10.73
	SD	2.123	0.150	2.588	1.006	1.473	2.937
	N	3	3	3	3	3	3
5/M	Mean	12.47	14.67	11.57	12.18	11.68	13.87
	SD	2.505	6.879	2.787	2.274	2.497	1.915
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase	WBC E3/uL Dosing				
	Day	57	85	113	141	169
1/M	Mean	12.21	11.00	7.79	9.95	8.52
	SD	6.222	5.774	2.278	0.765	2.717
	N	3	3	3	3	3
5/M	Mean	12.80	11.81	9.60	10.61	7.53
	SD	1.473	1.747	1.270	1.568	0.257
	N	3	3	3	3	3
	Statistics	AT	AT	A	A	AT

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

NEUT E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	6.49	6.23	5.47	6.11	5.60	4.09
	SD	2.969	1.151	4.025	2.022	1.142	1.722
	N	3	3	3	3	3	3
5/M	Mean	6.19	8.79	4.27	5.29	4.52	5.64
	SD	3.113	7.017	2.175	1.646	2.002	2.458
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

NEUT E3/uL

Group/ Sex	Phase	Dosing				
	Day	57	85	113	141	169
1/M	Mean	6.69	6.59	3.52	3.58	4.75
	SD	4.814	4.877	1.470	1.628	2.247
	N	3	3	3	3	3
5/M	Mean	5.53	4.66	4.05	2.77	3.23
	SD	1.926	1.654	2.594	0.974	0.704
	N	3	3	3	3	3
	Statistics	A	AT	A	A	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

LYM E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	4.68	4.89	5.24	3.72	4.45	5.93
	SD	0.999	1.249	2.008	0.963	1.765	1.720
	N	3	3	3	3	3	3
5/M	Mean	5.73	5.45	6.74	6.19	6.26	7.09
	SD	0.525	0.243	1.591	1.137	1.382	1.377
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

		LYM E3/uL				
	Phase	Dosing				
Group/ Sex	Day	57	85	113	141	169
1/M	Mean	5.01	4.05	4.00	5.87	3.48
	SD	1.972	1.130	0.800	2.248	0.898
	N	3	3	3	3	3
5/M	Mean	6.45	6.47	5.05	7.30	3.97
	SD	0.880	0.345	1.278	1.101	0.626
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MONO E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	0.38	0.25	0.30	0.31	0.45	0.48
	SD	0.107	0.032	0.076	0.081	0.197	0.142
	N	3	3	3	3	3	3
5/M	Mean	0.36	0.22	0.30	0.39	0.47	0.70
	SD	0.095	0.010	0.086	0.087	0.064	0.055
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	AT	AT	A

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

		MONO E3/uL				
	Phase	Dosing				
Group/ Sex	Day	57	85	113	141	169
1/M	Mean	0.31	0.26	0.17	0.33	0.20
	SD	0.098	0.129	0.045	0.035	0.026
	N	3	3	3	3	3
5/M	Mean	0.52	0.47	0.29	0.34	0.21
	SD	0.076	0.140	0.081	0.030	0.074
	N	3	3	3	3	3
	Statistics	A	A	A	AT	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

EOS E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	0.03	0.09	0.08	0.05	0.25	0.09
	SD	0.006	0.083	0.045	0.015	0.083	0.061
	N	3	3	3	3	3	3
5/M	Mean	0.04	0.05	0.10	0.16	0.31	0.33*
	SD	0.025	0.046	0.044	0.101	0.082	0.255
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	AT	A	AT

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e1

Group/ Sex	Phase	EOS E3/uL Dosing				
	Day	57	85	113	141	169
1/M	Mean	0.02	0.02	0.02	0.07	0.02
	SD	0.020	0.006	0.021	0.055	0.012
	N	3	3	3	3	3
5/M	Mean	0.15	0.07	0.06	0.06	0.02
	SD	0.074	0.032	0.020	0.017	0.010
	N	3	3	3	3	3
	Statistics	A	AT	A	A	AT

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

BASO E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	0.05	0.06	0.08	0.06	0.02	0.06
	SD	0.015	0.010	0.021	0.006	0.006	0.052
	N	3	3	3	3	3	3
5/M	Mean	0.07	0.08	0.10	0.08	0.04	0.05
	SD	0.020	0.050	0.035	0.023	0.006	0.010
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	A	A	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

BASO E3/uL

Group/ Sex	Phase	Dosing Day 57	Dosing Day 85	Dosing Day 113	Dosing Day 141	Dosing Day 169
1/M	Mean	0.09	0.03	0.05	0.04	0.02
	SD	0.068	0.010	0.020	0.015	0.006
	N	3	3	3	3	3
5/M	Mean	0.08	0.04	0.07	0.06	0.03
	SD	0.000	0.017	0.020	0.015	0.015
	N	3	3	3	3	3
	Statistics	AT	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

LUC E3/uL

Group/ Sex	Phase	Predose			Dosing		
	Day	8	28	41	1	15	29
1/M	Mean	0.07	0.08	0.07	0.07	0.06	0.08
	SD	0.025	0.025	0.015	0.010	0.010	0.021
	N	3	3	3	3	3	3
5/M	Mean	0.08	0.08	0.07	0.08	0.08	0.07
	SD	0.026	0.038	0.012	0.015	0.025	0.006
	N	3	3	3	3	3	3
	Statistics	X1	X1	X1	AT	AT	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase	LUC E3/uL Dosing				
	Day	57	85	113	141	169
1/M	Mean	0.08	0.05	0.04	0.06	0.05
	SD	0.025	0.012	0.021	0.010	0.006
	N	3	3	3	3	3
5/M	Mean	0.07	0.09	0.07	0.08	0.06
	SD	0.015	0.031	0.015	0.015	0.010
	N	3	3	3	3	3
	Statistics	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

PT sec

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	9.8	9.6	9.7	9.5	9.2	9.7
	SD	0.51	0.50	0.32	0.32	0.42	0.15
	N	3	3	3	3	3	3
5/M	Mean	10.0	10.2	9.4	9.4	9.5	9.4
	SD	0.72	0.44	0.93	0.65	0.78	0.72
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

Group/ Sex	Phase	PT sec Dosing					
	Day	57	71	85	113	141	169
1/M	Mean	9.5	9.6	9.9	9.9	9.6	10.2
	SD	0.21	0.26	0.29	0.25	0.20	0.15
	N	3	3	3	3	3	3
5/M	Mean	9.4	9.4	9.7	9.7	9.8	10.1
	SD	0.60	0.47	0.50	0.25	0.64	0.62
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

APTT sec

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	22.2	21.9	21.4	20.5	20.9	21.0
	SD	1.27	0.95	1.59	1.23	0.40	0.67
	N	3	3	3	3	3	3
5/M	Mean	20.5	21.0	19.2	18.9	19.3	18.5
	SD	1.12	1.27	2.66	0.78	1.32	0.78
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	AT	AT	AT

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

APTT sec
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	21.3	21.1	21.8	22.2	21.5	21.2
	SD	0.81	1.15	1.04	1.57	1.53	1.22
	N	3	3	3	3	3	3
5/M	Mean	19.5	20.0	22.1	22.8	21.7	21.3
	SD	2.60	4.16	4.76	3.07	1.61	0.97
	N	3	3	3	3	3	3
	Statistics	A	AT	AT	A	A	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

FIB mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	221	203	232	214	224	209
	SD	24.9	30.4	20.7	19.6	53.9	50.6
	N	3	3	3	3	3	3
5/M	Mean	242	231	277	279	300	256
	SD	14.1	23.7	29.8	21.7	54.0	41.4
	N	3	3	3	3	3	3
	Statistics	X1	X1	X5	A	X5	A

* P<=0.05
X1 = No analysis required
X5 = Not analyzed (values above/below the limit of quantitation)
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

Group/ Sex	Phase	FIB mg/dL Dosing					
	Day	57	71	85	113	141	169
1/M	Mean	212	219	227	181	172	216
	SD	41.0	59.2	80.6	20.6	4.9	34.4
	N	3	3	3	3	3	3
5/M	Mean	278	272	293	229	217	244
	SD	21.9	29.5	43.0	30.5	37.2	25.2
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

Table 5.2: Summary of Clinical Chemistry

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

GLU mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	78	59	57	89	70	88
	SD	11.2	12.1	11.1	27.0	13.5	7.4
	N	3	3	3	3	3	3
5/M	Mean	82	61	84	91	87	92
	SD	11.0	16.6	11.0	15.4	12.6	15.4
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

		Phase			GLU mg/dL Dosing					
Group/ Sex	Day		57	71	85	113	141	169
1/M	Mean		59	74	59	58	78	57
	SD		9.8	2.1	12.1	7.8	9.0	7.8
	N		3	3	3	3	3	3
5/M	Mean		84	87	79	80*	92	78
	SD		22.6	16.4	17.8	9.2	11.1	5.1
	N		3	3	3	3	3	3
	Statistics		A	AT	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

UN mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	25	20	21	20	22	22
	SD	7.9	1.5	1.5	1.5	3.8	2.5
	N	3	3	3	3	3	3
5/M	Mean	20	20	19	19	17	19
	SD	3.1	2.0	2.6	2.0	1.2	3.5
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	AT	A	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

UN mg/dL
Dosing

Group/ Sex	Phase Day	57	71	85	113	141	169
1/M	Mean	22	21	24	21	17	21
	SD	1.5	1.5	1.2	4.9	3.5	0.6
	N	3	3	3	3	3	3
5/M	Mean	18	19	17	16	18	21
	SD	4.0	4.0	1.5	2.1	3.2	3.5
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

CREAT mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	0.8	0.6	0.7	0.7	0.6	0.7
	SD	0.26	0.12	0.00	0.06	0.12	0.12
	N	3	3	3	3	3	3
5/M	Mean	0.6	0.7	0.8	0.7	0.7	0.6
	SD	0.12	0.10	0.15	0.17	0.10	0.06
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	AT

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

CREAT mg/dL
Dosing

Group/ Sex	Phase Day	57	71	85	113	141	169
1/M	Mean	0.7	0.7	0.7	0.7	0.7	0.7
	SD	0.06	0.06	0.06	0.00	0.10	0.10
	N	3	3	3	3	3	3
5/M	Mean	0.6	0.6	0.8	0.7	0.8	0.7
	SD	0.10	0.06	0.00	0.12	0.06	0.06
	N	3	3	3	3	3	3
	Statistics	A	X2	X2	X2	X2	X2

* P<=0.05
A = ANOVA and Dunnett's
X2 = Not analyzed (too few distinct values)

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

TP g/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	8.3	7.5	7.6	7.9	7.4	7.9
	SD	1.05	0.52	0.06	0.15	0.20	0.17
	N	3	3	3	3	3	3
5/M	Mean	8.0	7.5	7.8	7.9	7.5	7.7
	SD	0.85	0.51	0.72	0.66	0.51	0.47
	N	3	3	3	3	3	3
	Statistics	X1	X1	AT	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

TP g/dL

Group/ Sex	Phase / Day	Dosing 57	71	85	113	141	169
1/M	Mean	7.5	7.7	7.5	7.7	7.3	7.3
	SD	0.20	0.32	0.26	0.15	0.46	0.21
	N	3	3	3	3	3	3
5/M	Mean	7.5	7.9	8.1	7.7	7.2	7.3
	SD	0.50	0.36	0.40	0.44	0.32	0.44
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

ALB g/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	5.2	4.8	4.9	5.0	4.8	5.0
	SD	0.46	0.42	0.30	0.31	0.47	0.49
	N	3	3	3	3	3	3
5/M	Mean	5.2	4.9	5.2	5.2	5.1	5.1
	SD	0.46	0.25	0.51	0.32	0.31	0.23
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase / Day	ALB g/dL Dosing 57	71	85	113	141	169
1/M	Mean	4.8	4.6	4.6	4.8	4.8	4.7
	SD	0.51	0.55	0.47	0.46	0.46	0.35
	N	3	3	3	3	3	3
5/M	Mean	4.8	4.8	5.0	4.8	4.9	4.9
	SD	0.25	0.15	0.12	0.21	0.21	0.25
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

GLOB g/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	3.1	2.7	2.7	2.8	2.6	2.9
	SD	0.60	0.38	0.31	0.40	0.55	0.61
	N	3	3	3	3	3	3
5/M	Mean	2.8	2.6	2.6	2.7	2.3	2.7
	SD	0.40	0.26	0.21	0.35	0.21	0.25
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

GLOB g/dL
Dosing

Group/ Sex	Phase Day	57	71	85	113	141	169
1/M	Mean	2.7	3.0	2.9	2.9	2.5	2.6
	SD	0.40	0.25	0.25	0.32	0.00	0.17
	N	3	3	3	3	3	3
5/M	Mean	2.7	3.1	3.1	2.9	2.4	2.4
	SD	0.25	0.21	0.31	0.31	0.15	0.21
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

