VIELA BIO, INC.

STATISTICAL ANALYSIS PLAN

Investigational Product: **VIB4920**

Protocol Number: **VIB4920.P2.S3**

A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED, MECHANISTIC INSIGHT AND DOSAGE OPTIMIZATION STUDY OF THE EFFICACY AND SAFETY OF VIB4920 IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA) (SHORT TITLE: MIDORA)

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LIST OF ABBREVIATIONS

Abbreviation or Specialized Term	Definition
ACPA	anti-cyclic citrullinated peptide antibody
ADA	anti-drug antibodies
ATC	Anatomical Therapeutic Chemical
AUC	area under the concentration-time curve
bDMARD	biologic disease-modifying anti-rheumatic drug
CDAI	Clinical Disease Activity Index
cDMARD	conventional disease-modifying anti-rheumatic drug
CI	confidence interval
CL	systemic clearance
Cmax	maximum observed concentration
CRP	C-reactive protein
CTCAE	common terminology criteria for adverse event
DAS28-CRP	Disease Activity Score in 28 Joints Using C-reactive Protein
ECG	electrocardiogram
FACIT-Fatigue	Functional Assessment of Chronic Illness Therapy - Fatigue
HAQ	Health Assessment Questionnaire
IL-6	interleukin-6
IP	Investigational product
MDGA	physician global assessment of disease activity
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	mixed-effect model for repeated measures
MTX	methotrexate
LSMeans	least square means
PD	Pharmacodynamic(s)
PGA	patient global assessment of disease activity
PK	Pharmacokinetic(s)
PT	preferred term
QTc	corrected QT interval
RA	rheumatoid arthritis
RF	rheumatoid factor
sCD40L	soluble CD40 ligand
SDAI	Simplified Disease Activity Index
SE	standard error
SJC28	28 swollen joint count
SOC	system organ class

Abbreviation or Specialized Term	Definition
SPP	statistical programming plan
$t_{1/2}$	terminal elimination half-life
TEAE	treatment-emergent adverse event
TEAESI	treatment-emergent adverse event of special interest
TESAE	treatment-emergent serious adverse event
TJC28	28 tender joint count
VAS	visual analog scale
WHO	world health organization

1 INTRODUCTION

This document describes the statistical analysis for protocol VIB4920.P2.S3, a Phase 2 randomized, double-blind, placebo controlled, parallel-cohort study to evaluate the safety, efficacy, and pharmacokinetics (PK) of VIB4920 in adults with moderate-to-severe rheumatoid arthritis (RA).

2 STUDY OVERVIEW

2.1 Study Objectives and Endpoints

The objectives and corresponding endpoints are listed in Table 1 below:

Table 1 Study Objectives and Endpoints

Primary objective	**Endpoints/variables**
• To evaluate the effect of VIB4920 on disease activity as assessed by a composite measure in subjects with adult-onset RA	• Change in Disease Activity Score in 28 Joints Using C-reactive Protein (DAS28-CRP) from baseline to Day 113
• To evaluate the safety and tolerability of VIB4920 in subjects with adult-onset RA	• Incidence of treatment emergent adverse events (TEAEs), treatment emergent serious adverse events (TESAEs), and treatment emergent adverse events of special interest (TEAESIs)
Secondary objectives	**Endpoints/variables**
• To characterize the PK of VIB4920 in subjects with adult-onset RA	• PK profile
• To evaluate the pharmacodynamic (PD) effect of VIB4920 in subjects with adult-onset RA	• Total soluble CD40 ligand (sCD40L)
• To evaluate the immunogenicity of VIB4920 in subjects with adult-onset RA	• Anti-drug antibodies (ADA)
• To evaluate the effect of VIB4920 on autoantibodies in subjects with adult-onset RA	• Rheumatoid factor (RF) • Anti-cyclic citrullinated peptide antibody (ACPA)
• To assess the effect of VIB4920 on clinical remission as assessed by a composite measure in subjects with adult-onset RA	• DAS28-CRP < 2.6
• To evaluate the duration of clinical response to VIB4920 as assessed by time to institution of rescue therapy	• Time to start of new treatment for RA (rescue medication)
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Table 1 Study Objectives and Endpoints

