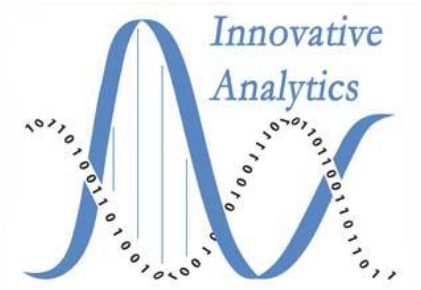


STATISTICAL ANALYSIS PLAN (SAP)

Protocol Number:	RIV-HU6-203
Protocol Title:	A 61-day Randomized, Double-blind, Placebo-controlled Trial to Assess the Safety and Efficacy of Three Doses of HU6 in Subjects with Elevated Liver Fat and High Body Mass Index (28 to 45 kg/m2)
Product Name or Number:	HU6
Protocol Version	Version 2.0, 04 May 2021
Sponsor:	Rivus Pharmaceuticals, Inc. 706b Forest Street, Charlottesville, VA 22903 USA
SAP Prepared by:	Kimberly T Perry, PhD Innovative Analytics, Inc. 161 East Michigan Ave Kalamazoo, MI 49007 USA
SAP Version Number (Date):	Version 4.0 (13 December 2021)

TABLE OF CONTENTS

1 LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation or Term	Definition
AE	adverse event
ANCOVA	analysis of covariance
BMI	body mass index
CAP	controlled attenuation parameter
CI	confidence interval
C_{max}	maximum plasma drug concentration
DNP	2,4-dinitrophenol
ECG	electrocardiogram
ELF	enhanced liver fibrosis
FAS	full analysis set
FFA	free fatty acid
HbA_{1c}	glycosylated hemoglobin (hemoglobin A1c)
HDL	high- density lipoprotein
HOMA-IR	homeostatic model assessment for insulin resistance
hs-CRP	high sensitivity C-reactive protein
ITT	intent-to-treat
LDL	low-density lipoprotein
LS Means	least squares means
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	mixed model for repeated measures
MRI	magnetic resonance imaging
MRI-PDFF	magnetic resonance imaging proton density fat fraction
OWL	One Way Liver
PD	pharmacodynamic(s)
PK	pharmacokinetic(s)
POPEth	phosphatidylethanol (PEth) 16.0/18.1
QD	once daily
TEAE	treatment-emergent adverse event
VCTE	vibration-controlled transient elastography

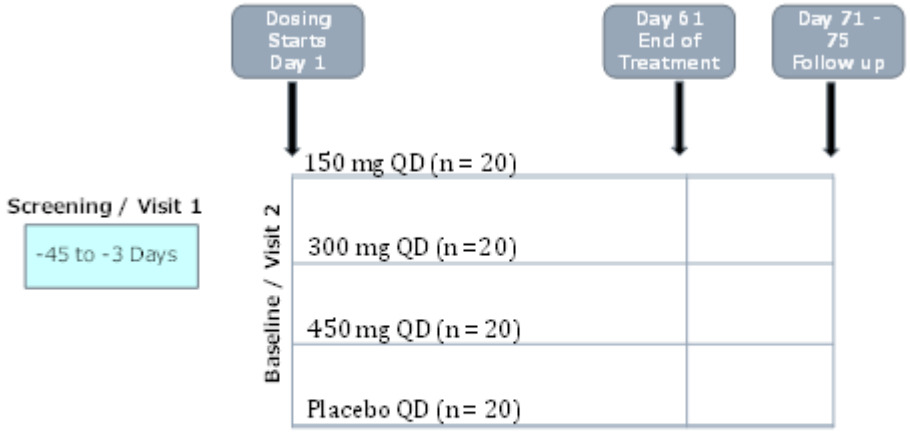
2 STUDY OVERVIEW

This is a Phase 2a, multi-site, randomized, parallel-group, placebo-controlled, double-blind, repeated-dose study to evaluate the safety and efficacy of three oral dose levels of HU6 compared to placebo over the course of 61 days in subjects with high body mass index (BMI) and evidence of elevated liver fat.

Subjects will be screened over a 45-day period to determine eligibility based on specific history, physical, laboratory and imaging evaluations. Due to scheduling of the procedures, multiple visits will likely be necessary to complete the screening process. However, if all screening assessments and procedures, including the magnetic resonance imaging (MRI), can be completed within 30 days of the first dose, then a single screening visit is permissible.