A:G Ratio

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	1.7	1.8	1.8	1.8	2.0	1.8
	SD	0.21	0.31	0.35	0.35	0.60	0.51
	N	3	3	3	3	3	3
5/M	Mean	1.9	1.9	2.0	2.0	2.2	1.9
	SD	0.12	0.12	0.06	0.17	0.06	0.10
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase / Day	A:G Ratio Dosing 57	71	85	113	141	169
1/M	Mean	1.8	1.5	1.6	1.7	1.9	1.8
	SD	0.45	0.31	0.31	0.32	0.15	0.26
	N	3	3	3	3	3	3
5/M	Mean	1.8	1.6	1.7	1.7	2.1	2.0
	SD	0.06	0.06	0.15	0.17	0.12	0.10
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

CHOL mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	138	114	120	171	156	163
	SD	50.8	29.5	34.7	66.0	69.7	65.3
	N	3	3	3	3	3	3
5/M	Mean	137	132	122	140	123	123
	SD	26.7	25.1	20.5	18.6	15.1	18.0
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	AT	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

CHOL mg/dL
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	137	128	139	130	111	127
	SD	45.4	38.4	38.1	52.7	28.9	32.0
	N	3	3	3	3	3	3
5/M	Mean	125	121	138	130	122	145
	SD	27.1	19.8	21.5	32.4	24.0	21.2
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

TRIG mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	28	26	36	38	34	46
	SD	13.9	5.1	12.3	15.2	7.2	43.6
	N	3	3	3	3	3	3
5/M	Mean	29	36	36	48	44	78
	SD	4.6	4.6	14.3	19.1	14.0	32.4
	N	3	3	3	3	3	3
	Statistics	X1	X1	X5	AT	AT	AT

X1 = No analysis required
X5 = Not analyzed (values above/below the limit of quantitation)
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

TRIG mg/dL
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	36	29	49	48	34	56
	SD	25.5	17.1	15.3	23.1	16.2	11.0
	N	3	3	3	3	3	3
5/M	Mean	56	63	61	55	47	66
	SD	7.8	16.8	18.1	10.6	12.7	15.6
	N	3	3	3	3	3	3
	Statistics	A	AT	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

TBIL mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	0.2	<0.2	0.2	<0.2	<0.2	<0.1
	SD	0.06	0.10	0.08	0.13	0.10	0.00
	N	3	3	3	3	3	3
5/M	Mean	0.2	<0.1	<0.1	<0.1	<0.1	<0.1
	SD	0.05	0.04	0.03	0.03	0.02	0.00
	N	3	3	3	3	3	3
	Statistics	X1	X1	X5	X5	X5	X5

X1 = No analysis required
X5 = Not analyzed (values above/below the limit of quantitation)

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

		TBIL mg/dL Dosing					
Group/ Sex	Phase Day	57	71	85	113	141	169
1/M	Mean	<0.1	<0.1	0.3	0.2	0.1	0.3
	SD	0.03	0.04	0.17	0.05	0.01	0.07
	N	3	3	3	3	3	3
5/M	Mean	<0.1	<0.1	<0.2	0.2	<0.1	0.3
	SD	0.00	0.01	0.08	0.06	0.02	0.09
	N	3	3	3	3	3	3
	Statistics	X5	X5	X5	X5	X5	A

* P<=0.05
X5 = Not analyzed (values above/below the limit of quantitation)
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

AST U/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	42	33	36	30	34	23
	SD	14.2	2.1	2.5	11.4	1.0	5.5
	N	3	3	3	3	3	3
5/M	Mean	37	44	30	33	26	28
	SD	9.0	8.1	3.2	7.0	1.0	4.4
	N	3	3	3	3	3	3
	Statistics	X1	X1	AT	A	AT	A

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

AST U/L
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	29	27	27	32	34	31
	SD	4.2	6.6	8.7	3.1	8.5	6.7
	N	3	3	3	3	3	3
5/M	Mean	34	30	29	35	37	31
	SD	10.2	10.4	4.6	8.1	13.9	7.6
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

ALT U/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	55	39	40	53	49	32
	SD	13.1	11.6	12.1	31.0	20.8	8.0
	N	3	3	3	3	3	3
5/M	Mean	46	42	40	37	37	30
	SD	16.7	13.3	9.8	12.9	7.9	6.8
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-		GC/kg	1.024e13	1.024e13

ALT U/L
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	32	32	32	38	35	35
	SD	5.9	7.8	15.0	6.1	7.6	7.2
	N	3	3	3	3	3	3
5/M	Mean	32	35	34	33	34	32
	SD	8.7	9.5	13.2	8.7	12.1	7.9
	N	3	3	3	3	3	3
	Statistics	AT	A	AT	A	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-		GC/kg	1.024e13	1.024e13

ALP U/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	333	275	400	353	363	354
	SD	61.4	24.5	94.6	80.5	76.0	57.9
	N	3	3	3	3	3	3
5/M	Mean	491	437	504	353	303	277
	SD	161.3	142.4	229.3	119.5	91.7	90.0
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	AT

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

ALP U/L
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	322	323	313	298	399	431
	SD	52.6	52.0	41.0	33.0	61.8	83.6
	N	3	3	3	3	3	3
5/M	Mean	256	239	224	330	546	588
	SD	92.1	70.0	65.1	122.6	175.3	183.5
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	AT	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

GGT U/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	64	59	60	65	66	64
	SD	9.3	13.2	14.2	16.1	21.4	13.9
	N	3	3	3	3	3	3
5/M	Mean	60	53	47	43	40	40
	SD	19.4	12.0	12.8	7.8	5.7	6.8
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	AT	A

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase	GGT U/L Dosing					
	Day	57	71	85	113	141	169
1/M	Mean	62	60	59	62	78	76
	SD	11.2	15.2	17.9	11.1	17.8	16.8
	N	3	3	3	3	3	3
5/M	Mean	40	39	41	47	65	70
	SD	7.6	7.2	6.6	9.7	15.8	16.4
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

CK U/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	169	127	121	122	172	114
	SD	63.3	15.9	11.6	6.4	96.7	12.4
	N	3	3	3	3	3	3
5/M	Mean	219	283	216	162	139	231
	SD	73.6	148.1	88.8	86.3	45.9	167.7
	N	3	3	3	3	3	3
	Statistics	X1	X1	AT	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

CK U/L

Group/ Sex	Phase / Dosing Day	57	71	85	113	141	169
1/M	Mean	102	255	107	121	156	196
	SD	9.8	196.4	5.5	17.6	12.5	79.0
	N	3	3	3	3	3	3
5/M	Mean	309	122	234	178	188	309
	SD	273.1	15.8	171.5	45.8	60.7	199.1
	N	3	3	3	3	3	3
	Statistics	A	AT	AT	AT	A	A

A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

Ca mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	10.9	10.1	9.7	10.0	9.8	10.8
	SD	0.70	0.21	0.26	0.12	0.15	0.21
	N	3	3	3	3	3	3
5/M	Mean	11.0	10.3	10.9*	10.4	10.4	11.1
	SD	0.31	0.15	0.17	0.32	0.12	0.15
	N	3	3	3	3	3	3
	Statistics	X1	X1	AT	AT	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Ca mg/dL
Dosing

Group/ Sex	Phase Day	57	71	85	113	141	169
1/M	Mean	9.9	10.4	10.1	10.0	10.2	9.7
	SD	0.06	0.29	0.26	0.00	0.25	0.21
	N	3	3	3	3	3	3
5/M	Mean	10.3	10.8	10.9	10.5	10.7	10.5
	SD	0.40	0.15	0.10	0.35	0.45	0.15
	N	3	3	3	3	3	3
	Statistics	A	AT	A	AT	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

PHOS mg/dL

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	7.4	6.4	5.5	6.7	5.8	5.6
	SD	1.56	0.51	1.25	0.97	1.18	0.81
	N	3	3	3	3	3	3
5/M	Mean	6.9	6.7	5.6	6.2	4.3	3.3*
	SD	0.35	0.15	0.90	0.62	0.68	0.52
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	A	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

PHOS mg/dL
Dosing

Group/ Sex	Phase / Day	57	71	85	113	141	169
1/M	Mean	5.9	6.2	6.9	5.7	5.4	7.6
	SD	0.95	0.80	1.35	0.49	0.42	0.59
	N	3	3	3	3	3	3
5/M	Mean	4.5	4.2*	5.8	6.1	5.8	7.4
	SD	0.25	0.30	1.20	0.06	0.26	0.72
	N	3	3	3	3	3	3
	Statistics	A	A	A	AT	A	A

* P<=0.05
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Na mmol/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	149	152	149	149	149	149
	SD	7.1	1.7	2.3	5.2	1.7	2.6
	N	3	3	3	3	3	3
5/M	Mean	156	151	151	150	150	149
	SD	1.7	1.5	2.6	3.1	3.1	3.1
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	A	AT	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

Group/ Sex	Phase	Na mmol/L Dosing					
	Day	57	71	85	113	141	169
1/M	Mean	151	150	146	148	148	147
	SD	4.4	5.7	4.0	2.6	2.6	3.0
	N	3	3	3	3	3	3
5/M	Mean	149	149	148	148	150	147
	SD	3.2	3.2	3.2	5.6	4.5	2.0
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

K mmol/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	5.1	4.9	3.8	4.7	4.4	4.7
	SD	0.52	0.26	0.26	0.25	0.57	0.81
	N	3	3	3	3	3	3
5/M	Mean	5.1	4.6	4.8	4.8	4.7	4.7
	SD	0.26	0.31	0.51	0.64	0.45	1.00
	N	3	3	3	3	3	3
	Statistics	X1	X1	AT	A	A	A

X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Group/ Sex	Phase Day	K mmol/L Dosing 57	71	85	113	141	169
1/M	Mean	4.7	4.6	4.6	4.4	4.7	4.5
	SD	0.55	0.35	0.66	0.31	0.56	0.47
	N	3	3	3	3	3	3
5/M	Mean	5.1	4.5	4.8	4.8	5.2	4.8
	SD	0.81	0.74	0.75	0.57	1.05	0.67
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

A = ANOVA and Dunnett's

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Cl mmol/L

Group/ Sex	Phase	Predose		Dosing			
	Day	8	28	1	15	29	43
1/M	Mean	101	104	104	107	106	105
	SD	5.1	1.2	3.0	2.5	2.6	2.3
	N	3	3	3	3	3	3
5/M	Mean	103	102	102	103	104	102
	SD	1.5	2.1	2.5	1.7	0.6	2.0
	N	3	3	3	3	3	3
	Statistics	X1	X1	A	AT	AT	A

* P<=0.05
X1 = No analysis required
A = ANOVA and Dunnett's
T = Rank-transformed data

VECTORSTUDYU1

Table
Summary of Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

Group/ Sex	Phase	Cl mmol/L Dosing					
	Day	57	71	85	113	141	169
1/M	Mean	107	107	104	105	106	104
	SD	5.0	5.5	3.6	4.2	3.2	4.7
	N	3	3	3	3	3	3
5/M	Mean	107	104	102	104	103	104
	SD	3.5	3.0	2.9	3.5	3.1	3.8
	N	3	3	3	3	3	3
	Statistics	A	A	A	A	A	A

* P<=0.05
A = ANOVA and Dunnett's

6. INDIVIDUAL ANIMAL DATA TABLES

Table 6.1: Individual Hematology

VECTORSTUDYU1

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

RBC E6/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		7.66	4.95	5.54	5.94	6.06	5.92
	P0002		5.40	5.21	5.50	5.60	5.51	5.46
	P0003		6.03	5.67	5.22	5.74	5.53	5.78
	Mean		6.36	5.28	5.42	5.76	5.70	5.72
	SD		1.166	0.365	0.174	0.171	0.312	0.236
	N		3	3	3	3	3	3
5/M	P0401		6.57	5.53	5.63	5.90	5.47	5.50
	P0402		5.98	4.92	5.29	5.32	5.26	5.36
	P0403		6.45	5.91	5.79	6.13	6.23	6.29
	Mean		6.33	5.45	5.57	5.78	5.65	5.72
	SD		0.312	0.499	0.255	0.417	0.510	0.501
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-		GC/kg	1.024e13	1.024e13

			RBC E6/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		6.01	6.12	5.58	5.72	5.78
	P0002		5.41	5.52	5.22	5.27	5.26
	P0003		5.90	5.63	5.62	5.50	5.31
	Mean		5.77	5.76	5.47	5.50	5.45
	SD		0.319	0.319	0.220	0.225	0.287
	N		3	3	3	3	3
5/M	P0401		5.43	5.51	5.41	5.40	5.46
	P0402		5.70	5.37	5.18	5.08	5.25
	P0403		6.24	6.36	6.37	6.01	6.03
	Mean		5.79	5.75	5.65	5.50	5.58
	SD		0.412	0.536	0.631	0.472	0.404
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

