RVT-1401-2003 Statistical Analysis Plan

Final Analysis – Cohort 1

Version 3.0

10 December 2021

A Phase 2, Multicenter, Non-Randomized, Open Label Study of RVT-1401 for the Treatment of Patients with Warm Autoimmune Hemolytic Anemia

Protocol (Version 3) Dated 23 December 2019

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ABBREVIATIONS

ADA	Anti-drug antibody
ADCC	Antibody dependent cell mediated cytotoxicity
AE	Adverse event
AESI	Adverse event of special interest
AIHA	Autoimmune hemolytic anemia
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
ATC	Anatomical Therapeutic Chemical
ATP	Adult treatment panel
BMI	Body mass index
BUN	Blood urea nitrogen
CI	Confidence intervals
CLL	Chronic lymphocytic leukemia
CO_2	Carbon dioxide
CPK	Serum creatine phosphokinase
CTCAE	Common Terminology Criteria for Adverse Events
[redacted]	
ECG	Electrocardiogram
FSH	Follicle stimulating hormone
GCP	Good Clinical Practice
GGT	Gamma glutamyl transferase
Hb	Hemoglobin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IB	Investigator's brochure
ICF	Informed consent form
ICH	International conference on harmonization
IEC	Independent ethics committee
IgA	Immunoglobulin A
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IND	Investigational new drug
INR	International normalized ratio

IP	Investigational product
IRB	Institutional review board
ITP	Idiopathic thrombocytopenia purpura
ITT	Intent to treat
IUD	Intrauterine device
LDH	Lactic acid dehydrogenase
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MedDRA	Medical Dictionary for Drug Regulatory Activities
MRC	Medical Research Council
PD	Pharmacodynamics
PK	Pharmacokinetics
RBC	Red blood cell
SAP	Statistical analysis plan
SGOT	Serum glutamic-oxaloacetic transaminase
SGPT	Serum glutamic-pyruvic transaminase
TBL	Total bilirubin
TEAE	Treatment-emergent adverse event
WAIHA	Warm Autoimmune Hemolytic Anemia
WBC	White blood cell
WHO	World Health Organization

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1 INTRODUCTION

This statistical analysis plan (SAP) contains the analysis information for the definition of the analysis populations, derivation of variables, convention of analysis scope, and statistical methodology for the analyses of safety and efficacy of RVT-1401 in the treatment of subjects with Warm Autoimmune Hemolytic Anemia (WAIHA). Based upon a composite review and data suggesting a drug-related effect of RVT-1401 on lipids, the study was paused, and a final analysis of Cohort 1 is being conducted based on the analyses outlined in this SAP. Subjects whose treatment was paused are referred to as curtailed.

At the time of the pause, 5 subjects had been enrolled in Cohort 1; 2 subjects completed the study through the Week 20 visit, 1 subject Early Terminated after Week 3, and 2 subjects were in the treatment period at the time of the pause. The analyses outlined in this plan pertain to the analysis of available data for Cohort 1.

The SAP Version 2.0 was created during the writing of the interim CSR for Cohort 1. A Sponsor decision was made to only include listings in the CSR given the small number of subjects, and SAP Version 2.0 reflects this decision.

This version of the SAP (Version 3.0) made further changes (such as removing all derived variables) to the SAP Version 2.0 to better align with the decision made to only include listings in the CSR.

2 OBJECTIVES AND ENDPOINTS

2.1 Objectives

The objective of the study is to investigate the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and efficacy of RVT-1401 (680 mg/weekly and 340 mg/weekly) in subjects with WAIHA.

2.2 Endpoints

2.2.1 Primary Endpoints

The primary endpoints are as follows:

- The proportion of responders at Week 13 (defined as Hb level ≥10g/dL with at least a ≥2 g/dL increase from baseline without rescue therapy or blood transfusions in the previous two weeks).
- Assessment of safety and tolerability by analysis of adverse event (AE) data and changes from baseline in vital signs, ECGs, and clinical laboratory values.

