Statistical Analysis Plan (SAP)

Study No. NAV3-24

An Evaluation of the Safety of Escalating Doses of Tc 99m Tilmanocept by Intravenous (IV) Injection and a Comparison to Subcutaneous (SC) Injection in Human Immunodeficiency Virus (HIV) Subjects Diagnosed with Kaposi Sarcoma (KS)

Version 1.0

July 23, 2020

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Approval Page

By entering into this Statistical Analysis Plan (SAP), the parties acknowledge and agree that this SAP shall be incorporated into and subject to the terms of the Master Services Agreement (MSA). Any changes requested by Client to this SAP shall be subject to Section I.C of the MSA requiring a mutually agreed upon "Change Order" prior to any modification of the procedures set forth herein.

I agree to the format and content of this document.

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Revision History

N/A

Table of Contents

1.0 Synopsis of Study Design Procedures

This study will enroll up to fourteen (14) HIV (human immunodeficiency virus) - positive female or male subjects at least 18 years of age who have biopsy-confirmed Kaposi Sarcoma (KS).

The primary objective of this study is:

- To determine the safety of escalating doses of Tc 99m tilmanocept in HIV subjects with biopsy-confirmed KS

The secondary objectives of this study are:

- Concordance between clinical assessment/diagnosis and the localization of Tc 99m tilmanocept by planar and/or SPECT (single photon emission computed tomography) / CT (X-ray computed tomography) imaging in cutaneous and non-cutaneous sites of KS.
- Qualify and quantify Tc 99m tilmanocept localization intensity on imaging with CD206 locale and quantity by histology and immunohistochemistry (IHC) in biopsied KS lesions to determine optimal IV dose.
- Concordance of localization of Tc 99m tilmanocept via IV and SC routes of administration by planar and/or SPECT/CT imaging in cutaneous and non-cutaneous sites of KS.

The exploratory objective of this study is:

- Quantify HHV8 in biopsied KS lesions by real-time polymerase chain reaction (qPCR)

General safety will be evaluated by examining the incidence of adverse events (AEs) and changes over time in laboratory tests, vital signs, ECGs (electrocardiogram) and physical examination findings.

1.1 Design and Treatment

This study is a prospective, open-label, single center study of Tc 99m tilmanocept in the localization of KS lesions. Subjects will receive an injection of tilmanocept at one of two mass doses radiolabeled with Tc 99m at one of two radiolabel doses according to the following table:

Table 1: Description of Cohorts

Cohort Number	Dose	Sample Size
1	100µg/5mCi (IV)	4
2	100µg/10mCi (IV)	4
3	200µg/5mCi SC, and 200µg/5mCi IV one week later.	up to 6

The 100 or 200 μg mass doses will require 1 vial of tilmanocept radiolabeled with the assigned mCi dose delivered in one syringe for IV injections and two syringes for SC injections. Subjects in Cohorts 1 and 2 will have whole body planar imaging beginning 60-75 minutes post-injection followed by optional SPECT/CT of regions of interest. Subjects in Cohort 3 will have a whole-body planar scan with optional SPECT/CT of region of interest scanning beginning at 60- 75 minutes following both the IV and SC injections and 4- 6 hours following SC injection.

1.1.1 Localization Definitions

A localized subject is one for whom Tc 99m tilmanocept by planar and/or SPECT/CT imaging results in the illumination of at least one site relative to background as determined by the nuclear medicine specialist.

A localized KS lesion is a lesion that is both clinically identified or suspected KS (via biopsy-confirmed diagnosis or clinical symptomology) and is illuminated by planar and/or SPECT/CT imaging.

Localization in areas other than KS will also be defined per subject and per area, where these areas are clinically negative KS locations based on clinical symptomology.

1.2 Study Procedures

The study includes procedures at screening (within 30 days of injection), pre-injection, injection, and post-injection. The post-injection time points include measurements at 30 minutes, 60 - 75 minutes, 4 - 6 hours, and 4 - 10 days post-injection. The following describes the procedures to be conducted on each study day at each time point.

1.2.1 Cohorts 1 and 2

Screening Visit (Visit 1, Day -29 to Day 0): The screening visit will include informed consent, review of study eligibility, allocation of unique subject number, demographic data, medical and surgical history, vital signs (henceforth, vital

signs refers to body temperature, heart rate, systolic and diastolic blood pressure and respiration rate), physical exam including height and body weight, assessment of edema/lymphedema, ECG, blood draw for clinical lab results, cutaneous and non-cutaneous KS evaluation, photographs of all visible cutaneous KS lesions, KS history and classification, urine sample collection for routine urinalysis, urine pregnancy test for women of child-bearing potential, and review of medications.

Pre-tilmanocept Injection (Visit 2, Day 1):

- Concomitant medication review
- A negative urine pregnancy test for women of child-bearing potential
- Vital signs (within 30 minutes preceding injection)

Tilmanocept Injection (Day 1): Based on Cohort assignment, subjects will receive their study drug dose by IV route of administration.

Post-tilmanocept Injection (Day 1):

- Within 30 minutes post-injection
    - ECG (completed before vital signs)
    - Vital signs
    - Adverse event assessment
- 60- 75 minutes post-injection:
    - Adverse event assessment
    - Whole body planar imaging
    - SPECT/CT imaging of region(s) of interest (optional)
    - After the imaging is complete
        - Blood sample for hematology and serum chemistry
        - Urine sample for routine urinalysis
        - Biopsy of designated non-visceral KS lesion
        - Photograph of biopsy lesion with a measurement scale. This image is to be stored within the subject's research file.

Follow-Up Telephone Call (7±3 days post-tilmanocept injection):

- Concomitant medication review
- Adverse event assessment

Each subject's participation in the study is complete after the follow-up telephone call.

For determination of secondary endpoints, the Tc 99m tilmanocept whole body planar and SPECT/CT images will be visually assessed for localization by a Nuclear Medicine Physician.

1.2.2 Cohort 3

Screening Visit (Visit 1, Day -29 to Day 0): The screening visit will include informed consent, review of study eligibility, allocation of unique subject number, demographic data, medical and surgical history, vital signs, physical exam including height and body weight, assessment of edema/lymphedema, ECG, blood draw for clinical lab results, cutaneous and non-cutaneous KS evaluation, photographs of all visible cutaneous KS lesions, KS history and classification, urine sample collection for routine urinalysis, urine pregnancy test for women of child-bearing potential, and review of medications.