Once qualified, subjects will be randomly assigned to one of the HU6 treatment groups or the matched placebo control group and dosed once daily (QD) in a fasting state for a total of 61 days. Subjects will return to the clinic for frequent assessment visits during the 61 days of dosing. A follow-up visit will occur within 10 to 14 days following the completion of dosing (Figure 1).

Figure 1: Study Schematic



10 Visits, Screening, Baseline/ First dose, Day 2, Day 7, Day 14, Day 28, Day 42, Day 49, Day 61 / end of treatment, and Follow up at Day 71 – 75.

Visit procedures include PK and PD measures and safety assessments.

Subjects will be instructed to maintain their same diet and activity/exercise level throughout the study as they had prior to participation in the study.

Dosing will take place once daily in a fasted state. Eligible subjects will be randomized equally (N = 20 per group) to 1 of 4 treatment groups:

- Group 1: matched placebo orally once daily for 61 days.
- Group 2: 150 mg HU6 orally once daily for 61 days.
- Group 3: 300 mg HU6 orally once daily for 61 days.
- Group 4: 450 mg HU6 orally once daily for 61 days.

The randomization will be blocked and stratified by HbA_{1c}. Subjects will be stratified into two HbA_{1c} strata: one subgroup of subjects with normal baseline HbA_{1c} defined as HbA_{1c} <5.7% and the other subgroup of subjects with high baseline HbA_{1c} defined as HbA_{1c} between 5.7% and 9.0% inclusive).

3 STUDY OBJECTIVES

The primary efficacy and safety objectives of this study are:

Efficacy:

- To evaluate the reduction in liver fat content, as assessed by magnetic resonance imaging proton density fat fraction (MRI-PDFF), from baseline to Day 61 in subjects with elevated BMI treated with HU6 compared to placebo.

Safety:

- To evaluate safety and tolerability of 61 days of repeated daily dosing of HU6 in overweight and obese subjects as defined by BMI.

The secondary objectives of this study are:

- To assess the rate and amount of body weight loss after 61 days of HU6 treatment.
- To assess change from baseline in whole body adiposity by MRI after 61 days of HU6 treatment.
- To characterize the pharmacokinetic (PK) profile of HU6 and its metabolites, DNP and M1, over 61 days of dosing in subjects with high BMI.
- To evaluate and correlate changes from baseline in measures of liver composition with changes in liver fat content after dosing with HU6.
- To investigate the pharmacodynamic (PD) effects of HU6 on metabolic and cardiovascular risk factors.
- To investigate the PD effects of HU6 on metabolomic, proteomic, and lipidomic profiles.
- To characterize the dose/exposure relationships of the efficacy and PD effects of HU6, as data allow.

4 STUDY ENDPOINTS

4.1 Primary Endpoint

- Relative change from baseline in liver fat content, as assessed by MRI-PDFF at Day 61.

4.2 Secondary Endpoints

Pharmacodynamics

- Change from baseline in body weight at Day 61.

- Change from baseline in whole body adiposity at Day 61 [i.e., total visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT)]
- Changes from baseline in surrogate measures of liver inflammation and fibrosis at Day 61: Fibroscan® Vibration-controlled Transient Elastography (VCTE), Fibroscan® Controlled Attenuation Parameter (CAP) score, and Enhanced Liver Fibrosis (ELF) score.
- Change from baseline in lipid parameters and cardiovascular risk biomarkers at Day 61: serum high sensitivity C-reactive protein (hs-CRP), Lp(A), Apo B, low-density lipoprotein (LDL), high-density lipoprotein (HDL), total cholesterol, triglycerides, and free fatty acids (FFA).
- Change from baseline in metabolic disease parameters at Day 61: homeostatic model assessment for insulin resistance (HOMA-IR), fasting blood glucose concentrations, glycated albumin concentrations, HbA_{1c}.

Safety and Tolerability

- Summary of physical examinations findings over the course of the study.
- Adverse event (AE) assessment over the course of the study.
- Assessment of vital sign parameters over the course of the study, including resting systolic and diastolic blood pressure, resting heart rate, resting respiratory rate, and oral body temperature.
- Assessment of body weight over the course of the study.
- Safety 12-lead electrocardiograms (ECGs) over the course of the study.
- Assessment of clinical laboratory values (hematology, full biochemistry panel (including lipid panel, creatinine phosphokinase (CPK), magnesium, liver function tests, and urinalysis over 61 days of dosing.
- Assessment of ophthalmologic examination, including slit lamp, prior to and after 61 days of dosing.