2.2.2 Secondary Endpoints

- Change from baseline in Hb levels,
- Time to response,
- Change from baseline in hematocrit levels,

- Proportion of subjects with Hb levels in the normal range at Week 13,
- Time to achieving Hb levels in the normal range,
- Change from baseline in FACIT-F score,
- Change from baseline in Medical Research Council (MRC) breathlessness scale,
- Change from baseline in EQ-5D-3L score,
- Change from baseline in levels of total IgG & IgG subclasses (1-4),
- Concentration of RVT-1401 at pre-dose,
- Change from baseline in LDH, bilirubin, and haptoglobin, and
- Immunogenicity determined by change from pre-dose in anti-RVT-1401 antibodies, and characterization of any anti-RVT-1401 antibodies to confirm neutralization potential.

2.2.3 Exploratory Endpoints

- [redacted]

3 STUDY DESIGN

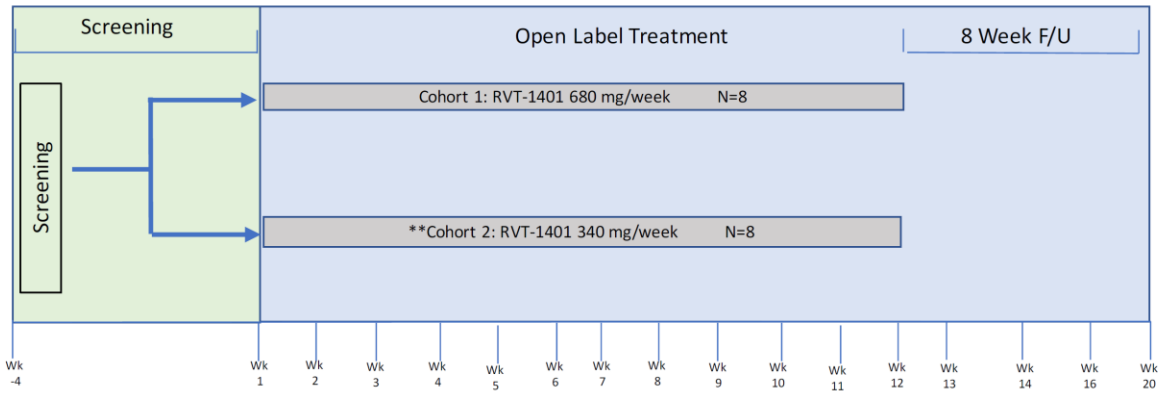
This is a Phase 2, non-randomized, sequential, open-label study to investigate the safety, tolerability, PK, PD, and efficacy of RVT-1401 (680 mg/weekly and 340 mg/weekly) in subjects with WAIHA. Two cohorts of subjects will be enrolled in a non-randomized sequential approach. Subjects will be enrolled into Cohort 1 (680 mg/weekly) first followed by Cohort 2 (340 mg/weekly). (See 5.2 Study Diagram and Flow Chart)

Following the initial dose at the Baseline Visit (Week 1, Day 1), study visits will occur weekly throughout the treatment period. Following the final dose at Week 12, visits will occur weekly through Week 14 and then at Week 16 and Week 20. Safety, PK, PD, and clinical assessments will be collected throughout the study.

3.1 Sample Size and Statistical Power Consideration

The sample size for this study was not determined using statistical methods. The sample size was chosen based on clinical and recruitment considerations for this Phase 2 study.

3.2 Study Diagram and Flow Chart



**Note-Cohort 1 will enroll first followed by Cohort 2

3.3 Time and events table

	Screening[1]	**Treatment Period (Weeks)**												**Follow-up Period (Weeks)**				**Early Withdrawal Visit**
Study Timepoint (Weeks)	Within 30 days	1 (B/ L)	2	3	4	5	6	7	8	9	10	11	12	13	14	16	20	
Time Window (days)			+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 Day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-2 days	+/-2 days	+/-2 days	+/- 2 days	
Informed consent	X																	
Inclusion/exclusion criteria	X	X																
Demographics and medical history[9]	X																	
Height	X																	
Body weight	X	X																
Complete physical examination	X	X																
Brief physical examination																	X	X
Vital signs[2]	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
12-lead Electrocardiogram[2]	X	X			X				X				X				X	X
Pregnancy test[3] (females)	X	X	X		X		X		X		X		X	X			X	X
Viral Serology	X																	
Vaccine Titers[2]		X												X			X	X
QuantiFERON® – TB GOLD	X																	
Urinalysis[2, 4]	X	X		X		X		X		X		X		X		X	X	X
Blood chemistry and hematology[2, 8]	X	X	X	X	X	X		X		X		X		X	X	X	X	X
Fasting Lipid Panel[2]		X												X			X	X