Pre-tilmanocept Injection (Visit 2, Day 1):

- Concomitant medication review
- A negative urine pregnancy test for women of child-bearing potential
- Vital signs (within 30 minutes preceding injection)

Tilmanocept Injection (Day 1): Subjects will receive their SC study drug dose of 5 mCi Tc 99m/200 μg tilmanocept.

Post-tilmanocept Injection (Day 1):

- Within 30 minutes post-injection
    - ECG (completed before vital signs)
    - Vital signs
    - Adverse event assessment
- 60- 75 minutes post-injection:
    - Adverse event assessment
    - Whole body planar imaging
    - SPECT/CT imaging of region(s) of interest (optional)
- 4- 6 hours post-injection:
    - Adverse event assessment
    - Whole body planar imaging
    - SPECT/CT imaging of region(s) of interest (optional)
    - After the imaging is complete
        - Blood sample for hematology and serum chemistry
        - Urine sample for routine urinalysis

Pre-tilmanocept Injection (Visit 3, Day 7±3):

- Concomitant medication review
- A negative urine pregnancy test for women of child-bearing potential
- Vital signs (within 30 minutes preceding injection)

Tilmanocept Injection (Day 7±3): Subjects will receive their IV study drug dose of 5 mCi Tc 99m/200 μg tilmanocept.

Post-tilmanocept Injection (Day 7±3):

- Within 30 minutes post-injection
  - ECG (completed before vital signs)
  - Vital signs
  - Adverse event assessment
- 60- 75 minutes post-injection:
  - Adverse event assessment
  - Whole body planar imaging
  - SPECT/CT imaging of region(s) of interest (optional)
  - After the imaging is complete
    - Blood sample for hematology and serum chemistry
    - Urine sample for routine urinalysis
    - Biopsy of designated non-visceral KS lesion
    - Photograph of biopsy lesion with a measurement scale. This image is to be stored within the subject's research file.

Follow-Up Telephone Call (7±3 days post-IV tilmanocept injection):

- Concomitant medication review
- Adverse event assessment

Each subject's participation in the study is complete after the follow-up telephone call.

For determination of secondary endpoints, the Tc 99m tilmanocept whole body planar and SPECT/CT images will be visually assessed for localization by a Nuclear Medicine Physician.

1.3 Sample Size

The dose escalation portion of this study is a design with no dose de-escalation. The sequential cohort enrollment characteristics of this design do not allow a fixed computation of sample size. In a previous study with subjects receiving a 400 µg dose radiolabeled at 10 mCi (i.e., twice the maximum dose planned for this study), zero (0) subjects had an Adverse Drug Reaction (ADR). Therefore, it is expected that no subjects will have an ADR in this study and that each cohort will enroll the minimum planned sample size of subjects. With 2 cohorts of 4 subjects and one cohort of up to 6 subjects, it is anticipated that the study will enroll no more than n=14 subjects.

2.0 Data Analysis Considerations

2.1 Types of Analyses

All results will be based on descriptive statistics. Unless otherwise stated, continuous variables will be summarized via sample size, mean, standard deviation, median, minimum, and maximum. Categorical variables will be summarized via frequency counts and percentages.

2.2 Analysis Populations

The following analysis populations will be defined:

Safety: The safety population will include all enrolled subjects who are injected with Tc 99m tilmanocept.

Intent-to-Diagnose (ITD): The ITD population will include all subjects who sign informed consent, who are injected with Tc 99m tilmanocept, and who are imaged.

The analysis of all efficacy endpoints will be conducted on the ITD population. The analysis of all safety and baseline subject characteristics will be conducted on the safety population.

2.2.1 Subgroup Definitions

Analyses may be performed by dose group (Cohort 1, 100μg/5mCi; Cohort 2, 100μg/10mCi; Cohort 3, 200μg/5mCi) and by route of administration (Cohort 3 SC and IV).

2.3 Missing Data Conventions

The analysis of the primary efficacy variables will be carried out on the observed data, i.e., a complete case analysis.

2.4 Interim Analyses

No interim analyses are planned for this study.

2.5 Study Center Considerations in the Data Analysis

A study center is defined as a treatment administration site or group of treatment administration sites under the control and supervision of the same Principal Investigator (PI).

Because this is a single-center study, there will be no selective pooling of study centers in the analysis.

2.6 Documentation and Other Considerations

The data analyses will be conducted using SAS© Software, version 9.4 or later.

3.0 Analysis of Baseline Patient Characteristics

Baseline and demographic characteristics will be summarized by dose group for all subjects in the safety population. Continuous variables will be displayed via summary statistics (mean, median, sample size, standard deviation, minimum, and maximum). Categorical variables will be summarized via counts and percentages.

A detailed listing of demographic data for each subject will also be provided as shown in Appendix B.

4.0 Analysis of Efficacy

4.1 Description of Efficacy Variables

Secondary objectives of the study are to determine the concordance between clinical assessment/diagnosis and the localization of Tc 99m tilmanocept by planar and/or SPECT/CT imaging in cutaneous and non-cutaneous sites of KS; to qualify and quantify Tc 99m tilmanocept localization intensity on imaging with CD 206 locale and quantity by histology and IHC in biopsied KS lesions to determine the optimal IV dose; and concordance of localization of Tc 99m tilmanocept via IV and SC routes of administration by planar and/or SPECT/CT imaging in cutaneous and non-cutaneous sites of KS. The relevant endpoints are the following:

- Per subject localization rate of Tc 99m tilmanocept in at least one KS suspected or confirmed lesion by planar and/or SPECT/CT imaging
- Per lesion/region concordance of Tc 99m localization with anatomical areas of active KS defined by confirmed diagnosis or clinical symptomology

- Localization intensity for each biopsied and clinically defined lesion localized on imaging following IV injection as determined by quantitative SPECT gamma counts
- Per biopsied lesion proportion of CD206-expressing cells and proportion of HHV8-expressing cells as determined by histology and relative IHC fluorescence
- Per lesion/region concordance of IV vs SC Tc 99m localization with anatomical areas of active KS defined by confirmed diagnosis or clinical symptomology.
- Per subject localization rate of Tc 99m tilmanocept in areas other than KS by planar and/or SPECT/CT imaging
- Per area localization rate of Tc 99m tilmanocept in the most frequently identified areas other than KS by planar and/or SPECT/CT imaging

An exploratory objective of the study is to use quantitative Polymerase Chain Reaction (qPCR) methods to measure the amount of Human Herpes Virus 8 (HHV8) present in the biopsy tissue.