Pharmacokinetics

- Population PK analysis of HU6 parent and metabolites, DNP and M1. The following PK parameters will be estimated as appropriate: maximum observed plasma drug concentration (C_{max}), time to peak plasma concentration (T_{max}), apparent terminal half-life ($t_{½}$), delay between the time of dosing and time of appearance of concentration in the sampling compartment (T_{lag}), area under the concentration-time curve from time zero to the time of the last measurable concentration (AUC_t), area under the concentration-time curve from time zero to infinity (AUC_{inf}), apparent oral clearance (CL/F), apparent volume of distribution (V_z/F), apparent terminal elimination rate constant (λ_z). Other PK parameters may be calculated, as data allow and as appropriate.
- As data permit, noncompartmental analysis of HU6 parent and metabolites, DNP and M1. The following PK parameters will be calculated: C_{max}, AUC, and accumulation.

- Modeling of exposure response relationships of HU6, DNP, and M1 and efficacy/pharmacodynamic endpoints, as appropriate.

4.3 Exploratory Endpoints

- Change from baseline in metabolomic and lipidomic profiles (One Way Liver-[OWL] metabolomic and lipidomic assays) at Day 61.
- Change from baseline in proteomic profiles (SomaScan®) at Day 61.
- Change from baseline in serum alanine aminotransferase (ALT) and aspartate aminotransferase (AST) concentrations at Day 61, as data allow.

5 GENERAL METHODS

5.1 Analysis Populations

The analysis populations will be as follows:

Intent-to-Treat (ITT): includes all randomized subjects. Subjects will be analyzed according to treatment as randomized.

Full Analysis Set (FAS): includes all randomized subjects who receive at least 1 dose of treatment and have <= 10 pounds of weight gain or weight lost from screening visit to Day 1. Subjects will be analyzed according to treatment as randomized.

Safety: includes all randomized subjects who receive at least 1 dose of treatment. Subjects will be analyzed according to treatment as received.

The PK concentration population and the PK parameter population will be defined in the PK analysis plan.

5.2 Summarization of Data

Study results will be summarized by treatment group (i.e., 150 mg QD, 300 mg QD, 450 mg QD, and Placebo) in tabular format with descriptive statistics and/or in subject listings.

For placebo-corrected results, at each visit, the average placebo mean change from baseline will be subtracted from each subject's mean change from baseline.

Statistical testing will be 2-sided and performed using a significance (alpha) level of 0.05. There will be no adjustment for multiple comparisons for this exploratory study.

No imputation of missing data will be performed. No windowing of visits will be performed unless otherwise specified.

5.3 Sample Size Justification

A sample size of 17 subjects per group provides at least 80% power to detect a 30% difference in the mean relative change from baseline in liver fat content at Day 61, when the standard deviation is 30% [PASS 2020: Two sample t-test, alpha=.05]. Assuming a 15% dropout rate, up

to 80 subjects should be enrolled to ensure that at least 68 subjects, 17 per group, are evaluable for the primary efficacy endpoint analysis.

5.4 Output Production and Validation

All analyses will be performed using SAS V 9.3 or higher (SAS Institute, Inc, Cary, North Carolina, USA). Validation and quality control of the tables and listings, which display the results of the statistical analysis of the data from this study, will follow the appropriate Innovative Analytics standard operating procedures (SOPs).

6 SUBJECT DISPOSITION

The number of subjects who are in the intent-to-treat (ITT) population, who are in the full analysis set (FAS) population, who are in the safety population, who complete the study, and who discontinue from the study, along with reason of study discontinuation, will be summarized in tabular format for the ITT population. Subject disposition information will be displayed for the ITT population in a subject listing.

7 DEMOGRAPHIC CHARACTERISTICS

For quantitative variables (e.g., age, height, weight, BMI), summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for all subjects in the safety population. For qualitative variables (e.g., sex, race, ethnicity), results will be summarized for all subjects in the safety population as counts and percentages. Individual demographic information for the safety population will be displayed in subject listings.

8 MEDICAL HISTORY

Medical history findings will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) coding system (using MedDRA Version stated in Data Management Plan). Medical history findings will be summarized by System Organ Class and Preferred Term. Individual medical history findings will be listed for the safety population.

9 PHYSICAL EXAMINATION

Abnormal physical examination findings will be listed for the safety population.