HGB g/dL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		17.5	11.0	12.4	13.3	13.2	13.3
	P0002		12.5	12.0	12.8	13.1	12.5	13.2
	P0003		14.7	13.9	12.8	14.3	13.1	14.4
	Mean		14.9	12.3	12.7	13.6	12.9	13.6
	SD		2.51	1.47	0.23	0.64	0.38	0.67
	N		3	3	3	3	3	3
5/M	P0401		15.3	12.8	13.0	14.0	12.5	13.2
	P0402		14.2	11.9	13.0	13.4	12.9	13.8
	P0403		15.0	13.9	13.5	14.4	14.3	14.8
	Mean		14.8	12.9	13.2	13.9	13.2	13.9
	SD		0.57	1.00	0.29	0.50	0.95	0.81
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			HGB g/dL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		13.1	13.0	12.1	12.6	12.6
	P0002		12.9	13.1	12.5	12.8	12.6
	P0003		14.4	13.7	13.8	13.5	13.3
	Mean		13.5	13.3	12.8	13.0	12.8
	SD		0.81	0.38	0.89	0.47	0.40
	N		3	3	3	3	3
5/M	P0401		13.2	13.4	12.9	12.9	13.1
	P0402		14.2	13.9	13.4	13.0	13.2
	P0403		14.8	15.0	15.2	14.1	14.2
	Mean		14.1	14.1	13.8	13.3	13.5
	SD		0.81	0.82	1.21	0.67	0.61
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Hct %

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		57.8	38.7	42.3	44.1	43.4	44.8
	P0002		43.7	41.1	43.2	42.6	41.1	42.4
	P0003		50.6	47.3	43.7	46.4	43.9	46.8
	Mean		50.7	42.4	43.1	44.4	42.8	44.7
	SD		7.05	4.44	0.71	1.91	1.49	2.20
	N		3	3	3	3	3	3
5/M	P0401		54.2	43.4	44.0	46.4	41.8	42.4
	P0402		50.0	40.5	42.8	42.9	41.8	44.1
	P0403		50.3	45.8	44.5	46.6	46.3	47.7
	Mean		51.5	43.2	43.8	45.3	43.3	44.7
	SD		2.34	2.65	0.87	2.08	2.60	2.71
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			Hct %				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		43.0	42.7	40.3	42.6	41.6
	P0002		42.4	43.1	41.7	43.6	41.7
	P0003		47.0	44.5	45.7	46.3	42.9
	Mean		44.1	43.4	42.6	44.2	42.1
	SD		2.50	0.95	2.80	1.91	0.72
	N		3	3	3	3	3
5/M	P0401		42.4	43.5	43.8	44.4	43.4
	P0402		46.6	44.3	43.6	44.2	43.2
	P0403		48.5	49.0	50.2	49.3	48.1
	Mean		45.8	45.6	45.9	46.0	44.9
	SD		3.12	2.97	3.75	2.89	2.77
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCV fL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		75.5	78.2	76.5	74.2	71.7	75.7
	P0002		80.9	78.9	78.5	76.0	74.6	77.7
	P0003		83.9	83.4	83.6	80.7	79.4	81.1
	Mean		80.1	80.2	79.5	77.0	75.2	78.2
	SD		4.26	2.82	3.66	3.36	3.89	2.73
	N		3	3	3	3	3	3
5/M	P0401		82.4	78.5	78.1	78.6	76.4	77.1
	P0402		83.6	82.4	80.9	80.7	79.4	82.4
	P0403		78.0	77.5	77.0	76.1	74.3	75.8
	Mean		81.3	79.5	78.7	78.5	76.7	78.4
	SD		2.95	2.59	2.01	2.30	2.56	3.50
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			MCV fL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		71.5	69.9	72.2	74.5	72.0
	P0002		78.4	78.1	79.9	82.8	79.2
	P0003		79.6	79.1	81.4	84.2	80.8
	Mean		76.5	75.7	77.8	80.5	77.3
	SD		4.37	5.05	4.94	5.24	4.69
	N		3	3	3	3	3
5/M	P0401		78.2	79.0	81.0	82.2	79.6
	P0402		81.8	82.6	84.1	87.1	82.2
	P0403		77.8	77.1	78.7	82.1	79.7
	Mean		79.3	79.6	81.3	83.8	80.5
	SD		2.20	2.79	2.71	2.86	1.47
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCH pg

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		22.8	22.2	22.4	22.3	21.7	22.4
	P0002		23.2	22.9	23.2	23.4	22.6	24.1
	P0003		24.4	24.5	24.5	25.0	23.7	24.9
	Mean		23.5	23.2	23.4	23.6	22.7	23.8
	SD		0.83	1.18	1.06	1.36	1.00	1.28
	N		3	3	3	3	3	3
5/M	P0401		23.3	23.1	23.1	23.6	22.9	24.1
	P0402		23.7	24.1	24.6	25.3	24.5	25.8
	P0403		23.2	23.5	23.3	23.5	22.9	23.6
	Mean		23.4	23.6	23.7	24.1	23.4	24.5
	SD		0.26	0.50	0.81	1.01	0.92	1.15
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCH pg

Group/ Sex	Animal Number	Phase Day	Dosing 57	85	113	141	169
1/M	P0001		21.7	21.2	21.7	22.0	21.7
	P0002		23.8	23.8	24.0	24.4	23.9
	P0003		24.4	24.3	24.6	24.6	25.0
	Mean		23.3	23.1	23.4	23.7	23.5
	SD		1.42	1.66	1.53	1.45	1.68
	N		3	3	3	3	3
5/M	P0401		24.3	24.3	23.9	23.9	24.0
	P0402		24.9	25.9	25.9	25.6	25.1
	P0403		23.8	23.6	23.8	23.5	23.6
	Mean		24.3	24.6	24.5	24.3	24.2
	SD		0.55	1.18	1.18	1.12	0.78
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCHC g/dL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		30.2	28.5	29.3	30.1	30.3	29.6
	P0002		28.7	29.1	29.5	30.8	30.4	31.0
	P0003		29.0	29.4	29.4	30.9	29.8	30.7
	Mean		29.3	29.0	29.4	30.6	30.2	30.4
	SD		0.79	0.46	0.10	0.44	0.32	0.74
	N		3	3	3	3	3	3
5/M	P0401		28.3	29.5	29.6	30.1	29.9	31.3
	P0402		28.4	29.3	30.4	31.3	30.9	31.3
	P0403		29.7	30.4	30.3	30.8	30.8	31.1
	Mean		28.8	29.7	30.1	30.7	30.5	31.2
	SD		0.78	0.59	0.44	0.60	0.55	0.12
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MCHC g/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	85	113	141	169
1/M	P0001		30.4	30.4	30.0	29.5	30.2
	P0002		30.4	30.5	30.0	29.4	30.2
	P0003		30.6	30.7	30.2	29.2	30.9
	Mean		30.5	30.5	30.1	29.4	30.4
	SD		0.12	0.15	0.12	0.15	0.40
	N		3	3	3	3	3
5/M	P0401		31.1	30.8	29.6	29.1	30.2
	P0402		30.4	31.4	30.8	29.3	30.6
	P0403		30.5	30.6	30.2	28.6	29.6
	Mean		30.7	30.9	30.2	29.0	30.1
	SD		0.38	0.42	0.60	0.36	0.50
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg		1.024e13	1.024e13

RDW %

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		12.5	13.3	12.4	11.6	12.2	11.5
	P0002		12.1	12.1	12.0	12.1	13.1	12.7
	P0003		12.5	12.8	12.7	12.3	14.2	12.9
	Mean		12.4	12.7	12.4	12.0	13.2	12.4
	SD		0.23	0.60	0.35	0.36	1.00	0.76
	N		3	3	3	3	3	3
5/M	P0401		12.0	12.4	12.2	11.8	13.3	12.8
	P0402		12.4	12.6	12.7	12.2	13.3	12.5
	P0403		11.0	11.3	11.5	11.2	12.0	11.9
	Mean		11.8	12.1	12.1	11.7	12.9	12.4
	SD		0.72	0.70	0.60	0.50	0.75	0.46
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

RDW %

Group/ Sex	Animal Number	Phase Day	Dosing 57	85	113	141	169
1/M	P0001		11.5	11.7	12.2	12.0	12.0
	P0002		12.1	12.4	12.2	12.0	12.5
	P0003		12.2	12.8	12.5	12.2	12.7
	Mean		11.9	12.3	12.3	12.1	12.4
	SD		0.38	0.56	0.17	0.12	0.36
	N		3	3	3	3	3
5/M	P0401		12.3	12.4	12.1	12.1	12.3
	P0402		12.1	12.2	11.9	12.1	12.3
	P0403		11.5	11.6	11.0	11.2	11.6
	Mean		12.0	12.1	11.7	11.8	12.1
	SD		0.42	0.42	0.59	0.52	0.40
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

RETIC E3/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		37.9	228.5	62.7	33.1	67.4	55.6
	P0002		58.2	102.1	74.5	33.6	101.8	71.8
	P0003		51.5	111.1	130.2	70.9	204.0	104.7
	Mean		49.2	147.2	89.1	45.9	124.4	77.4
	SD		10.34	70.52	36.05	21.68	71.05	25.02
	N		3	3	3	3	3	3
5/M	P0401		27.0	94.0	76.4	36.6	124.6	69.2
	P0402		47.1	103.4	73.0	45.3	106.0	76.0
	P0403		23.9	74.9	110.4	41.4	121.3	86.5
	Mean		32.7	90.8	86.6	41.1	117.3	77.2
	SD		12.60	14.52	20.68	4.36	9.92	8.72
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			RETIC E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		31.7	36.1	59.6	44.4	21.9
	P0002		40.6	58.3	36.5	61.9	35.0
	P0003		62.1	83.2	51.4	75.7	56.0
	Mean		44.8	59.2	49.2	60.7	37.6
	SD		15.63	23.56	11.71	15.69	17.20
	N		3	3	3	3	3
5/M	P0401		50.6	91.1	57.1	84.1	66.4
	P0402		52.4	84.1	40.3	84.6	41.0
	P0403		70.2	80.9	34.3	60.6	41.8
	Mean		57.7	85.4	43.9	76.4	49.7
	SD		10.83	5.22	11.82	13.71	14.44
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

PLT E3/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		615(1)	389	381	406	428	426(1)
	P0002		550	482	493	467	475	457
	P0003		244	226	210	188	222	205
	Mean		470	366	361	354	375	363
	SD		198.1	129.6	142.5	146.7	134.6	137.4
	N		3	3	3	3	3	3
5/M	P0401		427	438	403	408	432	376
	P0402		487	458	447	423	464	406
	P0403		469	572	594	597	699	561
	Mean		461	489	481	476	532	448
	SD		30.8	72.3	100.0	105.1	145.8	99.3
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			PLT E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		460	511	392	402	471
	P0002		432	442	515	479	426
	P0003		222	197	172	172(1)	201
	Mean		371	383	360	351	366
	SD		130.1	165.0	173.8	159.7	144.7
	N		3	3	3	3	3
5/M	P0401		492(1)	437	498	474	422
	P0402		431	512	429	389	478
	P0403		550	579	511	522(1)	598(1)
	Mean		491	509	479	462	499
	SD		59.5	71.0	44.1	67.4	89.9
	N		3	3	3	3	3

(1) = Platelet Clumps

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			WBC E3/uL					
		Phase	Predose			Dosing		
Group/ Sex	Animal Number	Day	8	28	41	1	15	29
1/M	P0001		13.53	11.42	8.95	10.51	11.65	14.07
	P0002		12.19	11.69	14.04	11.25	9.13	8.56
	P0003		9.37	11.67	10.68	9.26	11.71	9.55
	Mean		11.70	11.59	11.22	10.34	10.83	10.73
	SD		2.123	0.150	2.588	1.006	1.473	2.937
	N		3	3	3	3	3	3
5/M	P0401		10.34	9.71	9.03	9.62	9.25	12.16
	P0402		15.23	22.52	11.12	13.96	14.24	15.94
	P0403		11.84	11.77	14.55	12.97	11.56	13.52
	Mean		12.47	14.67	11.57	12.18	11.68	13.87
	SD		2.505	6.879	2.787	2.274	2.497	1.915
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			WBC E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		19.33	17.48	10.30	10.29	11.65
	P0002		7.80	6.41	7.23	9.07	6.82
	P0003		9.51	9.10	5.85	10.48	7.08
	Mean		12.21	11.00	7.79	9.95	8.52
	SD		6.222	5.774	2.278	0.765	2.717
	N		3	3	3	3	3
5/M	P0401		11.50	12.79	8.43	9.14	7.69
	P0402		14.40	12.84	10.95	10.42	7.66
	P0403		12.50	9.79	9.42	12.26	7.23
	Mean		12.80	11.81	9.60	10.61	7.53
	SD		1.473	1.747	1.270	1.568	0.257
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			NEUT E3/uL					
		Phase	Predose			Dosing		
Group/ Sex	Animal Number	Day	8	28	41	1	15	29
1/M	P0001		8.71	6.60	3.51	6.46	6.70	5.89
	P0002		7.65	7.15	10.10	7.94	5.67	3.91
	P0003		3.12	4.94	2.80	3.94	4.42	2.46
	Mean		6.49	6.23	5.47	6.11	5.60	4.09
	SD		2.969	1.151	4.025	2.022	1.142	1.722
	N		3	3	3	3	3	3
5/M	P0401		3.29	3.49	1.76	3.82	3.54	4.54
	P0402		9.48	16.75	5.44	7.07	6.82	8.46
	P0403		5.80	6.14	5.61	4.99	3.19	3.93
	Mean		6.19	8.79	4.27	5.29	4.52	5.64
	SD		3.113	7.017	2.175	1.646	2.002	2.458
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-		GC/kg	1.024e13	1.024e13