The relevant variables are the following:

- Nuclear medicine specialist determination of presence/absence of illumination (i.e., localization positive or negative per anatomic site) relative to background from planar and/or SPECT/CT imaging results for each subject;
- Clinically identified presence or absence of KS based on any previous diagnostic evaluation;
- Proportion of CD206-expressing cells (IHC fluorescence);
- Quantitative SPECT gamma counts for each biopsied lesion localized on imaging following IV injection; and,
- HHV8 concentrations as determined by qPCR for each biopsied lesion.

The calculations and analyses pertaining to each of the variables are shown in Sections 4.2.

4.2 Analysis of Efficacy Variables

Localization in KS Sites

The number and percentage of subjects with at least one biopsy-confirmed or clinically suspected KS lesion that has localized with Tc 99m tilmanocept by planar and/or SPECT/CT imaging will be computed. A 95% exact confidence interval on the per-subject localization rate will be computed. This analysis will be performed by dose group and route of administration.

Per-lesion/region localization of Tc 99m tilmanocept by planar and/or SPECT/CT imaging will be computed across all biopsy-confirmed or clinically suspected KS lesions of all subjects. A 95% exact confidence interval on the per-lesion/region localization will be calculated. This analysis will be performed by dose group and route of administration.

An analysis table will also be provided to display the counts of KS lesions localized by imaging that were not previously identified clinically.

Concordance between IV and SC tilmanocept in biopsy-confirmed or clinically-suspected KS lesion sites will be assessed with a cross-tabulation of the IV and SC findings, including the joint probability distribution. The sampling unit for this analysis will be the site. An exact conditional version of McNemar's test will be performed to test the hypotheses

$$H_0: \pi_{IV} = \pi_{SC}$$
$$H_A: \pi_{IV} \neq \pi_{SC},$$

where π_{IV} and π_{SC} represent the probabilities of localization with IV (only) tilmanocept and SC (only) tilmanocept, respectively. In addition, the number and proportion of subjects with concordance and reverse concordance of observed sites of discrete localization of Tc 99m tilmanocept following IV and SC localization will be summarized.

Localization Intensity by Planar and/or SPECT/CT Imaging
Tc 99m tilmanocept average pixel intensity and percent above background will be summarized with descriptive statistics (mean, standard deviation, minimum, median, maximum, and range) for each biopsied lesion localized on imaging following IV injection of Tc 99m tilmanocept by dose group. Summary statistics will be presented separately by imaging type (planar, SPECT/CT).

Proportion of CD206-expressing Cells
Per biopsied-lesion proportion of CD206-expressing cells as determined by histology and IHC fluorescence will be summarized by descriptive statistics (mean, standard deviation, minimum, median, maximum, and range) by dose group.

Localization in Non-KS Sites
The number and percentage of subjects with at least one anatomical site other than KS that has been localized with Tc 99m tilmanocept by planar and/or SPECT/CT imaging will be computed. A 95% exact confidence interval on the per subject localization rate will be computed. This analysis will be performed by dose group and route of administration.

Locations showing localization of Tc 99m tilmanocept by planar and/or SPECT/CT imaging will be computed across all sites other than biopsy-confirmed or clinically suspected KS sites of all subjects. A 95% exact confidence interval on per location localization will be calculated. (i.e. the rate of localization of each site with respect to the number of subjects). This analysis will be performed by dose group and route of administration.

5.0 Analysis of Safety

Adverse Drug Reactions (ADRs) are defined as all noxious and unintended responses to a medicinal product related to any dose or dose regimen. The phrase 'responses to a medicinal product' means that a causal relationship between a medicinal product and an adverse event. The primary safety variable is the proportion of patients experiencing at least one ADR. The number and percentage of subjects with ADRs will be tabulated by dose group and overall. Other safety endpoints are noted below.

Analysis of Safety Endpoints
Attention shall be paid to the occurrence of adverse events (AEs) from the time of signing informed consent until exit from the study. Events occurring prior to Tc 99m tilmanocept administration will be recorded in the subject's medical history unless determined to be related to the study procedure. A treatment emergent adverse event (TEAE) is defined as an adverse event whose start date is on or after the first study drug administration date. If the study drug administration date and/or the AE start date are missing, the AE will be considered treatment emergent.

Prior to analysis, all AEs will be coded using the Medical Dictionary for Regulatory Activities (MedDRA). The MedDRA version used will be stated in the final validated tables. Based on these coded terms, AEs and TEAEs will be summarized by dose group and overall as follows:

- by system organ class and preferred terms;
- by system organ class and preferred terms and relation to study drug; and,
- by system organ class and preferred terms and severity.

In addition to the above endpoints, the following describes the analyses of the other safety data being collected for the study.

Vital Signs
Vital signs will include heart rate, blood pressure, respiration rate, and body temperature. Vital signs will be taken during screening, prior to study drug administration on Day 1 (and Day 7 [± 3] for Cohort 3), and within 30 minutes following study drug administration. For each vital sign, summary statistics

(mean, standard deviation, minimum, median, maximum, range, n) on the raw values as well as their changes from pre-injection on Day 1 (and Day 7 [± 3] for Cohort 3) will be presented by dose group and overall. Time points included in this analysis are Day 1 (and Day 7 [± 3] for Cohort 3) within 30 minutes pre-injection and within 30 minutes post-Injection. If repeat vital signs are taken at a given time point, then the last measurement will be used for the analysis tables. A shift table will be created showing shifts Abnormal/Abnormal, Abnormal/Normal, Normal/Abnormal, Normal/Normal from pre-injection to post-injection of Tc 99m tilmanocept. This analysis will be performed by dose group and overall.

All vital signs will be listed, including those not presented in the analysis tables.

Physical Exams
A complete physical exam will be performed during screening. A data listing of the physical exam results will be created as shown in Appendix B.

Concomitant Medications
All concomitant medications will be coded with WHO Drug Dictionary (Uppsala Monitoring Centre) version March 2017 or later. A data listing will be constructed with Preferred Term, Verbatim Term, ATC Level 1 Code, and ATC Level 4 Code. A summary table will be provided to show the counts and percentages of subjects taken medications by ATC Level 4 Code and Preferred Term by dose group and overall.