10 PRIOR AND CONCOMITANT MEDICATIONS

Medications will be coded using World Health Organization Drug Dictionary (WHODRUG, version specified in the Data Management Plan). Prior medications and concomitant medications will be summarized separately by Anatomical Therapeutic Chemical (ATC) Level 4 term and Preferred Name. Prior medications are defined as medications taken prior to the first dose of study drug, including those medications that were continued during the study. Concomitant medications will be defined as medications started after the first dose of study medication. Individual medications will be displayed in subject listings.

11 EFFICACY ANALYSES

The primary efficacy endpoint will be the reduction in liver fat content measured by the relative change from baseline, as assessed by MRI-PDFF at Day 61. The hypotheses of interest are 2-sided tests comparing each active HU6 treatment group to the placebo group.

$$H_{01}: \mu_{placebo} = \mu_{HU6\ 150mg} \text{ vs } H_{11}: \mu_{placebo} \neq \mu_{HU6\ 150mg}$$
$$H_{02}: \mu_{placebo} = \mu_{HU6\ 300mg} \text{ vs } H_{12}: \mu_{placebo} \neq \mu_{HU6\ 300mg}$$
$$H_{03}: \mu_{placebo} = \mu_{HU6\ 450mg} \text{ vs } H_{13}: \mu_{placebo} \neq \mu_{HU6\ 450mg}$$

Summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for the observed values for MRI-PDFF at each time point for the FAS population, as described in Section 5.2, Summarization of Data. Summary statistics will also be presented for the change-from-baseline values to each postbaseline time point as well as placebo-corrected change-from-baseline values to each postbaseline time point. In these displays, baseline will be defined as the last non-missing value prior to first dose of study medication. Figures will be generated appropriate to the data output.

Mean change from baseline in liver fat content will be analyzed for the FAS population using an analysis of covariance (ANCOVA) model, including treatment group, HbA_{1c} stratification (normal range versus between 5.7% and 9.0% inclusive) and baseline liver fat from MRI-PDFF as fixed effects. This estimand will include available MRI-PDFF evaluations that occur before discontinuation of treatment. The difference in LS Means for the change from baseline, corresponding 95% CIs, and P values will be provided to assess the treatment differences between placebo and each HU6 treatment group. A separate comparison of the combined HU6 groups and placebo may be conducted.

Responder status (n, %) at Day 61 will be presented. A subject will be deemed a responder if their MRI-PDFF showed a 30% or more reduction from baseline at Day 61. Additional exploratory analysis may be performed such as a different threshold then the 30% or more reduction from baseline due to the short duration of the study.

The above summary statistics, an ANCOVA model including treatment group and the baseline score of the response variable as fixed effects, and the responder status will also be presented for the subjects randomized only to the HbA1c between 5.7% and 9.0% subgroup.

All MRI-PDFF results will be displayed in subject listings.

12 PHARMACODYNAMICS ANALYSES

For each pharmacodynamic variable, summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for the observed values at each time point for the FAS population, as described in Section 5.2, Summarization of Data. Summary statistics will also be presented for the change-from-baseline values to each postbaseline time point. For glycated albumin, placebo-corrected change-from-baseline values to each postbaseline time point will be presented. In these displays, baseline will be defined as the last non-missing value prior to first dose of study medication. Figures will be generated appropriate to the data output.

For pharmacodynamic variables with only a Day 61 post-baseline assessment [i.e., ELF variables, HbA_{1c}, abdominal MRI [liver volume, VAT, and SAT], and Fibroscan [Steatosis/VCTE and Fibrosis/CAP], summary statistics will be presented for the change-from-baseline values for each variable at Day 61. Placebo-corrected change-from-baseline values at Day 61 will be presented for abdominal MRI [liver volume, total visceral adipose tissue (VAT) and subcutaneous adipose tissue (SAT)], and Fibrosis/CAP. The ELF variables will be ELF score, hyaluronic acid, procollagen III amino-terminal peptide (PIIINP), and tissue inhibitor of matrix metalloproteinase 1 (TIMP-1). Figures will be generated appropriate to the data output.

For each pharmacodynamic variable with only a Day 61 post-baseline assessment, mean change from baseline will be analyzed for the FAS population using an ANCOVA model, including treatment group, HbA_{1c} stratification (normal range versus between 5.7% and 9.0% inclusive) and the baseline score of the response variable as fixed effects. The difference in LS Means for the change from baseline, corresponding 95% CIs, and P values will be provided to assess the treatment differences between placebo and each HU6 treatment group.