			NEUT E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		12.18	12.20	5.08	4.06	7.26
	P0002		4.70	3.39	3.32	4.92	4.08
	P0003		3.19	4.17	2.16	1.77	2.92
	Mean		6.69	6.59	3.52	3.58	4.75
	SD		4.814	4.877	1.470	1.628	2.247
	N		3	3	3	3	3
5/M	P0401		4.58	5.10	2.21	1.66	2.67
	P0402		7.75	6.05	7.02	3.47	4.02
	P0403		4.27	2.83	2.93	3.19	3.00
	Mean		5.53	4.66	4.05	2.77	3.23
	SD		1.926	1.654	2.594	0.974	0.704
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

LYM E3/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		4.12	4.24	4.93	3.63	4.18	7.26
	P0002		4.08	4.10	3.40	2.81	2.83	3.99
	P0003		5.83	6.33	7.38	4.73	6.33	6.55
	Mean		4.68	4.89	5.24	3.72	4.45	5.93
	SD		0.999	1.249	2.008	0.963	1.765	1.720
	N		3	3	3	3	3	3
5/M	P0401		6.32	5.73	6.58	5.18	4.84	6.52
	P0402		5.32	5.29	5.23	5.96	6.35	6.09
	P0403		5.54	5.33	8.40	7.42	7.60	8.66
	Mean		5.73	5.45	6.74	6.19	6.26	7.09
	SD		0.525	0.243	1.591	1.137	1.382	1.377
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			LYM E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		6.40	4.75	4.92	5.73	4.07
	P0002		2.75	2.75	3.55	3.69	2.45
	P0003		5.87	4.66	3.52	8.18	3.93
	Mean		5.01	4.05	4.00	5.87	3.48
	SD		1.972	1.130	0.800	2.248	0.898
	N		3	3	3	3	3
5/M	P0401		6.07	6.82	5.62	7.00	4.58
	P0402		5.83	6.13	3.59	6.38	3.33
	P0403		7.46	6.45	5.95	8.52	4.01
	Mean		6.45	6.47	5.05	7.30	3.97
	SD		0.880	0.345	1.278	1.101	0.626
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

MONO E3/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		0.50	0.23	0.23	0.22	0.36	0.64
	P0002		0.31	0.29	0.38	0.32	0.32	0.40
	P0003		0.32	0.24	0.28	0.38	0.68	0.39
	Mean		0.38	0.25	0.30	0.31	0.45	0.48
	SD		0.107	0.032	0.076	0.081	0.197	0.142
	N		3	3	3	3	3	3
5/M	P0401		0.47	0.23	0.39	0.37	0.44	0.76
	P0402		0.29	0.21	0.22	0.49	0.54	0.66
	P0403		0.33	0.22	0.28	0.32	0.42	0.67
	Mean		0.36	0.22	0.30	0.39	0.47	0.70
	SD		0.095	0.010	0.086	0.087	0.064	0.055
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			MONO E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		0.42	0.41	0.17	0.33	0.21
	P0002		0.23	0.17	0.21	0.36	0.22
	P0003		0.28	0.21	0.12	0.29	0.17
	Mean		0.31	0.26	0.17	0.33	0.20
	SD		0.098	0.129	0.045	0.035	0.026
	N		3	3	3	3	3
5/M	P0401		0.60	0.63	0.35	0.31	0.29
	P0402		0.45	0.43	0.20	0.37	0.18
	P0403		0.50	0.36	0.33	0.34	0.15
	Mean		0.52	0.47	0.29	0.34	0.21
	SD		0.076	0.140	0.081	0.030	0.074
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			EOS E3/uL				
		Phase	Predose			Dosing	
Group/ Sex	Animal Number	Day	8	28	41	1	15	29
1/M	P0001		0.03	0.18	0.12	0.07	0.34	0.06
	P0002		0.02	0.02	0.03	0.04	0.22	0.16
	P0003		0.03	0.06	0.08	0.05	0.18	0.05
	Mean		0.03	0.09	0.08	0.05	0.25	0.09
	SD		0.006	0.083	0.045	0.015	0.083	0.061
	N		3	3	3	3	3	3
5/M	P0401		0.07	0.10	0.13	0.14	0.33	0.23
	P0402		0.02	0.04	0.12	0.27	0.38	0.62
	P0403		0.04	0.01	0.05	0.07	0.22	0.14
	Mean		0.04	0.05	0.10	0.16	0.31	0.33
	SD		0.025	0.046	0.044	0.101	0.082	0.255
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			EOS E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		0.04	0.02	0.03	0.04	0.03
	P0002		0.00	0.02	0.04	0.03	0.01
	P0003		0.02	0.01	0.00	0.13	0.01
	Mean		0.02	0.02	0.02	0.07	0.02
	SD		0.020	0.006	0.021	0.055	0.012
	N		3	3	3	3	3
5/M	P0401		0.09	0.06	0.08	0.05	0.03
	P0402		0.23	0.11	0.04	0.08	0.02
	P0403		0.12	0.05	0.06	0.05	0.01
	Mean		0.15	0.07	0.06	0.06	0.02
	SD		0.074	0.032	0.020	0.017	0.010
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

BASO E3/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		0.07	0.07	0.07	0.06	0.02	0.12
	P0002		0.05	0.05	0.06	0.06	0.02	0.03
	P0003		0.04	0.06	0.10	0.07	0.03	0.03
	Mean		0.05	0.06	0.08	0.06	0.02	0.06
	SD		0.015	0.010	0.021	0.006	0.006	0.052
	N		3	3	3	3	3	3
5/M	P0401		0.09	0.07	0.10	0.05	0.04	0.04
	P0402		0.07	0.13	0.06	0.09	0.05	0.06
	P0403		0.05	0.03	0.13	0.09	0.04	0.05
	Mean		0.07	0.08	0.10	0.08	0.04	0.05
	SD		0.020	0.050	0.035	0.023	0.006	0.010
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology
Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

			BASO E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		0.17	0.04	0.07	0.06	0.03
	P0002		0.04	0.02	0.05	0.03	0.02
	P0003		0.07	0.03	0.03	0.04	0.02
	Mean		0.09	0.03	0.05	0.04	0.02
	SD		0.068	0.010	0.020	0.015	0.006
	N		3	3	3	3	3
5/M	P0401		0.08	0.06	0.09	0.04	0.04
	P0402		0.08	0.03	0.05	0.07	0.03
	P0403		0.08	0.03	0.07	0.06	0.01
	Mean		0.08	0.04	0.07	0.06	0.03
	SD		0.000	0.017	0.020	0.015	0.015
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article (dosage) 1M 5M
VECTOR A and VECTOR B- GC/kg 1.024e13 1.024e13

LUC E3/uL

Group/ Sex	Animal Number	Phase	Predose			Dosing		
		Day	8	28	41	1	15	29
1/M	P0001		0.09	0.10	0.08	0.06	0.05	0.10
	P0002		0.07	0.08	0.07	0.07	0.06	0.06
	P0003		0.04	0.05	0.05	0.08	0.07	0.07
	Mean		0.07	0.08	0.07	0.07	0.06	0.08
	SD		0.025	0.025	0.015	0.010	0.010	0.021
	N		3	3	3	3	3	3
5/M	P0401		0.10	0.10	0.08	0.06	0.05	0.07
	P0402		0.05	0.11	0.06	0.08	0.10	0.06
	P0403		0.09	0.04	0.08	0.09	0.08	0.07
	Mean		0.08	0.08	0.07	0.08	0.08	0.07
	SD		0.026	0.038	0.012	0.015	0.025	0.006
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B-		GC/kg	1.024e13	1.024e13

			LUC E3/uL				
		Phase	Dosing				
Group/ Sex	Animal Number	Day	57	85	113	141	169
1/M	P0001		0.11	0.06	0.03	0.07	0.05
	P0002		0.06	0.06	0.06	0.05	0.05
	P0003		0.08	0.04	0.02	0.06	0.04
	Mean		0.08	0.05	0.04	0.06	0.05
	SD		0.025	0.012	0.021	0.010	0.006
	N		3	3	3	3	3
5/M	P0401		0.09	0.12	0.08	0.08	0.07
	P0402		0.07	0.08	0.05	0.06	0.06
	P0403		0.06	0.06	0.07	0.09	0.05
	Mean		0.07	0.09	0.07	0.08	0.06
	SD		0.015	0.031	0.015	0.015	0.010
	N		3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

PT sec

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		10.2	9.1	9.9	9.6	8.7	9.7
	P0002		9.9	10.1	9.8	9.7	9.5	9.8
	P0003		9.2	9.5	9.3	9.1	9.3	9.5
	Mean		9.8	9.6	9.7	9.5	9.2	9.7
	SD		0.51	0.50	0.32	0.32	0.42	0.15
	N		3	3	3	3	3	3
5/M	P0401		10.8	10.7	10.5	10.1	10.4	10.2
	P0402		9.8	9.9	8.8(2)	8.8	8.9	8.8
	P0403		9.4	10.0	9.0	9.4	9.3	9.2
	Mean		10.0	10.2	9.4	9.4	9.5	9.4
	SD		0.72	0.44	0.93	0.65	0.78	0.72
	N		3	3	3	3	3	3

(2) = Slightly Hemolyzed

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

PT sec

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		9.3	9.5	10.1	9.9	9.8	10.1
	P0002		9.7	9.9	10.1	10.2	9.6	10.4
	P0003		9.6	9.4	9.6	9.7	9.4	10.2
	Mean		9.5	9.6	9.9	9.9	9.6	10.2
	SD		0.21	0.26	0.29	0.25	0.20	0.15
	N		3	3	3	3	3	3
5/M	P0401		10.0	9.9	10.2	10.0	10.5	10.8
	P0402		8.8	9.0	9.2	9.5	9.5	9.9
	P0403		9.3	9.2	9.7	9.7	9.3	9.6
	Mean		9.4	9.4	9.7	9.7	9.8	10.1
	SD		0.60	0.47	0.50	0.25	0.64	0.62
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

APTT sec

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		23.6	22.9	22.7	21.9	20.5	21.3
	P0002		22.0	21.8	21.8	19.5	21.3	21.4
	P0003		21.1	21.0	19.6	20.2	21.0	20.2
	Mean		22.2	21.9	21.4	20.5	20.9	21.0
	SD		1.27	0.95	1.59	1.23	0.40	0.67
	N		3	3	3	3	3	3
5/M	P0401		21.8	22.4	21.7	18.7	20.7	18.3
	P0402		19.7	20.0	16.4(2)	18.3	18.1	17.9
	P0403		20.1	20.5	19.4	19.8	19.0	19.4
	Mean		20.5	21.0	19.2	18.9	19.3	18.5
	SD		1.12	1.27	2.66	0.78	1.32	0.78
	N		3	3	3	3	3	3

(2) = Slightly Hemolyzed

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

APTT sec

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		21.4	22.0	22.5	23.6	22.4	21.5
	P0002		22.0	21.5	22.3	22.5	22.3	22.3
	P0003		20.4	19.8	20.6	20.5	19.7	19.9
	Mean		21.3	21.1	21.8	22.2	21.5	21.2
	SD		0.81	1.15	1.04	1.57	1.53	1.22
	N		3	3	3	3	3	3
5/M	P0401		22.1	24.7	27.6	26.2	23.4	22.4
	P0402		16.9	16.9	19.4	22.1	20.2	20.5
	P0403		19.4	18.3	19.3	20.2	21.5	21.1
	Mean		19.5	20.0	22.1	22.8	21.7	21.3
	SD		2.60	4.16	4.76	3.07	1.61	0.97
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

FIB mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		249	236	238	236	285	267
	P0002		202	176	209	209	202	176
	P0003		211	198	249	198	184	183
	Mean		221	203	232	214	224	209
	SD		24.9	30.4	20.7	19.6	53.9	50.6
	N		3	3	3	3	3	3
5/M	P0401		257	256	304	302	354	303
	P0402		240	209	245(2)	276	246	225
	P0403		229	227	282	259	299	240
	Mean		242	231	277	279	300	256
	SD		14.1	23.7	29.8	21.7	54.0	41.4
	N		3	3	3	3	3	3