Clinical Laboratory Parameters
Changes in hematology, clinical serum chemistry and urinalysis between screening (i.e., baseline) and the post-injection time point will be calculated, and descriptive statistics will be calculated on the raw and change from baseline values by dose group and overall. A copy of the normal laboratory values for all laboratories utilized for this study will be submitted to the Sponsor (or designee) prior to initiation of the study. A shift table will be created showing shifts Abnormal/Abnormal, Abnormal/Normal, Normal/Abnormal, Normal/Normal from screening baseline to post-injection of Tc 99m tilmanocept. This analysis will be performed by dose group and overall.

ECG
ECG recordings will be obtained during screening (i.e., baseline) and within 30 minutes following study drug administration. ECG parameters (heart rate, PR interval, QRS interval, QT interval, and QTcF interval) will be summarized as raw values and change-from-baseline (CFB). A shift table will be created showing shifts Abnormal/Abnormal, Abnormal/Normal, Normal/Abnormal, Normal/Normal from screening baseline to post-injection of Tc 99m tilmanocept. Both the quantitative and shift table analyses will be performed by dose group and overall.

6.0 Other Relevant Data Analyses and Summaries

6.1 Subject Completion

A table will be constructed with counts of screen failures and enrolled subjects. Of those enrolled, counts and percentages of the number of subjects withdrawing from the study before study completion and the number completing the study will be displayed. For those subjects that withdraw before completion of the study, counts and percentages of the reasons for withdrawal will be tabulated. The table will include summary counts and percentages by dose group and overall. A data listing of all subject completion and withdrawal data will also be constructed.

6.2 Study Drug Administration

The mass dose and radioactivity of Tc 99m tilmanocept injected will be summarized by dose group and overall.

6.3 Subject Imaging

Each subject will undergo whole body planar imaging. SPECT/CT imaging of region(s) of interest is optional for each subject. Results of all imaging procedures will be listed.

7.0 List of Analysis Tables, Figures and Listings

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
1	Subject Disposition by Cohort	X	X
2	Demographics and Baseline Data Summary Statistics by Cohort – Continuous Variables (Safety Population)	X	X
3	Demographics and Baseline Data Summary Statistics by Cohort – Categorical Variables (Safety Population)	X	X
4	Summary of Study Drug Administration by Cohort (Safety Population)	X	X
5	Subject-Level Localization of KS Lesions – Nuclear Medicine Findings (ITD Population)	X	X
6	Lesion-Level Localization of KS Lesions – Nuclear Medicine Findings (ITD Population)	X	X
7	Additional KS Lesions Identified from Imaging That Were Not Seen Clinically – Nuclear Medicine Findings (ITD Population)	X	X
8	Lesion-Level Non-Localization of KS Lesions – Nuclear Medicine Findings (ITD Population)	X	X
9	Number and Percentage of Concordant and Reverse Concordant Lesions (ITD Population)	X	X
10	Summary of Imaging-Localized Biopsied Lesion Localization Intensity by Cohort – Imaging = Planar (ITD Population)	X	X
11	Summary of Imaging-Localized Biopsied Lesion Localization Intensity by Cohort – Imaging = SPECT/CT (ITD Population)	X	X
12	Summary of Per Biopsied Lesion Proportion of CD206-Expressing Cells and Proportion of HHV8-Expressing Cells by IHC (ITD Population)	X	X
13	Summary of Per Biopsied Lesion HHV8 Quantitation by qPCR (ITD Population)	X	X
14	Subject-Level Localization in Areas Other Than KS Sites – Nuclear Medicine Findings (ITD Population)	X	X
15	Site-Level Localization in Areas Other Than KS Sites – Nuclear Medicine Findings (ITD Population)	X	X
16	Number and Percent of Subjects with Adverse Events (Safety Population)	X	X
17	Summary of Adverse Events (Safety Population)	X	X
18	Number and Percent of Subjects with Treatment Emergent Adverse Events (Safety Population)	X	X
19	Summary of Treatment Emergent Adverse Events (Safety Population)	X	X
20	Number and Percent of Subjects with Adverse Drug Reactions (Safety Population)	X	X
21	Number and Percent of Subjects with Serious Adverse Events (Safety Population)	X	X
22	Vital Sign Parameters Summary Statistics (Safety Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
23	Vital Sign Shift Table (Safety Population)	X	X
24	Clinical Laboratory Parameters Summary Statistics (Safety Population)	X	X
25	Clinical Laboratory Parameters Shift Table (Safety Population)	X	X
26	Electrocardiogram Parameters Summary Statistics (Safety Population)	X	X
27	Electrocardiogram Shift Table (Safety Population)	X	X
28	Number and Percent of Subjects Taking Concomitant Medications (Safety Population)	X	X

Listing No.	Data Listing Title	Included in Final Listings	Shown in Appendix B
DL1	Subject Disposition Data Listing	X	X
DL2	Inclusion/Exclusion Data Listing	X	X
DL3	Protocol Deviations Data Listing	X	X
DL4	Demographics Data Listing	X	X
DL5	Subjects Excluded from ITD Population Data Listing	X	X
DL6	Medical History Data Listing	X	X
DL7	Prior and Concomitant Medications Data Listing	X	X
DL8	Adverse Events Data Listing	X	X
DL9	Subject Laboratory Profiles - Hematology Data Listing	X	X
DL10	Subject Laboratory Profiles – Serum Chemistry Data Listing	X	X
DL11	Subject Laboratory Profiles – Urinalysis Data Listing	X	X
DL12	Electrocardiogram Data Listing	X	X
DL13	Physical Exam Data Listing	X	X
DL14	Vital Signs Data Listing	X	X
DL15	Study Drug Administration Data Listing	X	X
DL16	Post-Injection Imaging Data Listing	X	X
DL17	Quantitative Imaging Results Data Listing	X	X
DL18	Qualitative Imaging Results Data Listing	X	X
DL19	Lesion Biopsy Results Data Listing	X	X
DL20	Clinical KS Lesion Assessment Listing	X	X
DL21	Telephone Follow Up Contact Data Listing	X	X

8.0 References

NA

Appendix A – Tables, Figures and Listing Specifications

Orientation

Tables, figures, and listings will be displayed in landscape.

Margins

Margins will be 1 inch on all sides. Table, figure, and listing boundaries will not extend into the margins.

Font

Courier New, 8 point.

Headers

The table number will be on the second line of the title area. The title area will contain the Sponsor name, the study number, and the name of the table. The title area will contain the page number (Page x of y) on the far right, one line above the name of the table.