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[redacted]	[redacted]
[redacted]	[redacted]

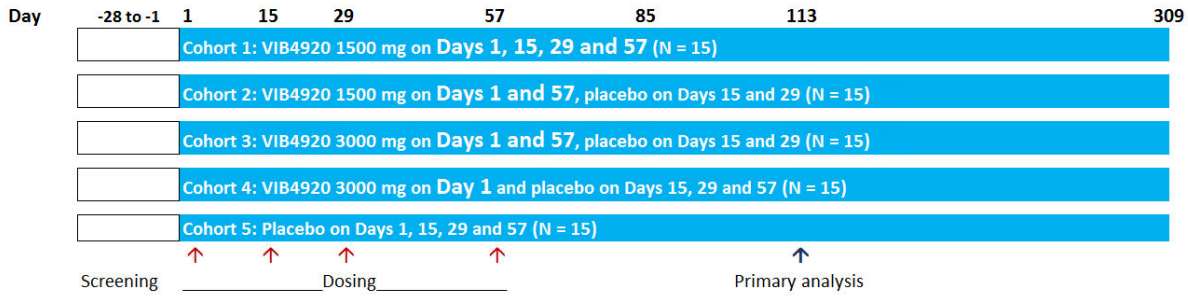
2.2 Study Design

This is a multicenter, randomized, double-blind, placebo-controlled, parallel-cohort study to evaluate the safety, efficacy, and PK of VIB4920 administered intravenously in adults with active, moderate-to-severe adult-onset RA who have had an inadequate response to methotrexate, conventional disease-modifying anti-rheumatic drug (cDMARD), or an anti-TNFα agent.

After a screening period of up to 28 days, approximately 75 subjects will be randomized in a 1:1:1:1:1 ratio into 5 cohorts (treatment groups) as shown in Figure 1 below. Subjects are to be followed on their stable background anti-RA therapy at least through 12 weeks (Day 85), at which time rescue therapy may be instituted. All subjects are followed at least through the primary analysis (Day 113), and those who have not instituted rescue therapy will be followed through Day 309 to determine the duration of clinical response.

A study schematic is presented in Figure 1.

Figure 1 Study Flow Diagram



2.3 Sample Size

The planned sample size of 75 subjects (15 subjects per treatment group) will provide approximately 80% power to detect a difference of 1.2 in mean change from baseline to Day 113 in DAS28-CRP (assumed standard deviation of 1.25) between the VIB4920 and placebo treatment groups at a 2-sided alpha level of 0.10 using a 2-sample t-test.

3 STATISTICAL METHODS

3.1 General Considerations

All statistical calculations will be primarily performed using SAS® System Version 9.4 or higher. Categorical data will be summarized by the frequency counts and percentage of subjects in each category. Continuous variables will be summarized by descriptive statistics, including number of observations, mean, standard deviation, median, first quartile, third quartile, minimum, and maximum.

3.1.1 Definition of Baseline

Unless otherwise specified, baseline will be defined as the last non-missing valid observation prior to the first administration of IP. In cases where baseline measurements are taken on the same day as IP and no times are reported, it will be assumed that these measurements are taken prior to IP being administered.

3.1.2 Analysis Windows

Analysis visit windows will be used for all visit-based assessments to map longitudinal observations to scheduled visits and thereby allow for by-visit analyses, since not all assessments are performed on the scheduled day. Unless otherwise specified, all longitudinal efficacy, safety, and biomarker data analyses will be based on the analysis visit windows. The analysis visit windows will be calculated by bisecting the interval between adjacent scheduled visit days except for the first post-treatment visit. The first post-treatment visit will start at Day 2. The detailed analysis visit windows will be specified in the statistical programming plan (SPP).

The actual assessment day will be mapped to the windows defined for each scheduled study visit with following rules:

- If more than one assessment falls within a visit window, the closest non-missing assessment to the scheduled day will be used in the analysis.
- If 2 non-missing assessment actual dates are equidistant from the target day, the later visit will be used in the analysis.
- For retest values of laboratory data, the retest value (the last valid observation assessed on the same visit day) will be chosen.