(2) = Slightly Hemolyzed

VECTORSTUDYU1

Table
Individual Hematology

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			FIB mg/dL					
		Phase	Dosing					
Group/ Sex	Animal Number	Day	57	71	85	113	141	169
1/M	P0001		259	287	320	205	174	256
	P0002		186	187	188	171	175	198
	P0003		190	182	174	168	166	195
	Mean		212	219	227	181	172	216
	SD		41.0	59.2	80.6	20.6	4.9	34.4
	N		3	3	3	3	3	3
5/M	P0401		303	291	337	259	249	273
	P0402		265	238	251	198	176	227
	P0403		265	287	292	231	225	232
	Mean		278	272	293	229	217	244
	SD		21.9	29.5	43.0	30.5	37.2	25.2
	N		3	3	3	3	3	3

Table 6.2: Individual Clinical Chemistry

VECTORSTUDYU1

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

			GLU mg/dL					
		Phase	Predose		Dosing			
Group/ Sex	Animal Number	Day	8	28	1	15	29	43
1/M	P0001		86	73	55	113	85	96
	P0002		65	52	47	60	66	82
	P0003		82	52	69	95	59	85
	Mean		78	59	57	89	70	88
	SD		11.2	12.1	11.1	27.0	13.5	7.4
	N		3	3	3	3	3	3
5/M	P0401		94	80	95	108	100	110
	P0402		78	54	73	78	75	85
	P0403		73	49	84	87	85	82
	Mean		82	61	84	91	87	92
	SD		11.0	16.6	11.0	15.4	12.6	15.4
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

GLU mg/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		48	72	73	62	68	59
	P0002		67	76	50	63	84	63
	P0003		62	73	55	49	83	48
	Mean		59	74	59	58	78	57
	SD		9.8	2.1	12.1	7.8	9.0	7.8
	N		3	3	3	3	3	3
5/M	P0401		90	106	98	85	104	74
	P0402		59	75	63	69	82	77
	P0403		103	81	75	85	91	84
	Mean		84	87	79	80	92	78
	SD		22.6	16.4	17.8	9.2	11.1	5.1
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

UN mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		34	18	19	19	20	22
	P0002		22	20	21	20	19	19
	P0003		19	21	22	22	26	24
	Mean		25	20	21	20	22	22
	SD		7.9	1.5	1.5	1.5	3.8	2.5
	N		3	3	3	3	3	3
5/M	P0401		23	20	22	21	18	23
	P0402		19	22	18	19	18	19
	P0403		17	18	17	17	16	16
	Mean		20	20	19	19	17	19
	SD		3.1	2.0	2.6	2.0	1.2	3.5
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

UN mg/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		22	19	23	18	13	21
	P0002		20	21	23	19	19	21
	P0003		23	22	25	27	19	22
	Mean		22	21	24	21	17	21
	SD		1.5	1.5	1.2	4.9	3.5	0.6
	N		3	3	3	3	3	3
5/M	P0401		22	23	18	18	22	25
	P0402		18	19	17	17	17	21
	P0403		14	15	15	14	16	18
	Mean		18	19	17	16	18	21
	SD		4.0	4.0	1.5	2.1	3.2	3.5
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

CREAT mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		1.1	0.5	0.7	0.7	0.7	0.8
	P0002		0.6	0.7	0.7	0.6	0.5	0.6
	P0003		0.7	0.7	0.7	0.7	0.7	0.6
	Mean		0.8	0.6	0.7	0.7	0.6	0.7
	SD		0.26	0.12	0.00	0.06	0.12	0.12
	N		3	3	3	3	3	3
5/M	P0401		0.7	0.7	0.9	0.8	0.7	0.6
	P0402		0.5	0.6	0.6	0.5	0.6	0.6
	P0403		0.7	0.8	0.8	0.8	0.8	0.7
	Mean		0.6	0.7	0.8	0.7	0.7	0.6
	SD		0.12	0.10	0.15	0.17	0.10	0.06
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

CREAT mg/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		0.7	0.7	0.8	0.7	0.8	0.8
	P0002		0.7	0.7	0.7	0.7	0.6	0.7
	P0003		0.6	0.6	0.7	0.7	0.7	0.6
	Mean		0.7	0.7	0.7	0.7	0.7	0.7
	SD		0.06	0.06	0.06	0.00	0.10	0.10
	N		3	3	3	3	3	3
5/M	P0401		0.6	0.6	0.8	0.8	0.8	0.7
	P0402		0.5	0.6	0.8	0.6	0.7	0.6
	P0403		0.7	0.7	0.8	0.8	0.8	0.7
	Mean		0.6	0.6	0.8	0.7	0.8	0.7
	SD		0.10	0.06	0.00	0.12	0.06	0.06
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

			TP g/dL					
		Phase	Predose		Dosing			
Group/ Sex	Animal Number	Day	8	28	1	15	29	43
1/M	P0001		9.4	7.2	7.6	7.9	7.4	8.0
	P0002		7.3	7.2	7.6	7.7	7.2	7.7
	P0003		8.2	8.1	7.7	8.0	7.6	8.0
	Mean		8.3	7.5	7.6	7.9	7.4	7.9
	SD		1.05	0.52	0.06	0.15	0.20	0.17
	N		3	3	3	3	3	3
5/M	P0401		8.9	7.9	8.6	8.6	7.9	8.1
	P0402		7.9	7.6	7.6	7.8	7.6	7.9
	P0403		7.2	6.9	7.2	7.3	6.9	7.2
	Mean		8.0	7.5	7.8	7.9	7.5	7.7
	SD		0.85	0.51	0.72	0.66	0.51	0.47
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13

TP g/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		7.3	7.3	7.2	7.6	6.9	7.1
	P0002		7.5	7.8	7.6	7.7	7.8	7.5
	P0003		7.7	7.9	7.7	7.9	7.2	7.2
	Mean		7.5	7.7	7.5	7.7	7.3	7.3
	SD		0.20	0.32	0.26	0.15	0.46	0.21
	N		3	3	3	3	3	3
5/M	P0401		8.0	8.3	8.5	8.2	7.6	7.5
	P0402		7.5	7.8	8.1	7.4	7.1	7.6
	P0403		7.0	7.6	7.7	7.5	7.0	6.8
	Mean		7.5	7.9	8.1	7.7	7.2	7.3
	SD		0.50	0.36	0.40	0.44	0.32	0.44
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

ALB g/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		5.7	4.3	4.6	4.7	4.3	4.4
	P0002		4.8	4.9	5.2	5.3	5.2	5.3
	P0003		5.1	5.1	4.9	5.1	5.0	5.2
	Mean		5.2	4.8	4.9	5.0	4.8	5.0
	SD		0.46	0.42	0.30	0.31	0.47	0.49
	N		3	3	3	3	3	3
5/M	P0401		5.7	5.1	5.8	5.6	5.4	5.2
	P0402		5.1	4.9	5.1	5.1	5.2	5.2
	P0403		4.8	4.6	4.8	5.0	4.8	4.8
	Mean		5.2	4.9	5.2	5.2	5.1	5.1
	SD		0.46	0.25	0.51	0.32	0.31	0.23
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

ALB g/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		4.2	4.0	4.1	4.3	4.4	4.3
	P0002		5.2	5.0	5.0	4.9	5.3	5.0
	P0003		4.9	4.9	4.8	5.2	4.7	4.7
	Mean		4.8	4.6	4.6	4.8	4.8	4.7
	SD		0.51	0.55	0.47	0.46	0.46	0.35
	N		3	3	3	3	3	3
5/M	P0401		5.1	5.0	5.1	5.0	5.1	4.9
	P0402		4.8	4.8	5.1	4.6	4.7	5.1
	P0403		4.6	4.7	4.9	4.9	4.8	4.6
	Mean		4.8	4.8	5.0	4.8	4.9	4.9
	SD		0.25	0.15	0.12	0.21	0.21	0.25
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

GLOB g/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		3.7	2.9	3.0	3.2	3.1	3.6
	P0002		2.5	2.3	2.4	2.4	2.0	2.4
	P0003		3.1	3.0	2.8	2.9	2.6	2.8
	Mean		3.1	2.7	2.7	2.8	2.6	2.9
	SD		0.60	0.38	0.31	0.40	0.55	0.61
	N		3	3	3	3	3	3
5/M	P0401		3.2	2.8	2.8	3.0	2.5	2.9
	P0402		2.8	2.7	2.5	2.7	2.4	2.7
	P0403		2.4	2.3	2.4	2.3	2.1	2.4
	Mean		2.8	2.6	2.6	2.7	2.3	2.7
	SD		0.40	0.26	0.21	0.35	0.21	0.25
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

			GLOB g/dL					
		Phase	Dosing					
Group/ Sex	Animal Number	Day	57	71	85	113	141	169
1/M	P0001		3.1	3.3	3.1	3.3	2.5	2.8
	P0002		2.3	2.8	2.6	2.8	2.5	2.5
	P0003		2.8	3.0	2.9	2.7	2.5	2.5
	Mean		2.7	3.0	2.9	2.9	2.5	2.6
	SD		0.40	0.25	0.25	0.32	0.00	0.17
	N		3	3	3	3	3	3
5/M	P0401		2.9	3.3	3.4	3.2	2.5	2.6
	P0402		2.7	3.0	3.0	2.8	2.4	2.5
	P0403		2.4	2.9	2.8	2.6	2.2	2.2
	Mean		2.7	3.1	3.1	2.9	2.4	2.4
	SD		0.25	0.21	0.31	0.31	0.15	0.21
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

A:G Ratio

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		1.5	1.5	1.5	1.5	1.4	1.2
	P0002		1.9	2.1	2.2	2.2	2.6	2.2
	P0003		1.6	1.7	1.8	1.8	1.9	1.9
	Mean		1.7	1.8	1.8	1.8	2.0	1.8
	SD		0.21	0.31	0.35	0.35	0.60	0.51
	N		3	3	3	3	3	3
5/M	P0401		1.8	1.8	2.1	1.9	2.2	1.8
	P0402		1.8	1.8	2.0	1.9	2.2	1.9
	P0403		2.0	2.0	2.0	2.2	2.3	2.0
	Mean		1.9	1.9	2.0	2.0	2.2	1.9
	SD		0.12	0.12	0.06	0.17	0.06	0.10
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

A:G Ratio

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		1.4	1.2	1.3	1.3	1.8	1.5
	P0002		2.3	1.8	1.9	1.8	2.1	2.0
	P0003		1.8	1.6	1.7	1.9	1.9	1.9
	Mean		1.8	1.5	1.6	1.7	1.9	1.8
	SD		0.45	0.31	0.31	0.32	0.15	0.26
	N		3	3	3	3	3	3
5/M	P0401		1.8	1.5	1.5	1.6	2.0	1.9
	P0402		1.8	1.6	1.7	1.6	2.0	2.0
	P0403		1.9	1.6	1.8	1.9	2.2	2.1
	Mean		1.8	1.6	1.7	1.7	2.1	2.0
	SD		0.06	0.06	0.15	0.17	0.12	0.10
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13	1.024e13	1.024e13	1.024e13

			CHOL mg/dL					
		Phase	Predose		Dosing			
Group/ Sex	Animal Number	Day	8	28	1	15	29	43
1/M	P0001		181	114	142	197	162	209
	P0002		82	84	80	96	84	88
	P0003		151	143	138	220	223	191
	Mean		138	114	120	171	156	163
	SD		50.8	29.5	34.7	66.0	69.7	65.3
	N		3	3	3	3	3	3
5/M	P0401		128	129	122	145	116	111
	P0402		116	108	101	119	112	115
	P0403		167	158	142	155	140	144
	Mean		137	132	122	140	123	123
	SD		26.7	25.1	20.5	18.6	15.1	18.0
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B		GC/kg	1.024e13	1.024e13	1.024e13	1.024e13	1.024e13

			CHOL mg/dL					
		Phase	Dosing					
Group/ Sex	Animal Number	Day	57	71	85	113	141	169
1/M	P0001		147	134	150	117	101	126
	P0002		87	87	97	85	89	96
	P0003		176	163	171	188	144	160
	Mean		137	128	139	130	111	127
	SD		45.4	38.4	38.1	52.7	28.9	32.0
	N		3	3	3	3	3	3
5/M	P0401		122	125	136	124	121	130
	P0402		99	100	117	101	98	135
	P0403		153	139	160	165	146	169
	Mean		125	121	138	130	122	145
	SD		27.1	19.8	21.5	32.4	24.0	21.2
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

TRIG mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		43	25	46	54	42	96
	P0002		16	22	22	35	28	16
	P0003		24	32	39	24	32	26
	Mean		28	26	36	38	34	46
	SD		13.9	5.1	12.3	15.2	7.2	43.6
	N		3	3	3	3	3	3
5/M	P0401		24	32	24	28	31	115
	P0402		30	35	33	50	59	61
	P0403		33	41	52	66	43	57
	Mean		29	36	36	48	44	78
	SD		4.6	4.6	14.3	19.1	14.0	32.4
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