Footers

- The first line will be a solid line.
- Next will be any footnotes regarding information displayed in the table.
- Below these footnotes will be displayed “STATKING Clinical Services (Date)” on the far left.
- The last line will display the name of the SAS program that generated the table and (if applicable) the source data reference.

Table Disclaimer

The format of the mock tables shown in the appendix of this Statistical Analysis Plan (SAP) will be the format of the deliverable tables to the extent that Word document constructed tables can match production tables produced by SAS. This formatting includes the content and format of the header and footer areas of the tables. The Sponsor agrees to the format of the tables as shown in the appendix.

Further programming charges will be applicable for changes in the format of tables (including title statements, notes, data dependent footnotes, etc.) made after the approval of the SAP.

Missing Values

All missing values will be displayed on the output tables/listings as blanks.

Computation Values for Study Dates

The date format to be used is dd-mmm-yyyy. Missing parts of dates are not shown (e.g., for a missing day value, the value displayed is in mmm-yyyy format). When date computations are necessary, the following table indicates the substitutions used in order to make those computations.

Scenario	Value Used for Computations
Start date – Missing month and day values	January 1 of the indicated year
Start date – Missing day values	The first day of the indicated month
Stop date – Missing month and day values	December 31 of the indicated year
Stop date – Missing day values	The last day of the indicated month

Appendix B – Table Shells

Page x of y

Table 1. Subject Disposition by Cohort
Navidea Biopharmaceuticals - Study No. NAV3-24

		Cohort 1	Cohort 2	Cohort 3	Overall
Screen Failures		xx	xx	xx	xx
Enrolled		xx	xx	xx	xx
Completed		xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
Withdrawn		xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
Reason for Withdrawal	Adverse Event	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Lost To Follow-Up	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Death	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Physician Decision	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Protocol Deviation	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Study Terminated by Sponsor	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Withdrawal by Subject	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)
	Other	xx (xxx%)	xx (xxx%)	xx (xxx%)	xx (xxx%)

The denominator for all percentages in the table is the number of enrolled subjects in the respective cohort and overall.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 2. Demographics and Baseline Data Summary Statistics by Cohort – Continuous Variables
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Variable	Group	Mean	Std Dev	n	Min	Max	Median
Age (years)	Cohort 1	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 2	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 3	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Height (in)	Cohort 1	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 2	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 3	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Weight (lb)	Cohort 1	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 2	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 3	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Number of KS lesions[a]	Cohort 1	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 2	xxx	xxx	xxx	xxx	xxx	xxx
	Cohort 3	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx

[a] Number of KS lesions identified in screening, including cutaneous and non-cutaneous lesions.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 3. Demographics and Baseline Data Summary Statistics by Cohort – Categorical Variables
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Demographics Variable	Category	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Gender	Male	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	Female	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Race	American Indian or Alaska Native	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	Asian	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	Black or African American	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	Native Hawaiian or Other Pacific Islander	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	White	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	Other	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Ethnicity	Hispanic or Latino	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
	Not Hispanic or Latino	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 4. Summary of Study Drug Administration by Cohort
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

	Group	Mean	Std Dev	n	Min	Max	Median
Tc 99m Dose (mCi)	Cohort 1 IV	xxxx	xxxx	xx	xxxx	xxxx	xxxx
	Cohort 2 IV	xxxx	xxxx	xx	xxxx	xxxx	xxxx
	Cohort 3 IV	xxxx	xxxx	xx	xxxx	xxxx	xxxx
	Cohort 3 SC	xxxx	xxxx	xx	xxxx	xxxx	xxxx
Mass Dose (µg)	Cohort 1 IV	xxxx	xxxx	xx	xxxx	xxxx	xxxx
	Cohort 2 IV	xxxx	xxxx	xx	xxxx	xxxx	xxxx
	Cohort 3 IV	xxxx	xxxx	xx	xxxx	xxxx	xxxx
	Cohort 3 SC	xxxx	xxxx	xx	xxxx	xxxx	xxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 5. Subject-Level Localization of KS Lesions–Nuclear Medicine Findings
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Number of Subjects	Number (Proportion) Localized	95% Exact One-Sided Binomial CI for Proportion
Cohort 1 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 2 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 SC	xx	xxx (xxx)	(xxx, xxx)
All Cohorts Combined	xx	xxx (xxx)	(xxx, xxx)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 6. Lesion-Level Localization of KS Lesions–Nuclear Medicine Findings
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Number of Clinically Identified Lesions[a]	Number (Proportion) Localized by Imaging	95% Exact One-Sided Binomial CI for Proportion
Cohort 1 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 2 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 SC	xx	xxx (xxx)	(xxx, xxx)
All Cohorts Combined	xx	xxx (xxx)	(xxx, xxx)

[a] Number of cutaneous and non-cutaneous lesions identified in screening.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 7. Additional KS Lesions Identified from Imaging That Were Not Seen Clinically – Nuclear Medicine Findings
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Number of Identified Lesions	Number (Proportion) of Subjects with at Least 1 Identified Lesion
Cohort 1 IV	xx	xxx (xxx)
Cohort 2 IV	xx	xxx (xxx)
Cohort 3 IV	xx	xxx (xxx)
Cohort 3 SC	xx	xxx (xxx)
All Cohorts Combined	xx	xxx (xxx)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 8. Lesion-level Non-Localization of KS Lesions – Nuclear Medicine Findings
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Number of Clinically Identified Lesions[a]	Number (Proportion) Not Localized by Imaging	95% Exact One-Sided Binomial CI for Proportion
Cohort 1 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 2 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 SC	xx	xxx (xxx)	(xxx, xxx)
All Cohorts Combined	xx	xxx (xxx)	(xxx, xxx)

[a] Number of cutaneous and non-cutaneous lesions identified in screening.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 9. Number and Percentage of Concordant and Reverse Concordant Lesions
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

	SC Result					
IV Result	Localized	Not Localized	Total	Concordance	Reverse Concordance	p-Value (McNemar's Test)
Localized	xx(xxx%)	xx(xxx%)	xx(xxx%)	xxx (xxx%)	xxx (xxx%)	xxx
Not Localized	xx(xxx%)	xx(xxx%)	xx(xxx%)			
Total	xx(xxx%)	xx(xxx%)				

STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 10. Summary of Imaging-Localized Biopsied Lesion Localization Intensity by Cohort – Imaging = Planar
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Variable[a]	Mean	Std Dev	n	Min	Max	Median
Cohort 2 IV	Avg Pixel Intensity	xx	xx	xx	xx	xx	xx
	Percent Above Background	xx	xx	xx	xx	xx	xx
Cohort 3 IV	Avg Pixel Intensity	xx	xx	xx	xx	xx	xx
	Percent Above Background	xx	xx	xx	xx	xx	xx
All Cohorts Combined	Avg Pixel Intensity	xx	xx	xx	xx	xx	xx
	Percent Above Background	xx	xx	xx	xx	xx	xx

[a] All summary statistics are performed on the subject level.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 11. Summary of Imaging-Localized Biopsied Lesion Localization Intensity by Cohort – Imaging = SPECT/CT
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Variable[a]	Mean	Std Dev	n	Min	Max	Median
Cohort 2 IV	Avg Pixel Intensity	xx	xx	xx	xx	xx	xx
	Percent Above Background	xx	xx	xx	xx	xx	xx
Cohort 3 IV	Avg Pixel Intensity	xx	xx	xx	xx	xx	xx
	Percent Above Background	xx	xx	xx	xx	xx	xx
All Cohorts Combined	Avg Pixel Intensity	xx	xx	xx	xx	xx	xx
	Percent Above Background	xx	xx	xx	xx	xx	xx

[a] All summary statistics are performed on the subject level.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 12. Summary of Per Biopsied Lesion Proportion of CD206-Expressing Cells and Proportion of HHV8-Expressing Cells by IHC
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Variable	Mean	Std Dev	n	Min	Max	Median
Cohort 2	Proportion of CD206-Expressing Cells	xx	xx	xx	xx	xx	xx
	Proportion of HHV8-Expressing Cells	xx	xx	xx	xx	xx	xx
Cohort 3	Proportion of CD206-Expressing Cells	xx	xx	xx	xx	xx	xx
	Proportion of HHV8-Expressing Cells	xx	xx	xx	xx	xx	xx
All Cohorts Combined	Proportion of CD206-Expressing Cells	xx	xx	xx	xx	xx	xx
	Proportion of HHV8-Expressing Cells	xx	xx	xx	xx	xx	xx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 13. Summary of Per Biopsied Lesion HHV8 Quantitation by qPCR
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Variable (Unit)	Mean	Std Dev	n	Min	Max	Median
Cohort 2	HHV8 (RFU)	xx	xx	xx	xx	xx	xx
Cohort 3	HHV8 (RFU)	xx	xx	xx	xx	xx	xx

STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 14. Subject-Level Localization in Areas Other Than KS Sites – Nuclear Medicine Findings
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Number of Subjects	Number (Proportion) Localized	95% Exact One-Sided Binomial CI for Proportion
Cohort 1 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 2 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 IV	xx	xxx (xxx)	(xxx, xxx)
Cohort 3 SC	xx	xxx (xxx)	(xxx, xxx)
All Cohorts Combined	xx	xxx (xxx)	(xxx, xxx)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 15. Site-Level Localization in Areas Other Than KS Sites – Nuclear Medicine Findings
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Group	Anatomical Site	Number (Proportion) of Subjects with Site Localized	95% Exact One-Sided Binomial CI for Proportion
Cohort 1 IV	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxx (xxx)	(xxx, xxx)
Cohort 2 IV	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxx (xxx)	(xxx, xxx)
Cohort 3 IV	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxx (xxx)	(xxx, xxx)
Cohort 3 SC	xxxxxxxxxxxxxxx xxxxxxxxxxxxxxx	xxx (xxx)	(xxx, xxx)
All Cohorts Combined	xxxxxxxxxxxxxxx	xxx (xxx)	(xxx, xxx)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 16. Number and Percent of Subjects with Adverse Events
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Adverse Event Category[a]:	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Total Number of Adverse Events	xxx	xxx	xxx	xxx
Subjects with at Least One Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 17. Summary of Adverse Events
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxxx)

	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Subjects with at Least One Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Maximum AE Severity Grade				
Mild	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Moderate	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Severe	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Highest Relationship of AE to Tc 99m Tilmanocept				
Definitely Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Possibly [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Definitely [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Highest Relationship of AE to Study Procedure				
Definitely Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Possibly [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Definitely [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Subjects with at Least One Serious Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 18. Number and Percent of Subjects with Treatment Emergent Adverse Events
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Adverse Event Category[a]:	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Total Number of Treatment Emergent Adverse Events (TEAEs)	xxx	xxx	xxx	xxx
Subjects with at Least One TEAE	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 19. Summary of Treatment Emergent Adverse Events
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxxx)