3.2 Protocol Deviations

All protocol deviations will be classified as either major protocol deviations or minor protocol deviations. The major protocol deviations are considered as the important protocol

deviations, which may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a subject's rights, safety, or well-being. All the protocol deviations will be listed, and the major protocol deviation will be summarized. Some classifications of major protocol deviations are listed below.

- Did not meet inclusion criteria or met exclusion criteria.
- Blindness of treatment assignment was broken by site investigator
- Received prohibited concomitant medication
- Serious breach of good clinical practice.

The list may be updated and will be finalized and documented prior to the database lock for the primary analysis.

3.3 Analysis Sets

3.3.1 Full analysis set

The full analysis set includes all randomized subjects who received any dose of IP. Subjects will be analyzed according to the treatment randomized. The efficacy analysis will be based on the full analysis set.

3.3.2 Safety analysis set

The safety analysis set includes all subjects who received any dose of IP. Subjects will be analyzed according to the treatment that they actually received. The safety and ADA analyses will be based on the safety analysis set.

3.3.3 Pharmacokinetics analysis set

The PK analysis set includes all subjects who received IP and have at least one quantifiable plasma PK observation post-first dose. Subjects will be analyzed according to the treatment that they actually received. PK analyses will be based on the PK analysis set.

3.4 Study Subjects

3.4.1 Subject Disposition

A summary of subject disposition will be presented using the categories presented below.

- Screened
- Screen failed with reasons
- Randomized
- Randomized but not treated
- Randomized and treated

- Completed treatment
- Discontinued treatment with reasons
- Completed study
- Discontinued study with reasons

A Kaplan-Meier curve of the time to study discontinuation will be provided.

3.4.2 Demographics, Baseline Characteristics, and Medical History

The demographics (age, gender, race, ethnicity, height, weight, and body mass index) will be summarized by treatment group and overall for the full analysis set.

A summary of baseline disease characteristics, by treatment group and overall for the full analysis set will include DAS28-CRP, [redacted], MDGA, PGA, CDAI, SDAI, HAQ, CRP, ACPA (positive/negative), RF (positive/negative), and presence of rheumatoid nodules.

Significant medical history findings will be summarized by Medical Dictionary for Regulatory Activities (MedDRA) system organ class (SOC) and preferred term (PT) by treatment group and overall for the full analysis set.

3.4.3 Investigational product Exposure

The number of doses received, amount (mg) of the IP received, durations of the IP exposure, and total subject years exposure will be summarized by treatment using the safety analysis set.

- Duration of the IP exposure is defined as (last dose date + 28 – first dose date + 1)
- The amount of IP received: if a subject received partial dose at a dosing visit, then the amount of IP at that dosing visit will be estimated based on the actual volume administered.
- Treatment compliance for an individual patient = (Total number of doses received)/ (Total number of doses planned per protocol) ×100%.

Number of subjects with at least one entire dose not administered, infusion interrupted, and infusion rate decreased will be summarized using the safety analysis set.

3.4.4 Prior and Concomitant Medications

Number (%) of subjects who receive prior medications and concomitant medications will be summarized by world health organization (WHO) Drug dictionary Anatomical Therapeutic Chemical (ATC) category and PT based on the safety analysis set. At each level of summarization, a subject is counted once if he/she reported one or more medications at that level. The prior and concomitant medications are defined as below.

- Prior medications are defined as medications with a stop date occurring before the first IP administration date.

- Concomitant medications are defined as medications with a stop date on or after the first IP administration date.

RA medication history will be summarized by medication category (cDMARD, biologic DMARD [bDMARD], JAK Inhibitor, etc.). The reasons for treatment discontinuation will also be summarized.

Use of RA-related medications at baseline, defined as all RA-related medications with an intake at the date of first dose of IP (ie, start date on or before the date of first dose and end date on or after date of first dose or ongoing) will be summarized for the full analysis set. The number and percentage of subjects who receive rescue therapy will also be summarized for the full analysis set.