	Screening[1]	**Treatment Period (Weeks)**												**Follow-up Period (Weeks)**				**Early Withdrawal Visit**
Study Timepoint (Weeks)	Within 30 days	1 (B/L)	2	3	4	5	6	7	8	9	10	11	12	13	14	16	20	
Time Window (days)			+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 Day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-2 days	+/-2 days	+/-2 days	+/- 2 days	
Serum complement (CH50, C3)[2]		X		X		X		X		X		X		X		X	X	X
Immunoglobulins (IgM, IgA)[2]		X		X		X		X		X		X		X		X	X	X

	Screening[1]	Treatment Period (Weeks)												Follow-up Period (Weeks)				Early Withdrawal Visit
Study Timepoint (Weeks)	Within 30 days	1 (B/L)	2	3	4	5	6	7	8	9	10	11	12	13	14	16	20	
Time Window (days)			+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 Day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-1 day	+/-2 days	+/-2 days	+/-2 days	+/- 2 days	
RVT-1401 PK sampling[2]		X	X	X	X	X	X		X		X		X	X				X
Total IgG[2,6]	X	X	X	X	X	X	X		X		X		X	X	X	X	X	X
Immunoglobins (IgG subclasses)[2]		X		X			X		X		X			X		X	X	X
[redacted]																		
Anti- RVT-1401antibody[2, 5]		X		X		X			X					X			X	X
NAb Assessment[2]		X		X		X			X					X			X	X
[redacted]																		
Drug administration		X	X	X	X	X	X	X	X	X	X	X	X					
Injection Site Reaction[7]		X	X	X	X	X	X	X	X	X	X	X	X					
FACIT-F Scale[2]		X		X		X		X		X		X		X		X	X	X
MRC Breathlessness Scale[2]		X		X		X		X		X		X		X		X	X	X
EQ-5D-3L[2]		X				X				X				X		X	X	X
Satisfaction Questionnaire														X				X
Adverse events	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Concomitant medication	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

1. Screening can take place over multiple days.
2. Assessments collected on dosing days will be collected pre-dose.

3. Pregnancy tests will be collected pre-dose (via urine dipstick) on dosing days where specified. Serum pregnancy tests should be collected at screening and the final follow up visit.
4. Microalbumin/creatinine ratio at baseline, Week 13, and Week 20 only.
5. Subjects with treatment emergent positive results (change from baseline) for anti- RVT-1401 antibody at Week 20 will be requested to return at approximately 6-, 9-, and 12-months post-dose for additional samples or until their result is no longer positive. However, for purposes of safety follow-up and database lock participation ends at the Week 20 visit.
6. Two samples for IgG will be collected: one will be sent to the central lab for safety monitoring, while the other sample will be sent to Intertek as the PD endpoint.
7. Local injection site reactions will be assessed at approximately 10 minutes post dose.
8. Hematology, HbA1c and [redacted] will be drawn for site local laboratory analysis, at minimum, and results collected in the instance where central laboratory samples are received hemolyzed. If other central laboratory tests are received hemolyzed, the local result will be captured in the eCRF.
9. History of WAIHA and prior WAIHA treatments will be captured in the eCRFs.

4 ANALYSIS POPULATIONS (ANALYSIS SETS)

The populations defined in this section guide the selection of subjects for a given set of listings.

4.1 Efficacy Population

All subjects who enroll in the study and receive at least one dose of study treatment and have a post-baseline visit will be included in the efficacy population.

4.2 Safety Population

All subjects who enroll in the study and receive at least one dose of study treatment will be included in the Safety Population. This will be the population for the safety analyses, as well as for presentation and summarization of baseline/demographic characteristics and subject disposition.