TRIG mg/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		65	49	67	72	51	67
	P0002		17	18	41	26	19	45
	P0003		26	21	40	46	31	56
	Mean		36	29	49	48	34	56
	SD		25.5	17.1	15.3	23.1	16.2	11.0
	N		3	3	3	3	3	3
5/M	P0401		51	67	40	44	36	64
	P0402		65	78	68	57	45	51
	P0403		52	45	74	65	61	82
	Mean		56	63	61	55	47	66
	SD		7.8	16.8	18.1	10.6	12.7	15.6
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

TBIL mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		0.3	<0.1#	0.2	<0.1#	<0.1#	<0.1#
	P0002		0.2	0.3	0.2	0.4	0.3	<0.1#
	P0003		0.2	0.2	0.3	0.2	0.2	<0.1#
	Mean		0.2	<0.2	0.2	<0.2	<0.2	<0.1
	SD		0.06	0.10	0.08	0.13	0.10	0.00
	N		3	3	3	3	3	3
5/M	P0401		0.2	<0.1#	<0.1#	<0.1#	<0.1#	<0.1#
	P0402		0.2	0.2	0.2	0.2	0.1	<0.1#
	P0403		0.3	0.2	0.1	0.2	<0.1#	<0.1#
	Mean		0.2	<0.1	<0.1	<0.1	<0.1	<0.1
	SD		0.05	0.04	0.03	0.03	0.02	0.00
	N		3	3	3	3	3	3

= Value shown used in descriptive statistics

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

			TBIL mg/dL					
		Phase	Dosing					
Group/ Sex	Animal Number	Day	57	71	85	113	141	169
1/M	P0001		<0.1#	0.2	0.2	0.2	0.2	0.3
	P0002		0.2	0.2	0.5	0.3	0.1	0.4
	P0003		0.1	<0.1#	0.3	0.2	0.1	0.3
	Mean		<0.1	<0.1	0.3	0.2	0.1	0.3
	SD		0.03	0.04	0.17	0.05	0.01	0.07
	N		3	3	3	3	3	3
5/M	P0401		<0.1#	<0.1#	<0.1#	0.1	0.1	0.2
	P0402		<0.1#	0.1	0.3	0.2	0.1	0.3
	P0403		<0.1#	<0.1#	0.2	0.2	<0.1#	0.2
	Mean		<0.1	<0.1	<0.2	0.2	<0.1	0.3
	SD		0.00	0.01	0.08	0.06	0.02	0.09
	N		3	3	3	3	3	3

= Value shown used in descriptive statistics

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

AST U/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		58	35	36	25	34	23
	P0002		33	32	34	43	35	29
	P0003		34	31	39	22	33	18
	Mean		42	33	36	30	34	23
	SD		14.2	2.1	2.5	11.4	1.0	5.5
	N		3	3	3	3	3	3
5/M	P0401		46	53	31	41	27	30
	P0402		28	38	26	30	25	23
	P0403		38	40	32	28	26	31
	Mean		37	44	30	33	26	28
	SD		9.0	8.1	3.2	7.0	1.0	4.4
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

AST U/L

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		32	28	22	35	42	34
	P0002		30	33	37	33	35	35
	P0003		24	20	22	29	25	23
	Mean		29	27	27	32	34	31
	SD		4.2	6.6	8.7	3.1	8.5	6.7
	N		3	3	3	3	3	3
5/M	P0401		46	42	33	44	53	40
	P0402		27	24	24	31	30	26
	P0403		30	24	30	29	28	28
	Mean		34	30	29	35	37	31
	SD		10.2	10.4	4.6	8.1	13.9	7.6
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

ALT U/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		67	50	38	42	45	31
	P0002		41	41	53	88	72	40
	P0003		57	27	29	29	31	24
	Mean		55	39	40	53	49	32
	SD		13.1	11.6	12.1	31.0	20.8	8.0
	N		3	3	3	3	3	3
5/M	P0401		43	57	51	52	43	35
	P0402		31	31	32	28	28	22
	P0403		64	39	37	32	40	32
	Mean		46	42	40	37	37	30
	SD		16.7	13.3	9.8	12.9	7.9	6.8
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
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			ALT U/L					
		Phase	Dosing					
Group/ Sex	Animal Number	Day	57	71	85	113	141	169
1/M	P0001		34	30	23	42	33	40
	P0002		36	41	49	41	43	39
	P0003		25	26	23	31	28	27
	Mean		32	32	32	38	35	35
	SD		5.9	7.8	15.0	6.1	7.6	7.2
	N		3	3	3	3	3	3
5/M	P0401		42	42	48	43	48	41
	P0402		25	24	22	26	27	26
	P0403		30	38	31	31	27	29
	Mean		32	35	34	33	34	32
	SD		8.7	9.5	13.2	8.7	12.1	7.9
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13

ALP U/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		403	299	475	390	373	380
	P0002		290	275	432	409	433	395
	P0003		305	250	294	261	282	288
	Mean		333	275	400	353	363	354
	SD		61.4	24.5	94.6	80.5	76.0	57.9
	N		3	3	3	3	3	3
5/M	P0401		627	564	691	456	371	345
	P0402		534	464	572	381	340	311
	P0403		313	283	248	222	199	175
	Mean		491	437	504	353	303	277
	SD		161.3	142.4	229.3	119.5	91.7	90.0
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

ALP U/L

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		369	362	305	282	441	453
	P0002		331	343	357	336	428	502
	P0003		265	264	276	276	328	339
	Mean		322	323	313	298	399	431
	SD		52.6	52.0	41.0	33.0	61.8	83.6
	N		3	3	3	3	3	3
5/M	P0401		283	274	276	430	685	770
	P0402		331	284	245	366	604	590
	P0403		153	158	151	193	349	403
	Mean		256	239	224	330	546	588
	SD		92.1	70.0	65.1	122.6	175.3	183.5
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

GGT U/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		63	54	61	65	52	57
	P0002		73	74	74	82	90	80
	P0003		55	49	45	50	55	55
	Mean		64	59	60	65	66	64
	SD		9.3	13.2	14.2	16.1	21.4	13.9
	N		3	3	3	3	3	3
5/M	P0401		83	66	61	51	45	45
	P0402		50	50	45	41	41	42
	P0403		49	43	36	36	34	32
	Mean		60	53	47	43	40	40
	SD		19.4	12.0	12.8	7.8	5.7	6.8
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

GGT U/L

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		54	50	44	53	80	73
	P0002		75	78	79	74	94	94
	P0003		58	53	55	58	59	60
	Mean		62	60	59	62	78	76
	SD		11.2	15.2	17.9	11.1	17.8	16.8
	N		3	3	3	3	3	3
5/M	P0401		47	46	48	58	82	88
	P0402		42	40	40	43	64	65
	P0403		32	31	35	40	50	56
	Mean		40	39	41	47	65	70
	SD		7.6	7.2	6.6	9.7	15.8	16.4
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

CK U/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		242	138	132	125	283	128
	P0002		126	109	109	127	123	106
	P0003		140	135	123	115	109	107
	Mean		169	127	121	122	172	114
	SD		63.3	15.9	11.6	6.4	96.7	12.4
	N		3	3	3	3	3	3
5/M	P0401		304	447	295	261	189	137
	P0402		183	159	120	125	128	132
	P0403		171	243	234	101	99	425
	Mean		219	283	216	162	139	231
	SD		73.6	148.1	88.8	86.3	45.9	167.7
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

CK U/L

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		105	479	101	141	169	198
	P0002		91	171	107	108	156	274
	P0003		110	114	112	114	144	116
	Mean		102	255	107	121	156	196
	SD		9.8	196.4	5.5	17.6	12.5	79.0
	N		3	3	3	3	3	3
5/M	P0401		614	139	430	172	258	533
	P0402		87	108	163	136	150	240
	P0403		226	118	110	227	156	153
	Mean		309	122	234	178	188	309
	SD		273.1	15.8	171.5	45.8	60.7	199.1
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

Ca mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		11.6	9.9	9.5	10.1	9.9	11.0
	P0002		10.2	10.0	10.0	9.9	9.6	10.6
	P0003		10.8	10.3	9.6	10.1	9.8	10.7
	Mean		10.9	10.1	9.7	10.0	9.8	10.8
	SD		0.70	0.21	0.26	0.12	0.15	0.21
	N		3	3	3	3	3	3
5/M	P0401		11.3	10.3	11.1	10.3	10.3	11.0
	P0402		10.9	10.4	10.8	10.2	10.5	11.3
	P0403		10.7	10.1	10.8	10.8	10.3	11.1
	Mean		11.0	10.3	10.9	10.4	10.4	11.1
	SD		0.31	0.15	0.17	0.32	0.12	0.15
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

Ca mg/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		9.9	10.2	10.3	10.0	10.0	9.5
	P0002		9.9	10.2	9.8	10.0	10.5	9.6
	P0003		10.0	10.7	10.2	10.0	10.2	9.9
	Mean		9.9	10.4	10.1	10.0	10.2	9.7
	SD		0.06	0.29	0.26	0.00	0.25	0.21
	N		3	3	3	3	3	3
5/M	P0401		10.3	10.7	10.8	10.5	10.3	10.3
	P0402		10.7	10.8	10.9	10.2	10.7	10.5
	P0403		9.9	11.0	11.0	10.9	11.2	10.6
	Mean		10.3	10.8	10.9	10.5	10.7	10.5
	SD		0.40	0.15	0.10	0.35	0.45	0.15
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

PHOS mg/dL

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		8.9	5.8	6.1	5.6	5.1	6.3
	P0002		5.8	6.5	4.1	6.9	5.2	4.7
	P0003		7.6	6.8	6.4	7.5	7.2	5.7
	Mean		7.4	6.4	5.5	6.7	5.8	5.6
	SD		1.56	0.51	1.25	0.97	1.18	0.81
	N		3	3	3	3	3	3
5/M	P0401		7.3	6.7	5.5	5.7	4.1	2.7
	P0402		6.7	6.6	4.7	6.0	3.8	3.6
	P0403		6.7	6.9	6.5	6.9	5.1	3.6
	Mean		6.9	6.7	5.6	6.2	4.3	3.3
	SD		0.35	0.15	0.90	0.62	0.68	0.52
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

PHOS mg/dL

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		6.2	6.2	5.6	5.4	5.3	7.8
	P0002		4.8	5.4	8.3	5.5	5.1	8.0
	P0003		6.6	7.0	6.8	6.3	5.9	6.9
	Mean		5.9	6.2	6.9	5.7	5.4	7.6
	SD		0.95	0.80	1.35	0.49	0.42	0.59
	N		3	3	3	3	3	3
5/M	P0401		4.5	4.5	5.7	6.0	6.1	8.2
	P0402		4.3	3.9	4.6	6.1	5.6	7.2
	P0403		4.8	4.2	7.0	6.1	5.7	6.8
	Mean		4.5	4.2	5.8	6.1	5.8	7.4
	SD		0.25	0.30	1.20	0.06	0.26	0.72
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

Na mmol/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		141	151	148	146	148	147
	P0002		150	151	148	146	148	148
	P0003		155	154	152	155	151	152
	Mean		149	152	149	149	149	149
	SD		7.1	1.7	2.3	5.2	1.7	2.6
	N		3	3	3	3	3	3
5/M	P0401		158	151	152	149	149	146
	P0402		155	149	148	147	147	150
	P0403		155	152	153	153	153	152
	Mean		156	151	151	150	150	149
	SD		1.7	1.5	2.6	3.1	3.1	3.1
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
		---	--	--	---	---	--

			Na mmol/L					
		Phase	Dosing					
Group/ Sex	Animal Number	Day	57	71	85	113	141	169
1/M	P0001		149	148	142	147	146	144
	P0002		148	145	146	146	147	147
	P0003		156	156	150	151	151	150
	Mean		151	150	146	148	148	147
	SD		4.4	5.7	4.0	2.6	2.6	3.0
	N		3	3	3	3	3	3
5/M	P0401		147	147	147	147	146	147
	P0402		148	148	146	143	150	145
	P0403		153	153	152	154	155	149
	Mean		149	149	148	148	150	147
	SD		3.2	3.2	3.2	5.6	4.5	2.0
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

K mmol/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		5.4	5.2	3.7	4.4	5.0	5.6
	P0002		4.5	4.7	4.1	4.9	3.9	4.1
	P0003		5.4	4.8	3.6	4.7	4.2	4.3
	Mean		5.1	4.9	3.8	4.7	4.4	4.7
	SD		0.52	0.26	0.26	0.25	0.57	0.81
	N		3	3	3	3	3	3
5/M	P0401		5.0	4.3	4.4	4.3	4.3	3.6
	P0402		4.9	4.7	4.7	4.5	4.7	5.1
	P0403		5.4	4.9	5.4	5.5	5.2	5.5
	Mean		5.1	4.6	4.8	4.8	4.7	4.7
	SD		0.26	0.31	0.51	0.64	0.45	1.00
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