Rescue therapy is any new or intensified immunosuppressive, cDMARD, or bDMARD treatment for RA, including:

- Initiation of or increase in dose of any cDMARD

- Initiation of bDMARD therapy or Janus kinase inhibitor therapy

- Increase in baseline corticosteroid dose

- Intraarticular steroid injection > 40 mg methylprednisolone (or its equivalent) OR more than one intraarticular steroid injection of any dose. One intraarticular steroid injection ≤ 40 mg methylprednisolone in one joint is permitted and not considered rescue therapy

The missing start/stop date of medications will be imputed as appropriate and the details of the imputation will be included in the SPP.

3.5 Efficacy Analyses

3.5.1 Primary Efficacy Endpoint(s) and Analyses

3.5.1.1 Primary efficacy endpoint

The primary efficacy endpoint is change from baseline DAS28-CRP to Day 113.

DAS28-CRP:

DAS28-CRP values will be calculated as follows (Wells et al, 2009):

DAS28-CRP = $0.56 \times \sqrt{(TJC28)} + 0.28 \times \sqrt{(SJC28)} + 0.014 \times$ PGA (0 - 100 mm visual analogue scale [VAS]) + $0.36 \times \ln(CRP[mg/L] + 1) + 0.96$

Low disease activity is defined as DAS28-CRP ≤ 3.2, and an improvement of DAS28-CRP score > 0.6 defines a responder. Remission is defined as DAS28-CRP < 2.6.

3.5.1.2 Primary efficacy analysis

The primary efficacy endpoint will be analyzed using the mixed-effect model for repeated measures (MMRM) approach for the full analysis set. The model will include fixed effects for treatment, visit, visit by treatment interaction, and baseline DAS28-CRP score.

From the model, the estimated treatment effect (ie the difference [VIB4920 – placebo] in least square means [LSMeans]) at Day 113 will be obtained, together with a two-sided 90% confidence interval (CI), standard error (SE) and p-value. The significance of treatment effect will be tested by using a two-sided test at significance level α of 0.1. Additionally, estimates of the LSMeans for each treatment group will be obtained, together with the associated SE.

Longitudinal presentations of results over time based on the same analysis will be created.

Model assumptions for MMRM will be checked with graphical displays (residual plots and a quartile-quartile plot). If the model assumptions are not met, appropriate data transformations or the non-parametric approaches will be used.

3.5.1.3 Handling plan for Intercurrent Events

Rescue medication use:

For subjects who take rescue medications defined in section 3.4.4, the data collected after administration of the rescue medications will not be included in the primary analysis. This approach attempts to reduce the confounding effects of rescue medications.

Treatment discontinuation:

Subjects who discontinue IP without receiving rescue medications will be asked to come to scheduled evaluations until the end of study. The data collected after discontinuation of IP will be included in the analysis.

3.5.1.4 Handling plan for missing data

Missing data will be handled using the MMRM approach. If any of the DAS28-CRP component cannot be evaluated at a visit, that component will be imputed using last observation carried forward (LOCF) approach.

3.5.1.5 Sensitivity analysis of primary efficacy endpoint

The sensitivity analysis will be performed for the primary efficacy endpoint using the same model as the primary analysis with the following handling plan for the rescue medication use and treatment discontinuation.

- Impute result after rescue medications using the worst score including baseline. For subjects who discontinue IP without receiving rescue medications, include data collected after discontinuation of study treatment.

- Include data collected after rescue medications and data collected after discontinuation of study treatment.

CRP, RF, and ACPA values were provided unblinded by the central laboratory in violation of the protocol starting from 20Jan2021. Reports were required to be accessed by site, signed by investigator, and filed, and thus the assumption is that a very wide set of people at site, CRO and sponsor had access to these potentially unblinding data. The blinding was restored on 27Jan2021. After consulting with DSMB statistician, we will perform a sensitivity analysis by removing data that might have introduced bias (see Appendix 1).

3.5.1.6 Subgroup analyses of primary endpoint

No subgroup analyses are planned for the primary endpoint due to the small sample size per treatment group in the study.

3.5.1.7 Multiplicity adjustment

The type I error rate will be controlled at 0.1 level (2-sided) for the primary efficacy analysis using the following sequential testing strategy.