	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Subjects with at Least One Treatment Emergent Adverse Event (TEAE)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Maximum TEAE Severity Grade				
Mild	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Moderate	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Severe	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Highest Relationship of TEAE to Tc 99m Tilmanocept				
Definitely Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Possibly [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Definitely [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Highest Relationship of TEAE to Study Procedure				
Definitely Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably Not [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Possibly [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Probably [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Definitely [n(%)]	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Subjects with at Least One Serious TEAE Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 20. Number and Percent of Subjects with Adverse Drug Reactions
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Adverse Event Category[a]:	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Total Number of Adverse Drug Reactions[b]	xxx	xxx	xxx	xxx
Subjects with at Least One Adverse Drug Reaction	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] Adverse drug reactions are defined as all noxious and unintended responses to a medicinal product related to any dose or dose regimen. The phrase 'responses to a medicinal product' means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e. the relationship cannot be ruled out.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 21. Number and Percent of Subjects with Serious Adverse Events
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Adverse Event Category[a]:	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Total Number of Serious Adverse Events	xxx	xxx	xxx	xxx
Subjects with at Least One Serious Adverse Event	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
System Organ Class 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 22. Vital Sign Parameters Summary Statistics
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Group	Vital Sign Parameter (units)	Visit	Data Type[a]	Mean	Std Dev	n	Min	Max	Median
Cohort 1 IV	xxxxxxxxxx (xxx)	Pre-Injection (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 2 IV	xxxxxxxxxx (xxx)	Pre-Injection (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 3 IV	xxxxxxxxxx (xxx)	Pre-Injection (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 3 SC	xxxxxxxxxx (xxx)	Pre-Injection (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
All IV Cohorts	xxxxxxxxxx (xxx)	Pre-Injection (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = data recorded in database; CFB = change from baseline
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 23. Vital Sign Shift Table
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Group	Vital Sign Parameter (units)	Baseline Normal/Post Normal	Baseline Abnormal/Post Normal	Baseline Normal/Post Abnormal	Baseline Abnormal/Post Abnormal
Cohort 1 IV	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
Cohort 2 IV	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
Cohort 3 IV	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
Cohort 3 SC	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
All IV Cohorts	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 24. Clinical Laboratory Parameters Summary Statistics
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Group	Laboratory Panel/ Parameter (units)	Visit	Data Type[a]	Mean	Std Dev	n	Min	Max	Median
Cohort 1 IV	xxxxxxxxxxxx/ xxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 2 IV	xxxxxxxxxxxx/ xxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 3 IV	xxxxxxxxxxxx/ xxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 3 SC	xxxxxxxxxxxx/ xxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
All IV Cohorts	xxxxxxxxxxxx/ xxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = data recorded in database; CFB = change from baseline
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 25. Clinical Laboratory Parameters Shift Table
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Group	Laboratory Panel/Parameter (units)	Baseline Normal/Post Normal	Baseline Abnormal/Post Normal	Baseline Normal/Post Abnormal	Baseline Abnormal/Post Abnormal
Cohort 1 IV	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
Cohort 2 IV	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
Cohort 3 IV	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
Cohort 3 SC	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
All IV Cohorts	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
	xxxxxxxxxxxx/xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Table 26. Electrocardiogram Parameters Summary Statistics
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Group	Parameter (units)	Visit	Data Type[a]	Mean	Std Dev	n	Min	Max	Median
Cohort 1 IV	xxxxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 2 IV	xxxxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 3 IV	xxxxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Cohort 3 SC	xxxxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
All IV Cohorts	xxxxxxxxxxxx (xxx)	Screening (Baseline)	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		30 min Post-Injection	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = data recorded in database; CFB = change from baseline
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Table 27. Electrocardiogram Shift Table
Navidea Biopharmaceuticals – Study No. NAV3-24
Safety Population (N=xxx)

Group	Baseline Normal/Post Normal	Baseline Abnormal/Post Normal	Baseline Normal/Post Abnormal	Baseline Abnormal/Post Abnormal
Cohort 1 IV	xxx	xxx	xxx	xxx
Cohort 2 IV	xxx	xxx	xxx	xxx
Cohort 3 IV	xxx	xxx	xxx	xxx
Cohort 3 SC	xxx	xxx	xxx	xxx
All IV Cohorts	xxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 28. Number and Percent of Subjects Taking Concomitant Medications
Navidea Biopharmaceuticals – Study No. NAV3-24
Safety Population (N=xxx)

Medication[a]:	Cohort 1 (N=xxx)	Cohort 2 (N=xxx)	Cohort 3 (N=xxx)	Overall (N=xxx)
Total Number of Medications	xxx	xxx	xxx	xxx
Patients Taking at Least One Medication	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
ATC Level 4 Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
ATC Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
ATC Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
ATC Level 4 Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
ATC Preferred Term 1	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)
ATC Preferred Term 2	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)	xxx (xxx%)

[a] Medications coded with WHO Coding Dictionary xxxxxxxx.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 1. Subject Disposition Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24

Cohort	Subject No.	Disposition Status	Date of Completion or Withdrawal	Withdrawal Reason
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 2. Inclusion/Exclusion Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24

Cohort	Subject No.	Did Subject Meet All Eligibility Criteria?	Criterion	Criterion Category	Was a Waiver Granted?	Is Subject a Screen Failure?
xxxxxx	xxxx	xxxx	Xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxx	Xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxx	Xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxx	Xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxx	xxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 3. Protocol Deviations Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24

Cohort	Subject No.	Subject Visit	Date of Deviation	Deviation Description	Deviation Category
xxxxxx	xxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxxxx	xxxx	xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 4. Demographics Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	Informed Consent Date/Time	Date of Birth	Age (yrs)	Gender	Race	Ethnicity	Screening Height (in)	Screening Weight (lb)	KS Lesions at Screening
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxx	xxxxxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 5. Subjects Excluded from ITD Population Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
All Enrolled Subjects (N=xxx)

Cohort	Subject No.	Reason for Exclusion
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 6. Medical History Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Start Date	Ongoing?
xxxxxx	xxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxx
		xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxx

[a] Medical history terms coded with MedDRA Coding Dictionary Version xxx.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 7. Prior and Concomitant Medications Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	WHO Drug Preferred Term[a]/ Verbatim Drug Name/ Indication/ ATC Level 1 Code/ ATC Level 4 Code	Start Date	Stop Date	Route	Ongoing?
xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	xxxxx	xxxxx
xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	xxxxx	xxxxx

[a] Concomitant medications coded with WHO Coding Dictionary xxxxxxxxx
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 8. Adverse Events Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	AE Start Date and Time/ End Date and Time	Start Date and Time of most recent tilmanocept Injection	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Treatment Emergent?	Adverse Drug Reaction (Y/N)	Severity	Relation to: Tc-99m tilmanocept/ Procedure	Serious	Outcome
xxxxxx	xxxxxxxxx	xxxxxxx xxxxxxx/ xxxxxxx xxxxxxx	xxxxxxx xxxxxxx	xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx	xxx	xxx	xxxxxxxx	xxxxxxxx/ xxxxxxxx	xxx	xxxxxxx x
xxxxxx	xxxxxxxxx	xxxxxxx xxxxxxx/ xxxxxxx xxxxxxx	xxxxxxx xxxxxxx	xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx	xxx	xxx	xxxxxxxx	xxxxxxxx/ xxxxxxxx	xxx	xxxxxxx x

[a] Adverse events coded with MedDRA Coding Dictionary Version xxx.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 9. Subject Laboratory Profiles - Hematology Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

						Normal Range		
Cohort	Subject No.	Visit	Sample Date/ Time	Parameter (Units)	Result	Lab Low	Lab High	Clin. Sig?
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx xx:xx	xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 10. Subject Laboratory Profiles – Serum Chemistry Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

						Normal Range		
Cohort	Subject No.	Visit	Sample Date/ Time	Parameter (Units)	Result	Lab Low	Lab High	Clin. Sig?
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx xx:xx	xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 11. Subject Laboratory Profiles – Urinalysis Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