K mmol/L

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		5.3	4.8	5.3	4.7	5.3	5.0
	P0002		4.3	4.2	4.5	4.3	4.2	4.3
	P0003		4.4	4.8	4.0	4.1	4.6	4.1
	Mean		4.7	4.6	4.6	4.4	4.7	4.5
	SD		0.55	0.35	0.66	0.31	0.56	0.47
	N		3	3	3	3	3	3
5/M	P0401		4.2	3.7	4.0	4.3	4.2	4.2
	P0402		5.5	4.8	4.8	4.6	5.1	4.6
	P0403		5.7	5.1	5.5	5.4	6.3	5.5
	Mean		5.1	4.5	4.8	4.8	5.2	4.8
	SD		0.81	0.74	0.75	0.57	1.05	0.67
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry
Test Article (dosage) 1M 5M

VECTOR A and VECTOR B GC/kg 1.024e13 1.024e13

Cl mmol/L

Group/ Sex	Animal Number	Phase	Predose		Dosing			
		Day	8	28	1	15	29	43
1/M	P0001		95	105	101	107	103	104
	P0002		105	105	104	105	108	104
	P0003		102	103	107	110	107	108
	Mean		101	104	104	107	106	105
	SD		5.1	1.2	3.0	2.5	2.6	2.3
	N		3	3	3	3	3	3
5/M	P0401		102	100	99	102	104	100
	P0402		103	101	102	102	103	102
	P0403		105	104	104	105	104	104
	Mean		103	102	102	103	104	102
	SD		1.5	2.1	2.5	1.7	0.6	2.0
	N		3	3	3	3	3	3

VECTORSTUDYU1

Table
Individual Clinical Chemistry

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
			--	--			

Cl mmol/L

Group/ Sex	Animal Number	Phase Day	Dosing 57	71	85	113	141	169
1/M	P0001		102	103	100	102	105	99
	P0002		107	104	105	104	104	106
	P0003		112	113	107	110	110	108
	Mean		107	107	104	105	106	104
	SD		5.0	5.5	3.6	4.2	3.2	4.7
	N		3	3	3	3	3	3
5/M	P0401		103	101	99	102	100	101
	P0402		107	104	104	102	104	102
	P0403		110	107	104	108	106	108
	Mean		107	104	102	104	103	104
	SD		3.5	3.0	2.9	3.5	3.1	3.8
	N		3	3	3	3	3	3

9.9 Anatomic Pathology Report

Draft Anatomic Pathology Report

Study Title	24 Week Toxicity Study of Vector A and Vector B Following a Single Intravenous Injection in Adult Cynomolgus Macaques
TESTING FACILITY Study Number	VECTORSTUDYU1

TABLE OF CONTENTS

1. SUMMARY

This report describes anatomic pathology findings for TESTING FACILITY Study VECTORSTUDYU1. The purpose of this study was to evaluate the efficacy and tolerability of VECTOR A and VECTOR B when administered as a single dose via intravenous (IV) injection to cynomolgus monkeys.

Minimal microscopic findings in the kidney and colon were noted in VECTOR A and VECTOR B treated animals, kidney effects consisted of minimal tubule basophilia. Effects in the colon consisted of minimal mononuclear cell infiltrates in the mucosa.

All microscopic findings were considered spontaneous and/or incidental because they occurred at a low incidence, were randomly distributed across groups (including concurrent controls), and/or their severity was as expected for cynomolgus monkeys of this age; therefore, they were considered not test article related.

2. METHODS

Cynomolgus monkeys were administered VECTOR A and VECTOR B by an single intravenous injection via a saphenous vein on Day 1, as indicated in the following table.

Group Designation and Dose Levels - Test Article

Group[a,b]	No. of Animals Males	Dose Level (GC/kg)	Dose Concentration (GC/mL)
1 (VECTOR A)	3	$1.024x10^{13}$	$1.28x10^{13}$
5 (VECTOR B)	3	$1.024x10^{13}$	$1.28x10^{13}$

GC = Genome copies.
a All groups were administered test article via intravenous (bolus) injection on Day 1.
b Animals were dosed at a volume of 0.8 mL/kg.

At necropsy, macroscopic examinations were conducted. Protocol-specified tissues (when present) were examined from each animal.

3. RESULTS AND DISCUSSION

3.1 Mortality

All animals survived to their scheduled sacrifice.

3.2 Macroscopic Observations

Macroscopic observation data are summarized in Table 5.1, and Table 5.2; individual data are listed in Table 6.1.

No test article-related macroscopic findings were noted. All macroscopic findings were considered spontaneous and/or incidental because they occurred at a low incidence, were

randomly distributed across groups (including concurrent controls), and/or were as expected for cynomolgus monkeys of this age; therefore, they were considered not test article related.

3.3 Microscopic Observations

Microscopic observation data are summarized in Table 5.3, and Table 5.4; individual data are listed in Table 6.1.

Minimal microscopic findings in the kidney and colon in VECTOR A and VECTOR B treated animals (see Text Table 3.1).

Kidney effects consisted of minimal tubule basophilia. Effects in the cecum and colon consisted of minimal mononuclear cell infiltrates in the mucosa.

Text Table 3.1: Incidence and Severity of Test Article-Related Microscopic Findings

		Sex	Male
Test article(s)		VECTOR A	VECTOR B
	Number examined/group	3	3
Kidney			
Basophilic tubule			
	Minimal	0	1
Infiltrate, mononuclear cell			
	Minimal	2	2
Colon			
Infiltrate, mononuclear cell			
	Minimal	2	3

All other microscopic findings were considered spontaneous and/or incidental because they occurred at a low incidence, were randomly distributed across groups (including concurrent controls), and/or their severity was as expected for cynomolgus monkeys of this age; therefore, they were considered not test article related.

4. ASSOCIATED STUDY INFORMATION

4.1 Abbreviations

The following lists of abbreviations are used by TESTING FACILITY. Some, but not necessarily all, of this information may be needed for this report.

Abbreviation	*Definition*
Neoplastic Findings	
B	Primary, benign neoplasm
F	Infiltrating neoplasm
I	Locally invasive neoplasm
M	Primary, malignant neoplasm
N	Metastatic neoplasm
X	Other neoplasm
Grades for Severity or Amount	
1	Minimal - describes an inconspicuous change
2	Slight - referring to a noticeable but not prominent feature
3	Moderate - a prominent feature
4	Marked - a dominant but not overwhelming feature
5	Severe - implies an overwhelming condition
Tissue Abbreviations	
BALT	Bronchi-associated lymphoid tissue
GALT	Gut-associated lymphoid tissue

4.2 Comments on the Data

The following comments on the data are used by TESTING FACILITY. Some, but not necessarily all, of this information may be needed for this report.

Various models of calculators, computers, and computer programs were used to analyze data in this study. Values in some tables (e.g., means, standard deviations, or individual values) may differ slightly from those in other tables, from individually calculated data, or from statistical analysis data because different models round off or truncate numbers differently. Neither the integrity nor the interpretation of the data was affected by these differences.

The number of animals listed in the heading of the anatomic pathology summary tables indicates the number of animals assigned to each respective necropsy interval.

Data for replaced animals, removed from study, may appear in the individual animal data tables; however, are not discussed further in the study results.

Terminal body weight values in the organ weight tables and in the Individual Animal Data table are reported to the tenth of a gram; however, they were originally recorded to the tenth of a kilogram. The terminal body weight values in the mean organ weight tables reflect the accuracy of the absolute organ weight values.

5. SUMMARY TABLES

Table 5.1: Incidence of Macroscopic Observations - Terminal Sacrifice (Dosing Phase)

			VECTORSTUDYU1
Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B-	GC/kg	1.024e13	1.024e13

Tissue/	Group/Sex:	1/M	5/M
Observation	Number of Animals:	3	3
	Unremarkable:	1	1
Adrenal	Number Examined:	3	3
	Unremarkable:	3	3
Animal	Number Examined:	3	3
	Unremarkable:	3	3
Aorta	Number Examined:	3	3
	Unremarkable:	3	3
Brain	Number Examined:	3	3
	Unremarkable:	3	3
Cecum	Number Examined:	3	3
	Unremarkable:	3	2
Discolored		0	1

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			
Tissue/	Group/Sex:	1/M	2/M	3/M	5/M		
Observation	Number of Animals:	3	2	4	3		
	Unremarkable:	1	1	2	1		
Colon	Number Examined:	3	2	4	3		
	Unremarkable:	3	2	4	1		
Discolored		0	0	0	2		
Duodenum	Number Examined:	3	2	4	3		
	Unremarkable:	3	2	4	3		
Epididymis	Number Examined:	3	2	4	3		
	Unremarkable:	3	2	4	3		
Esophagus	Number Examined:	3	2	4	3		
	Unremarkable:	3	2	4	3		
Eye	Number Examined:	3	2	4	3		
	Unremarkable:	3	2	4	3		

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Tissue/Observation	Group/Sex:	1/M	2/M	3/M	5/M
	Number of Animals:	3	2	4	3
	Unremarkable:	1	1	2	1
Femur	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Gall Bladder	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
GALT/Peyer's Patch	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Heart	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Ileum	Number Examined:	3	2	4	3
	Unremarkable:	2	2	3	2
Discolored		1	0	1	1

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: 1/M	2/M	3/M	5/M
	Number of Animals: 3	2	4	3
	Unremarkable: 1	1	2	1
Intravenous Injection Site	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Jejunum	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Kidney	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Liver	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Lung	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: 1/M	2/M	3/M	5/M
	Number of Animals: 3	2	4	3
	Unremarkable: 1	1	2	1
Lymph Node, Mandibular	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Lymph Node, Mesenteric	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Mandibular Salivary Gland	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Marrow, Femur	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
	Unremarkable:	1	1	2	1
Marrow, Sternum	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Muscle, Biceps Femoris	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Nerve, Optic	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Nerve, Sciatic	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Pancreas	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
	Unremarkable:	1	1	2	1
Parathyroid	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Pituitary	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Prostate	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Rectum	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Seminal Vesicle	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
	Unremarkable:	1	1	2	1
Skin/Subcutis	Number Examined:	3	2	4	3
	Unremarkable:	2	2	4	2
Scab		1	0	0	1
Spinal Cord	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Spleen	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Sternum	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: 1/M	2/M	3/M	5/M
	Number of Animals: 3	2	4	3
	Unremarkable: 1	1	2	1
Stomach	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	2
Discolored	0	0	0	1
Testis	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Thymus	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Thyroid	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3
Tongue	Number Examined: 3	2	4	3
	Unremarkable: 3	2	4	3

VECTORSTUDYU1

Table
Incidence of Macroscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Tissue/ Observation	Group/Sex:	1/M	2/M	3/M	5/M
	Number of Animals:	3	2	4	3
	Unremarkable:	1	1	2	1
Trachea	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Urinary Bladder	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3

Table 5.3: Summary of Severity of Microscopic Observations - Terminal Sacrifice (Dosing Phase)

VECTORSTUDYU1

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B GC/kg		1.024e13	1.024e13			
Tissue/ Group/Sex:		1/M	2/M	3/M	5/M	
Observation Number of Animals:		3	2	4	3	
Cecum Number Examined:		3	2	4	3	
Unremarkable:		1	0	0	0	
Hemorrhage, lymphoid tissue						
finding not present -		3	1	2	2	
minimal	1	0	0	1	0	
slight	2	0	1	1	1	
Total Incidence:		0	1	2	1	
Hemorrhage, mucosa						
finding not present -		3	1	3	2	
minimal	1	0	0	0	1	
slight	2	0	1	1	0	
Total Incidence:		0	1	1	1	

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Cecum	Number Examined:	3	2	4	3
	Unremarkable:	1	0	0	0
Infiltrate, mononuclear cell					
	finding not present -	1	0	1	1
	minimal 1	2	1	2	2
	slight 2	0	1	1	0
	Total Incidence:	2	2	3	2

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article		(dosage)	1M		5M		
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Colon	Number Examined:	3	2	4	3
	Unremarkable:	1	0	1	0
Hemorrhage					
	finding not present -	3	2	4	2
	slight 2	0	0	0	1
	Total Incidence:	0	0	0	1
Infiltrate, mononuclear cell					
	finding not present -	1	0	1	0
	minimal 1	2	2	2	3
	slight 2	0	0	1	0
	Total Incidence:	2	2	3	3
Duodenum	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Gall Bladder	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3
Ileum	Number Examined:	3	2	4	3
	Unremarkable:	2	2	4	2
Hemorrhage, lymphoid tissue	finding not present -	2	2	4	2
	minimal 1	1	0	0	1
	Total Incidence:	1	0	0	1
Jejunum	Number Examined:	3	2	4	3
	Unremarkable:	3	2	4	3

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Kidney	Number Examined:	3	2	4	3
	Unremarkable:	1	2	3	1
Basophilic tubule					
	finding not present -	3	2	4	2
	minimal 1	0	0	0	1
	Total Incidence:	0	0	0	1
Cast, proteinaceous					
	finding not present -	3	2	3	3
	minimal 1	0	0	1	0
	Total Incidence:	0	0	1	0