1. The primary endpoint will be tested for Cohort 1 (VIB4920 1500 mg on Days 1, 15, 29, and 57) compared with placebo
2. If p-value is ≤ 0.1 in step 1, the primary endpoint will be tested for Cohort 3 (VIB4920 3000 mg on Days 1 and 57) compared with placebo
3. If p-value is ≤ 0.1 in both step 1 and step 2, the primary endpoint will be tested for Cohort 2 (VIB4920 1500 mg on Days 1 and 57) and Cohort 4 (VIB4920 3000 mg on Day 1) compared with placebo using the Hochberg method (Hochberg, 1988).

3.5.2 Secondary Efficacy Endpoints and Analyses

3.5.2.1 Secondary efficacy endpoints

The secondary efficacy endpoints are as follows:

- The proportion of subjects with clinical remission defined as DAS28-CRP < 2.6 at Day 113
- Time to start of rescue medication
- Change in RF and ACPAs from baseline to Day 113

3.5.2.2 Secondary efficacy analysis

The proportion of subjects with DAS28-CRP < 2.6 at Day 113 will be analyzed for the full analysis set using a logistic regression model, with treatment and baseline DAS28-CRP score included in the model. Subjects who receive rescue medications before Day 113 and who prematurely discontinue from the study before Day 113 will be considered non-responders. Intermittent missing data and missing DAS28-CRP component will be imputed using LOCF approach.

The estimated treatment effect (ie, the odds ratio for VIB4920 versus placebo), corresponding 90% CI, and 2-sided p-value will be presented.

Longitudinal presentations of results over time will be created using the full analysis set. Subjects who receive rescue medications will be considered non-responder for the visits after

rescue. Subjects who prematurely discontinue from the study will be considered non-responder for the visits after discontinuation.

Time to start of rescue medication will be analyzed using the Cox proportional hazards model with treatment group included in the model. Subjects without rescue will be censored. The hazard ratio of VIB4920 versus placebo will be estimated together with its associated 90% CI. The Kaplan-Meier curve of the time to rescue will be provided.

The change in RF and ACPAs from baseline to Day 113 will be analyzed for the full analysis set using the MMRM approach, with treatment, visit, visit by treatment interaction, and corresponding baseline value. The data collected after discontinuation of IP will be included in the analysis. The data collected after administration of the rescue medications will be excluded. The sensitivity analysis will be performed with the data collected after administration of the rescue medications included.

The details of these analyses and presentations of results will be the same as those described for the primary efficacy endpoint in section 3.5.1.2.

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3.6 Safety Analysis

3.6.1 Adverse Events

In general, if an AE onset is on or after the first dose of IP administration, the AE will be considered as a TEAE. Otherwise, the AE will be considered as a non-treatment emergent AE.

An overall summary table will be showing the number and percentage of subjects with at least 1 event in any of the following categories: TEAE, TESAE, TEAE with outcome of death, TEAE leading to discontinuation of IP, grade 3 or higher TEAE, serious and/or grade 3 or higher TEAE, IP related TEAE, IP related TESAE.

AEs will be coded using the most recent version of MedDRA. All TEAEs will be summarized overall and by MedDRA SOC and PT, by severity and by relationship to IP. Specific AEs will be counted once for each subject for calculating rates, but all events will be presented in subject listings. In addition, if the same AE occurs multiple times within a particular subject, the highest severity and level of causality will be reported.

The TEAEs, TESAEs, TEAEs resulting in death, TEAEs leading to discontinuation of IP, Grade 3 or higher TEAEs, IP related TEAEs, and IP related TESAEs will be summarized by SOC and PT. TESAEs will be summarized by SAE criteria as well. In addition, a summary of TEAEs sorted by frequency will be presented by PT.

An AESI is one of scientific and medical interest specific to understanding of the IP. AESIs for this protocol include:

- Thrombotic and embolic events
- Anaphylaxis and clinically significant (Grade 3 or higher) hypersensitivity reactions
- Severe Infusion-related reactions (common terminology criteria for adverse event (CTCAE) Grade 3 or higher)
- Immune complex disease
- Severe (Grade 3 or higher) and/or opportunistic infections
- Hepatic function abnormality (meeting the definition of Hy's Law)
- Malignant neoplasm

TEAESIs will be summarized by SOC and PT.

Listings will be provided for all TEAEs and non-treatment emergent AEs.