4.3 Pharmacokinetic Population

The PK Population will include all subjects who undergo PK sampling and have evaluable concentration-time data for analysis.

4.4 Pharmacodynamic Population

The PD population will include all subjects who have a baseline measure, along with a post baseline measure and receive at least one dose of study treatment.

5 TREATMENT DESCRIPTIONS

Unless otherwise indicated, the treatment will be identified by RVT-1401 680 mg/week (Cohort 1).

6 STATISTICAL ANALYSIS METHODS AND ISSUES

6.1 Statistical Methods

All available data will be presented in the data listings.

6.2 Missing Data

Other than missing dates as described below, no imputation methods will be used for missing data.

Missing dates are imputed in the following cases:

For the analysis of safety variables, only partial dates may be imputed; otherwise, missing data will be treated simply as missing. The algorithms for imputation of partial dates depend upon the parameter.

Adverse Event Onset

- If onset date is completely missing, date is set to date of first dose. If onset time is missing, the time will not be imputed.
- If year is present and month and day are missing or year and day are present and month is missing:
  - If year = year of first dose, then set month and day to month and day of first dose.
  - If year < year of first dose, then set month and day to December 31.
  - If year > year of first dose, then set month and day to January 1.
- If month and year are present and day is missing:
  - If year = year of first dose and
    - month = month of first dose, then set day to day of first dose date.
    - month < month of first dose, then set day to last day of month.
- For all other cases, set date to date of first dose.

Adverse Event End Date

- If year is present and month and day are missing or year and day are present and month is missing, set end month and day to December 31.
- If month and year are present and day is missing, set the day to last day of the month.
  - If fatal event, date is set to minimum of imputed end date and death date.
  - For all other cases, set date to missing.

The imputed dates must be logical, ensuring that no end date is after database lock or death or before the start date.

If site queries fail to resolve partial dates for laboratory values and vital signs, the date is missing and will not be imputed.

6.3 Data Issues

Unless otherwise noted, values reported as greater than or less than some quantifiable limit (e.g., <1.0) will include the sign in all listings.

If there are multiple assessments collected on the same scheduled time, all values will be displayed. All data from all visits will be eligible for inclusion in the listings.

Study day is the day relative to the date of first dose. Day 1 is defined as the date of first dose, unless otherwise specified for the calculation of baseline.

For visits (or events) after first dose, day is calculated as:

- Study day = visit (or event) date - date of first dose + 1

For visits (or events) before first dose, day is calculated as:

- Study day = visit (or event) date - date of first dose

6.4 Baseline Definition

Baseline is the last available assessment prior to time of the first dose unless it is specified otherwise.

Subject's age in years at baseline is defined as the age derived at Screening in the EDC system.

7 DISPOSITION, DEMOGRAPHICS AND BASELINE CHARACTERISTICS

7.1 Subject Disposition and Exposure

The disposition listing will include the disposition of treatment and discontinuation of study by each subject. For discontinuations, the listing will include the reason for discontinuation.

Disposition of subjects in the Follow-up Period will be presented in listings.

Administration of RVT-1401 will be presented in listings denoting each visit and dose, and the treatment satisfaction questionnaire will be listed by treatment and by visit.

WAIHA treatment listing will also be provided.

7.2 Demographics and Baseline Characteristics

The demographics (age, gender, race, ethnicity, and childbearing potential if female) and baseline characteristics (height, weight, body mass index) will be presented in listings.

7.3 Prior WAIHA treatment

Based on the coded data of prior WAIHA medication(s) using the World Health Organization (WHO) Drug Reference List, the data will be presented in listings per the Anatomical Therapeutic Chemical (ATC) classification.

8 ANALYSIS OF EFFICACY ENDPOINTS

Each endpoint noted below will be presented in a listing.

- FACIT-F score
- MRC breathlessness scale
- EQ-5D-3L score

9 ANALYSIS OF SAFETY ENDPOINTS

Safety analyses will be performed on the Safety population unless otherwise indicated.