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Kidney	Number Examined:	3	2	4	3
	Unremarkable:	1	2	3	1
Infiltrate, mononuclear cell					
	finding not present -	1	2	3	2
	minimal 1	2	0	1	1
	Total Incidence:	2	0	1	1

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Liver	Number Examined:	3	2	4	3
	Unremarkable:	0	0	0	0
Infiltrate, mixed cell					
	finding not present -	2	1	4	3
	minimal 1	1	1	0	0
	Total Incidence:	1	1	0	0
Infiltrate, mononuclear cells					
	finding not present -	2	2	4	3
	minimal 1	1	0	0	0
	Total Incidence:	1	0	0	0

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Liver	Number Examined:	3	2	4	3
	Unremarkable:	0	0	0	0
Vacuolation, hepatocyte					
	finding not present -	0	0	0	0
	minimal 1	2	2	2	3
	slight 2	1	0	2	0
	Total Incidence:	3	2	4	3

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Pancreas	Number Examined:	3	2	4	3
	Unremarkable:	1	2	2	0
Hemorrhage					
	finding not present -	3	2	3	2
	minimal 1	0	0	1	1
	Total Incidence:	0	0	1	1
Vacuolation					
	finding not present -	1	2	3	1
	minimal 1	2	0	1	2
	Total Incidence:	2	0	1	2

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Rectum	Number Examined:	3	2	4	3
	Unremarkable:	3	1	3	3
Infiltrate, mononuclear cell	finding not present -	3	1	3	3
	minimal 1	0	1	1	0
	Total Incidence:	0	1	1	0

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Skin/Subcutis	Number Examined:	1	0	0	1
	Unremarkable:	0	0	0	0
Acanthosis/hyperkeratosis					
	finding not present -	1	0	0	0
	slight 2	0	0	0	1
	Total Incidence:	0	0	0	1
Erosion/ulcer					
	finding not present -	0	0	0	1
	moderate 3	1	0	0	0
	Total Incidence:	1	0	0	0

VECTORSTUDYU1

Table
Summary of Severity of Microscopic Observations
Terminal Sacrifice (Dosing Phase)

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Tissue/ Observation	Group/Sex: / Number of Animals:	1/M 3	2/M 2	3/M 4	5/M 3
Stomach	Number Examined:	3	2	4	3
	Unremarkable:	3	1	3	1
Hemorrhage					
	finding not present -	3	2	4	2
	slight 2	0	0	0	1
	Total Incidence:	0	0	0	1
Infiltrate, mononuclear cell					
	finding not present -	3	1	3	1
	minimal 1	0	1	0	2
	slight 2	0	0	1	0
	Total Incidence:	0	1	1	2

6. INDIVIDUAL ANIMAL DATA TABLES

Table 6.1: Individual Animal Data

VECTORSTUDYU1

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Animal Number: P0001 Group: 1 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 2900.0

Macroscopic Observation(s)	Microscopic Observation(s)
Intravenous Injection Site: TISSUE COMMENT: Both left and right were collected	Cecum: Infiltrate, mononuclear cell; minimal; mucosa Colon: Infiltrate, mononuclear cell; minimal; mucosa Liver: Vacuolation, hepatocyte; minimal

The following tissues were examined macroscopically and were unremarkable:
Adrenal; Animal; Aorta; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Femur; GALT/Peyer's Patch; Gall Bladder; Heart; Ileum; Intravenous Injection Site; Jejunum; Kidney; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mandibular Salivary Gland; Marrow, Femur; Marrow, Sternum; Muscle, Biceps Femoris; Nerve, Optic; Nerve, Sciatic; Pancreas; Parathyroid; Pituitary; Prostate; Rectum; Seminal Vesicle; Skin/Subcutis; Spinal Cord; Spleen; Sternum; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder

The following tissues were examined microscopically and were unremarkable:
Duodenum; Gall Bladder; Ileum; Jejunum; Kidney; Pancreas; Rectum; Stomach

VECTORSTUDYU1

Table
Individual Animal Data

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Animal Number: P0002 Group: 1 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 2600.0

Macroscopic Observation(s)	Microscopic Observation(s)
Intravenous Injection Site: TISSUE COMMENT: Both left and right IV were collected, per study director request due to neither being marked by inlife in pristima	Cecum: Infiltrate, mononuclear cell; minimal; mucosa
Skin/Subcutis: Scab; tail, distal end; single, up to 10 mm2; red; collected	Colon: Infiltrate, mononuclear cell; minimal; mucosa
	Kidney: Infiltrate, mononuclear cell; minimal
	Liver: Infiltrate, mononuclear cells; minimal
	Liver: Vacuolation, hepatocyte; slight
	Pancreas: Vacuolation; minimal
	Skin/Subcutis: Erosion/ulcer; moderate

VECTORSTUDYU1

Table
Individual Animal Data

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Animal Number: P0002 Group: 1 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 2600.0

The following tissues were examined macroscopically and were unremarkable:
Adrenal; Animal; Aorta; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Femur; GALT/Peyer's Patch; Gall Bladder; Heart; Ileum; Intravenous Injection Site; Jejunum; Kidney; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mandibular Salivary Gland; Marrow, Femur; Marrow, Sternum; Muscle, Biceps Femoris; Nerve, Optic; Nerve, Sciatic; Pancreas; Parathyroid; Pituitary; Prostate; Rectum; Seminal Vesicle; Spinal Cord; Spleen; Sternum; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder

The following tissues were examined microscopically and were unremarkable:
Duodenum; Gall Bladder; Ileum; Jejunum; Rectum; Stomach

VECTORSTUDYU1

Table
Individual Animal Data

Test Article	(dosage)	1M	5M
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13

Animal Number: P0003 Group: 1 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 3400.0

Macroscopic Observation(s)	Microscopic Observation(s)
Ileum: Discolored; mucosa; single, up to 10 mm2; dark red; collected/ileocecal junction	Ileum: Hemorrhage, lymphoid tissue; minimal /ileocecal junction
Intravenous Injection Site: TISSUE COMMENT: Both left and right were collected	Kidney: Infiltrate, mononuclear cell; minimal
	Liver: Infiltrate, mixed cell; minimal
	Liver: Vacuolation, hepatocyte; minimal
	Pancreas: Vacuolation; minimal

VECTORSTUDYU1

Table
Individual Animal Data

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

Animal Number: P0003 Group: 1 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 3400.0

The following tissues were examined macroscopically and were unremarkable:
Adrenal; Animal; Aorta; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Femur; GALT/Peyer's Patch; Gall Bladder; Heart; Intravenous Injection Site; Jejunum; Kidney; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mandibular Salivary Gland; Marrow, Femur; Marrow, Sternum; Muscle, Biceps Femoris; Nerve, Optic; Nerve, Sciatic; Pancreas; Parathyroid; Pituitary; Prostate; Rectum; Seminal Vesicle; Skin/Subcutis; Spinal Cord; Spleen; Sternum; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder

The following tissues were examined microscopically and were unremarkable:
Cecum; Colon; Duodenum; Gall Bladder; Jejunum; Rectum; Stomach

VECTORSTUDYU1

Table
Individual Animal Data

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

Animal Number: P0401 Group: 5 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 3200.0

Macroscopic Observation(s)	Microscopic Observation(s)
Cecum: Discolored; mucosa; single, up to 10 mm2; red; collected/discoloration located on the ileocecal junction	Cecum: Hemorrhage, lymphoid tissue; slight
Colon: Discolored; mucosa; multiple, up to 10 mm2; red; collected/collected on routine section	Cecum: Hemorrhage, mucosa; minimal
Ileum: Discolored; mucosa; single, up to 10 mm2; red; collected/collected on routine section	Colon: Infiltrate, mononuclear cell; minimal; mucosa
Intravenous Injection Site: TISSUE COMMENT: both left and right IV sites collected per study directors request due to lack of specification in pristima	Ileum: Hemorrhage, lymphoid tissue; minimal
Skin/Subcutis: Scab; tail, distal end; single, linear, up to 10 mm in length; red; collected	Liver: Vacuolation, hepatocyte; minimal
	Pancreas: Hemorrhage; minimal; focal; islets

VECTORSTUDYU1

Table
Individual Animal Data

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Animal Number: P0401 Group: 5 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 3200.0

Macroscopic Observation(s)	Microscopic Observation(s)
	Skin/Subcutis: Acanthosis/hyperkeratosis; slight /healed ulcer

The following tissues were examined macroscopically and were unremarkable:
Adrenal; Animal; Aorta; Brain; Duodenum; Epididymis; Esophagus; Eye; Femur; GALT/Peyer's Patch; Gall Bladder; Heart; Intravenous Injection Site; Jejunum; Kidney; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mandibular Salivary Gland; Marrow, Femur; Marrow, Sternum; Muscle, Biceps Femoris; Nerve, Optic; Nerve, Sciatic; Pancreas; Parathyroid; Pituitary; Prostate; Rectum; Seminal Vesicle; Spinal Cord; Spleen; Sternum; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder

The following tissues were examined microscopically and were unremarkable:
Duodenum; Gall Bladder; Jejunum; Kidney; Rectum; Stomach

VECTORSTUDYU1

Table
Individual Animal Data

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

Animal Number: P0402 Group: 5 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 3000.0

Macroscopic Observation(s)	Microscopic Observation(s)
Intravenous Injection Site: TISSUE COMMENT: Both left and right were collected	Cecum: Infiltrate, mononuclear cell; minimal; mucosa Colon: Infiltrate, mononuclear cell; minimal; mucosa Kidney: Basophilic tubule; minimal Liver: Vacuolation, hepatocyte; minimal Pancreas: Vacuolation; minimal Stomach: Infiltrate, mononuclear cell; minimal; mucosa, epithelium

VECTORSTUDYU1

Table
Individual Animal Data

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

Animal Number: P0402 Group: 5 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 3000.0

The following tissues were examined macroscopically and were unremarkable:
Adrenal; Animal; Aorta; Brain; Cecum; Colon; Duodenum; Epididymis; Esophagus; Eye; Femur; GALT/Peyer's Patch; Gall Bladder; Heart; Ileum; Intravenous Injection Site; Jejunum; Kidney; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mandibular Salivary Gland; Marrow, Femur; Marrow, Sternum; Muscle, Biceps Femoris; Nerve, Optic; Nerve, Sciatic; Pancreas; Parathyroid; Pituitary; Prostate; Rectum; Seminal Vesicle; Skin/Subcutis; Spinal Cord; Spleen; Sternum; Stomach; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder

The following tissues were examined microscopically and were unremarkable:
Duodenum; Gall Bladder; Ileum; Jejunum; Rectum

VECTORSTUDYU1

Table
Individual Animal Data

Test Article	(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg	1.024e13	1.024e13			

Animal Number: P0403 Group: 5 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 2700.0

Macroscopic Observation(s)	Microscopic Observation(s)
Colon: Discolored; mucosa; entire; red; collected	Cecum: Infiltrate, mononuclear cell; minimal; mucosa
Intravenous Injection Site: TISSUE COMMENT: both left and right collected per study directors request due to lack of differentiation in pristima	Colon: Hemorrhage; slight; mucosa
Stomach: Discolored; mucosa, body; single, up to 10 mm2; red; collected	Colon: Infiltrate, mononuclear cell; minimal; mucosa
	Kidney: Infiltrate, mononuclear cell; minimal
	Liver: Vacuolation, hepatocyte; minimal
	Pancreas: Vacuolation; minimal
	Stomach: Hemorrhage; slight; mucosa, epithelium
	Stomach: Infiltrate, mononuclear cell; minimal; mucosa, epithelium

VECTORSTUDYU1

Table
Individual Animal Data

Test Article		(dosage)	1M	5M			
VECTOR A and VECTOR B	GC/kg		1.024e13	1.024e13			

Animal Number: P0403 Group: 5 Sex: M Fate Status: Terminal Sacrifice
Date of Fate: 14 Jan 19 Phase of Fate: Dosing Phase Wk/Day of Fate: 25/169 TBW(g): 2700.0

The following tissues were examined macroscopically and were unremarkable:
Adrenal; Animal; Aorta; Brain; Cecum; Duodenum; Epididymis; Esophagus; Eye; Femur; GALT/Peyer's Patch; Gall Bladder; Heart; Ileum; Intravenous Injection Site; Jejunum; Kidney; Liver; Lung; Lymph Node, Mandibular; Lymph Node, Mesenteric; Mandibular Salivary Gland; Marrow, Femur; Marrow, Sternum; Muscle, Biceps Femoris; Nerve, Optic; Nerve, Sciatic; Pancreas; Parathyroid; Pituitary; Prostate; Rectum; Seminal Vesicle; Skin/Subcutis; Spinal Cord; Spleen; Sternum; Testis; Thymus; Thyroid; Tongue; Trachea; Urinary Bladder

The following tissues were examined microscopically and were unremarkable:
Duodenum; Gall Bladder; Ileum; Jejunum; Rectum

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