For the abdominal MRI liver volume and adiposity, the above summary statistics, an ANCOVA model including treatment group and the baseline score of the response variable as fixed effects, and the responder status will also be presented for the subjects randomized only to the HbA1c between 5.7% and 9.0% subgroup.

Continuous pharmacodynamic endpoints with repeated post-baseline assessments [changes from baseline in ApoB, Lp(a), glycated albumin, hs-CRP, liver panel parameters (total cholesterol, HDL, calculated LDL, VLDL, triglycerides, and FFA), HOMA-IR Calc (i.e., the average of the 3 blood draws 5 minutes apart at each scheduled visit), body weight (via InBody Scale), and fasting blood glucose] will be analyzed for the FAS population using a mixed model for repeated measures (MMRM). The estimand will include available post-baseline response data that occur before discontinuation of treatment. The baseline score will be included as the covariate, and HbA_{1c} stratification, treatment group, visit, and the interaction between treatment group and visit will be estimated based on the LSMeans from the MMRM.

For body weight, a responder status (n, %) at Day 61 will be presented. A subject will be deemed a responder if their body weight showed a 1% or more reduction from baseline at Day 61. Additional exploratory analysis may be performed.

In addition, for body weight, the above summary statistics, an MMSE analysis and the responder status will also be presented for the subjects randomized only to the HbA1c between 5.7% and 9.0% subgroup. For the MMRM, the baseline score will be included as the covariate, and treatment group, visit, and the interaction between treatment group and visit will be estimated based on the LSMeans from the MMRM.

All pharmacodynamic results will be displayed in subject listings.

13 SAFETY ANALYSES

13.1 Adverse Events

Adverse events will be coded using the MedDRA coding system (using MedDRA Version stated in Data Management Plan). An overall summary table will be presented to summarize all

treatment-emergent AEs (TEAEs), all treatment-emergent study drug-related AEs, all severe TEAEs, deaths, all serious TEAEs, and all study drug discontinuations due to TEAEs for all subjects in the safety population as described in Section 5.2, Summarization of Data. In addition, frequency tables will present all TEAEs by System Organ Class and Preferred Term and study drug-related TEAEs by System Organ Class and Preferred Term, with a separate display of study-drug related TEAEs by maximum severity for all subjects in the safety population.

If an AE occurs after the informed consent form has been signed and before the time of the first dose of study drug, it will be considered a pretreatment AE. If an AE occurs at the time of or after the first dose of study drug or if the pretreatment AE worsens, it will be considered a treatment-emergent AE.

If the relationship to study medication is missing, it will be assumed to be related to study medication for analysis purposes.

In all displays, AEs will be displayed by MedDRA System Organ Class and Preferred Term, with subjects who have the same AE counted only once for that event and subjects who have more than one AE within a System Organ Class counted only once in that System Organ Class.

13.2 Laboratory Tests (Hematology, Serum Chemistry, Urinalysis, and PEth 16.0/18.1 (POPEth))

Summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for the observed values for hematology, serum chemistry, urinalysis, and PEth 16.0/18.1 (POPEth) at each time point for the safety population, as described in Section 5.2, Summarization of Data. Summary statistics will also be presented for the change-from-baseline values to each postbaseline time point. In these displays, baseline will be defined as the last non-missing value prior to first dose of study medication. Figures will be generated appropriate to the data output.

A shift table will be presented for baseline versus each post-baseline visit for absolute neutrophil count using following grades:

- Normal: >=2.5 neutrophils (10**9/L);
- Grade 1: 1.5 to <2.5 neutrophils (10**9/L);
- Grade 2: 1.0 to <1.5 neutrophils (10**9/L);
- Grade 3: 0.5 to <1.0 neutrophils (10**9/L);
- Grade 4: <0.5 neutrophils (10**9/L)

Hematology, chemistry, urinalysis, and POPEth panel results will be listed, with values falling outside the laboratory reference range flagged.

Laboratory reference ranges will be provided by the laboratory site(s) and will be included in the clinical study report.

13.3 Vital Signs

Supine vital signs will be collected. Summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for the observed values for systolic and diastolic blood pressures, pulse rate, respiratory rate, body temperature, and weight at each time point for the safety population, as described in Section 5.2, Summarization of Data. Summary statistics will also be presented for the change-from-baseline values to each postbaseline time point. In these displays, baseline will be defined as the last non-missing value prior to first dose of study medication. Figures will be generated appropriate to the data output.

All vital sign results will be displayed in subject listings.