9.1 Adverse Events

The adverse events (AEs) will be coded by the Medical Dictionary for Drug Regulatory Activities (MedDRA) version 22.1 or higher. A treatment-emergent adverse event (TEAE) is defined as any AE onset post first treatment. A listing of all subjects reporting TEAEs will be presented. A separate listing of serious TEAEs will be provided. A by-subject listing containing the AEs by the MedDRA system organ class and preferred term will be created. This listing will include start and end dates of the event, severity, and relationship to study drug. Injection site reactions will also be presented in a separate listing.

The AE data will not be imputed other than a missing date.

9.2 Vital Signs

The vital signs (systolic / diastolic blood pressure, pulse rate, pulse oximetry, and body temperature) will be presented in a listing at each visit.

9.3 Laboratory Test Results

The test results of clinical chemistry, hematology, and urinalysis (including the lipid panel) are to be presented in listings by visit.

All test results will be presented in listings.

9.3.1 Hematology

Platelet Count:	*RBC Indices*:	*Automated WBC Differential:*
Red Blood Cell (RBC) Count	Mean corpuscular volume (MCV)	Neutrophils
White Blood Cell (WBC) Count (absolute)	Mean corpuscular hemoglobin (MCH)	Lymphocytes
Reticulocyte Count	Mean corpuscular hemoglobin concentration (MCHC)	Monocytes
Hemoglobin		Eosinophils
Hematocrit		Basophils
Haptoglobin		

9.3.2 Clinical Chemistry

Blood urea nitrogen (BUN)	Potassium	AST (SGOT)	Total (TBL) and direct bilirubin
Creatinine	Chloride	ALT (SGPT)	Uric Acid
Total Protein	Total carbon dioxide (CO_2)	Gamma glutamyl transferase (GGT)	Albumin
Sodium	Calcium (corrected)	Alkaline phosphatase (ALP)	Lactic acid dehydrogenase (LDH)
Serum complement (CH50, C3)	Immunoglobulin M (IgM)	Immunoglobulin A (IgA)	Immunoglobulin G (IgG)
HbA1c			

9.3.3 Routine Urinalysis

- Specific gravity, pH
- Glucose, protein, blood, and ketones by dipstick
- Microscopic examination (if blood or urine protein is abnormal)
- Microalbumin/creatinine ratio at baseline, Week 12, and Week 20, only if urine protein is abnormal

9.3.4 Lipid Panel

- Total cholesterol
- HDL cholesterol
- LDL cholesterol (calculated)
- Non-HDL cholesterol (calculated)
- Triglycerides
- Total cholesterol/HDL cholesterol ratio (calculated)
- LDL / HDL cholesterol ratio (calculated)

Analyses will include the following:

- Listings of raw lipid values will be provided.
- Listings for the full lipid panel will be presented.

9.4 Concomitant Medications, Rescue Therapy, and Procedures

Based on the coded data of concomitant medication using the WHO Drug Reference List, the concomitant medications and rescue therapy will be presented in a listing per the ATC classification.

Procedures will be listed by treatment and by subject.

9.5 Electrocardiogram

The parameters of electrocardiography will be presented in a listing by visit. The overall evaluation (Normal/Abnormal) will be included as well.

9.6 Physical Examination

Physical examination listing will be provided by treatment and by visit.

9.7 Pregnancy Testing

Pregnancy testing will be listed by treatment and by visit.

9.8 COVID-19 Impact

COVID-19 impact on study visits and the reason for impact will be listed by treatment and by visit.

COVID-19 impact on study and treatment discontinuation will be listed by treatment and by visit.

10 ANALYSIS OF PHARMACOKINETIC, PHARMACODYNAMIC, AND ANTI-DRUG ANTIBODY ENDPOINTS

- Serum total IgG concentrations will be listed by subject and visit and will include treatment, date and time of sample collection, and the actual time (days) that the PD sample was collected relative to the prior dose.
- Serum RVT-1401 concentrations will be listed by subject and visit and will include treatment, date and time of sample collection, and the actual time (days) that the PK sample was collected relative to the prior dose.

Anti-drug antibody results will be listed by subject and visit and will include treatment and date and time of sample collection.

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