						Normal Range		
Cohort	Subject No.	Visit	Sample Date/ Time	Parameter (Units)	Result	Lab Low	Lab High	Clin. Sig?
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx xx:xx	xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx
				xxxxxxxxxxxxx (xxx)	xxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 12. Electrocardiogram Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	Visit	Date	Time	Heart Rate (bpm)	PR Interval (msec)	QRS Duration (msec)	QT Interval (msec)	QTcF Interval (msec)	ECG Assessment/ If Abnormal, Specify
xxxxxx	xxxx	xxxxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxxxx/ xxxxxxxxxxxxxxxxxxx
		xxxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxx	xxxxxxx/ xxxxxxxxxxxxxxxxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 13. Physical Exam Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	Visit	Date	Body System	Result	Abnormality
xxxxxx	xxxx	xxxxxxx	xxxxxxx	General Appearance	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Skin	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Eyes, Ears, Nose, Throat	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Head and Neck	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Heart	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Lungs	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Abdomen	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Lymph Nodes	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				Musculoskeletal	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				CNS/Neurological	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 14. Vital Signs Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	Visit/ Date	Time	Temperature (°F) Value	Temperature (°F) Normal (Y/N)	Systolic Blood Pressure (mmHg) Value	Systolic Blood Pressure (mmHg) Normal (Y/N)	Diastolic Blood Pressure (mmHg) Value	Diastolic Blood Pressure (mmHg) Normal (Y/N)	Heart Rate (bpm) Value	Heart Rate (bpm) Normal (Y/N)	Respirations per Minute Value	Respirations per Minute Normal (Y/N)
xxxxxx	xxxx	xxxxxxx/ xxxxxx	xxxxx	xxx	x	xxx	x	xxx	x	xxx	x	xxx	x
			xxxxx	xxx	x	xxx	x	xxx	x	xxx	x	xxx	x
			xxxxx	xxx	x	xxx	x	xxx	x	xxx	x	xxx	x
xxxxxx	xxxx	xxxxxxx/ xxxxxx	xxxxx	xxx	x	xxx	x	xxx	x	xxx	x	xxx	x
			xxxxx	xxx	x	xxx	x	xxx	x	xxx	x	xxx	x
			xxxxx	xxx	x	xxx	x	xxx	x	xxx	x	xxx	x

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 15. Study Drug Administration Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	Date/ Time of Injection	Anatomic Location of Injection	Pre-Injection Radioactivity (mCi)/Time of Measurement	Post-Injection Radioactivity (mCi)/Time of Measurement	Calculated Amount of Administered Radioactivity (mCi)	Calculated Mass Dose (µg)	Lot Number
xxxxxx	xxxx	xxxxxxxx/ xxxx	xxxxxxxx	xxx/ xxxx	xxx/ xxxx	xxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxx/ xxxx	xxxxxxxx	xxx/ xxxx	xxx/ xxxx	xxx	xxx	xxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 16. Post-Injection Imaging Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Cohort	Subject No.	Date of Imaging	Start Time of Planar Imaging	SPECT/CT Imaging Start Time
xxxxxx	xxxx	xxxxxx	xx:xx	xx:xx
xxxxxx	xxxx	xxxxxx	xx:xx	xx:xx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 17. Quantitative Imaging Results Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Cohort	Subject No.	Identified Clinically or with Imaging?	Lesion[a]	Average Pixel Intensity	Average Background Intensity	Percent Above Background
xxxxxx	xxxx	xxxxxxx	xxxxxxxxxx	xxxx	xxxx	xxxx
xxxxxx	xxxx	xxxxxxx	xxxxxxxxxx	xxxx	xxxx	xxxx

[a] Lesions previously identified clinically and biopsied.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 18. Qualitative Imaging Results Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Cohort	Subject No.	Identified Clinically or with Imaging?	Lesion[a]	Reader Visualization
xxxxxx	xxxx	xxxxxxx	xxxxxxxxxx	xxx
xxxxxx	xxxx	xxxxxxx	xxxxxxxxxx	xxx

[a] Lesions previously identified clinically and those additional lesions identified on imaging.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 19. Lesion Biopsy Results Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)

Cohort	Subject No.	Biopsy Date/Time	Location of Lesion[a]	Measurement of Biopsy (mm)	HHV8 RFU	Proportion of CD206-expressing Cells	Proportion of HHV8-expressing Cells
xxxxxx	xxxx	xxxxxxxxxxx / xx:xx	xxxxxxxxxx	xxx	xxxxx	xxxx	xxxx
xxxxxx	xxxx	xxxxxxxxxxx / xx:xx	xxxxxxxxxx	xxx	xxxxx	xxxx	xxxx

[a] Lesions previously identified clinically and biopsied.
Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Page x of y

Data Listing 20. Clinical KS Lesion Assessment Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)
Part 1 of 2

Cohort[a]	Subject No.	Assessment Date	KS Diagnosis Date	Biopsy Confirmation Date	KS Classification[b]
xxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx	x
xxxxxx	xxxx	xxxxxxxxxx	xxxx	xxxx	x

[a] Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
[b] 1 = Confirmed cutaneous or oral lesions without edema, 2 = Confirmed cutaneous or oral lesions with edema, 3 = Confirmed cutaneous or oral lesions with or without edema and suspected or confirmed non-cutaneous lesions.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas

Data Listing 20. Clinical KS Lesion Assessment Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
ITD Population (N=xxx)
Part 2 of 2

Suspected Non-Cutaneous KS/Location Symptomology	Confirmed Non-Cutaneous KS/Location Symptomology	Number of Overall Lesions	Lesion Number	Lesion Type/Location	Edema Present?/ Edema Scale
xxxx	x	xxx	xx	xxxx/xxxxx	xxx/x
			xx	xxxx/xxxxx	xxx/x
			xx	xxxx/xxxxx	xxx/x
xxxx	x	xxx	xx	xxx/xxxx	xxx/x
			xx	xxxx/xxxxx	xxx/x

Data Listing 21. Telephone Follow Up Contact Data Listing
Navidea Biopharmaceuticals - Study No. NAV3-24
Safety Population (N=xxx)

Cohort	Subject No.	Was Telephone Contact Performed?	Date of Contact	Time of Contact	Any AEs Since Previous Visit?	Changes in Medications Since Previous Visit?
xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx

Cohort 1 = 100µg/5mCi IV; Cohort 2 = 100µg/10mCi IV; Cohort 3 = 200µg/5mCi IV and SC.
STATKING Clinical Services (DD-MMM-YYYY)
Source Program: xxxxxxx.sas