13.4 InBody Scale Measurements

Summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for the observed values for InBody scale measurements (i.e., total body water, lean body mass, percent body fat, body fat mass, skeletal muscle mass, dry lean mass, and visceral fat) at each time point for the safety population, as described in Section 5.2, Summarization of Data. Summary statistics will also be presented for the change-from-baseline values to each postbaseline time point as well as placebo-corrected change-from-baseline values to each postbaseline time point. In these displays, baseline will be defined as the last non-missing value prior to first dose of study medication. Figures will be generated appropriate to the data output.

For body fat mass and lean body mass, a responder status (n, %) at Day 61 will be presented. A subject will be deemed a responder if their body fat mass showed a 1% or more reduction from baseline at Day 61. The same criteria will be used for the lean body mass. Additional exploratory analysis may be performed.

The responder status will also be presented for the subjects randomized only to the HbA1c between 5.7% and 9.0% subgroup.

InBody measurement results will be listed.

13.5 Electrocardiograms

Single 12-lead ECGs will be collected. For the quantitative variables RR, QRS, PR, QT, QTcF (QT interval corrected for heart rate by Fridericia's method), and heart rate, summary statistics (n, mean, standard deviation, minimum, median, and maximum) will be presented for the observed values at each time point, as described in Section 5.2, Summarization of Data. Summary statistics will also be presented for the change-from-baseline values to each postbaseline time point. In these displays, baseline will be defined as the last non-missing value prior to first dose of study medication.

The following results will be tabulated (n, %) by treatment group:

- Potential QTcF values of concern at any time post-baseline for:
    - Increase from Baseline of >30 and <= 60 msec
    - Increase from Baseline of > 60 msec

- Post-baseline value > 500 msec

All ECG results will be displayed in subject listings for the safety population.

13.6 Lipidomic (OWL Metabolomics)

Lipidomic analyses are not described in this statistical analysis plan. A separate lipidomic analysis plan will be provided.

13.7 Metabolomic (OWL Metabolomics)

Metabolomic analyses are not described in this statistical analysis plan. A separate metabolomic analysis plan will be provided.

13.8 Proteomic (SomaScan® Assay)

Proteomic (SomaScan Assay) analyses are not described in this statistical analysis plan. A separate proteomic analysis plan will be provided.

14 PHARMACOKINETIC ANALYSES

PK analyses are not described in this statistical analysis plan. A separate PK analysis plan will be provided prior to the commencement of the study.

15 SUBJECT LISTINGS

Data that are collected and entered into the study database but that are not displayed in the summary tables that are specified in the preceding sections will be presented in subject listings. These will include (but will not be limited to) data from the following modules:

Dosing Information

Inclusion/Exclusion Criteria

Protocol Deviation

Neurological Examination

Ophthalmology Examination

Concomitant Procedures

16 INTERIM ANALYSES

No statistical interim analysis is planned.

17 FINAL SIGN-OFF FOR RIVUS PHARMACEUTICALS, INC, PROTOCOL RIV-HU6-203 STATISTICAL ANALYSIS PLAN

DocuSigned by:
[redacted]
Signer Name: Kim Perry
Signing Reason: I approve this document
Signing Time: 13-Dec-2021 | 12:01 PM EST
8591934695604099AB4CD1BAE333216F

13-Dec-2021 | 12:01 PM EST

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13-Dec-2021 | 12:55 PM EST

Roger Morgan, MD
Vice President Medical Affairs
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Date

18 REVISIONS TO STATISTICAL ANALYSIS PLAN

Date	Revision
03 September 2021	The SAP was revised to analyze the HOMA-IR Calc only (i.e., the average of the 3 blood draws 5 minutes apart at each scheduled visit). Insulin, glucose, and C-peptide results will be listed only.
02 December 2021	Added summary statistics for placebo-corrected change-from-baseline values to each postbaseline time point for specified parameters and figures will be generated appropriate to the data output. Added responder status summary statistics for specified parameters at Day 61.
09 December 2021	For subjects in HbA1c 5.7% - 9.0% subgroup only, added summary statistics for change-from-baseline values to each postbaseline time point for specified parameters, placebo-corrected change-from-baseline values to each postbaseline time point for specified parameters, and MMRM or ANCOVA analysis as appropriate. Figures will be generated appropriate to the data output. In addition, added responder status summary statistics for specified parameters at Day 61. An addition, a criterion on body weight was added to the definition of Full Analysis Set (FAS).