3.6.2 Clinical Laboratory Evaluation

The hematology, coagulation, serum chemistry, urinalysis, and immunoglobulins parameters, as well as changes from baseline, will be summarized with descriptive statistics at each visit. Shift from the baseline relative to the normal range will also be summarized. Additionally, worst toxicity grade, ≥grade 3 toxicity post-baseline, and shift from baseline to worst toxicity grade in hematology, coagulation and serum chemistry parameter will be produced.

3.6.3 Other Safety Evaluations

3.6.3.1 Overdose

The incidence of TEAE associated with overdose will be summarized by MedDRA SOC and PT if applicable.

3.6.3.2 Vital signs

The observed values along with the changes from baseline will be summarized for systolic blood pressure, diastolic blood pressure, body temperature, heart rate, and respiratory. In addition, a summary of subjects with clinically significant vital signs values (meeting any of following criteria) will be provided.

- Systolic blood pressure: <90 mmHg, >160 mmHg
- Diastolic blood pressure: <60 mmHg, >100 mmHg
- Heart rate: <50 Beats/min, >100 beats/min
- Respiratory rate: <12 breaths/min, >23 breaths/min
- Temperature: <36°C, >38°C

3.6.3.3 Electrocardiogram

The observed values along with the changes from baseline will be summarized for heart rate, RR interval, PR Interval, QRS duration, QT interval and the corrected QT interval (QTc) using Bazett's and Fridericia's corrections. The number (%) of subjects meeting the following criteria will be summarized.

- QTc > 450 msec
- QTc > 480 msec
- QTc > 500 msec
- QTc increases from baseline > 30 msec
- QTc increases from baseline > 60 msec

In addition, the overall clinical evaluation of ECG results (normal, abnormal, not clinically significant abnormal, clinically significant abnormal) will also be summarized.

3.6.3.4 Weight

The observed values and the changes from baseline in the weight and BMI will be summarized.

3.7 Pharmacokinetics

Plasma VIB4920 concentration data will be tabulated by dose cohort together with descriptive statistics. Individual and mean plasma concentration-time profiles of VIB4920 by treatment will be generated.

Noncompartmental analysis will be performed for VIB4920-treated subjects. When possible, the following PK parameters will be accessed for VIB4920 plasma concentration: maximum observed concentration (C_{max}), area under the concentration-time curve (AUC), systemic clearance (CL), and terminal elimination half-life ($t_{1/2}$). Additional PK parameters may be determined and reported as appropriate. Descriptive statistics for PK parameters will be provided.

The plasma concentration of VIB4920, summary statistics, PK profile, and the additional PK-related analyses will be reported in a clinical PK report (an addendum to the clinical study report).

3.8 Immunogenicity

The ADA status will be summarized for the safety analysis set by the categories defined in Table 2. The ADA incidence rate will also be summarized, where the incidence is the proportion of the subjects with ADA positive post-baseline only or boosted their pre-existing ADA during the study period. The boosted ADA is defined as ADA level of ≥4× baseline level. If data allow, the ADA titer for the ADA positive subjects will be summarized and the impact of ADA on efficacy and safety will be evaluated.

Table 2 [redacted]

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3.9 Pharmacodynamics

Total sCD40L level, as well as change from baseline, will be summarized with descriptive statistics at each visit.

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[redacted]

4 PLANNED ANALYSIS

4.1 Primary Efficacy Analysis

The primary efficacy analysis will be conducted after all subjects have completed the Day 113 visit or discontinued early from the study. As the primary analysis will be an interim analysis, a small prespecified number of Sponsor staff who are not directly involved in the conduct of the study will be unblinded for decision-making purposes. Study site personnel, subjects, and CRO and Sponsor personnel directly associated with the conduct of the study will remain blinded to the treatment assignment for individual subjects and the results of the primary analysis until the completion of the study. The efficacy and safety data prior to the data cut-off for the primary analysis will be analyzed.

4.2 Final Analysis

The final analysis will be conducted after all subjects have completed the study.

5 REFERENCES

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Revision History:

Version #	Description of Change
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[redacted]	[redacted]

6 APPENDIX

Appendix 1: Memo to File

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From: [redacted]

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     a. [redacted]

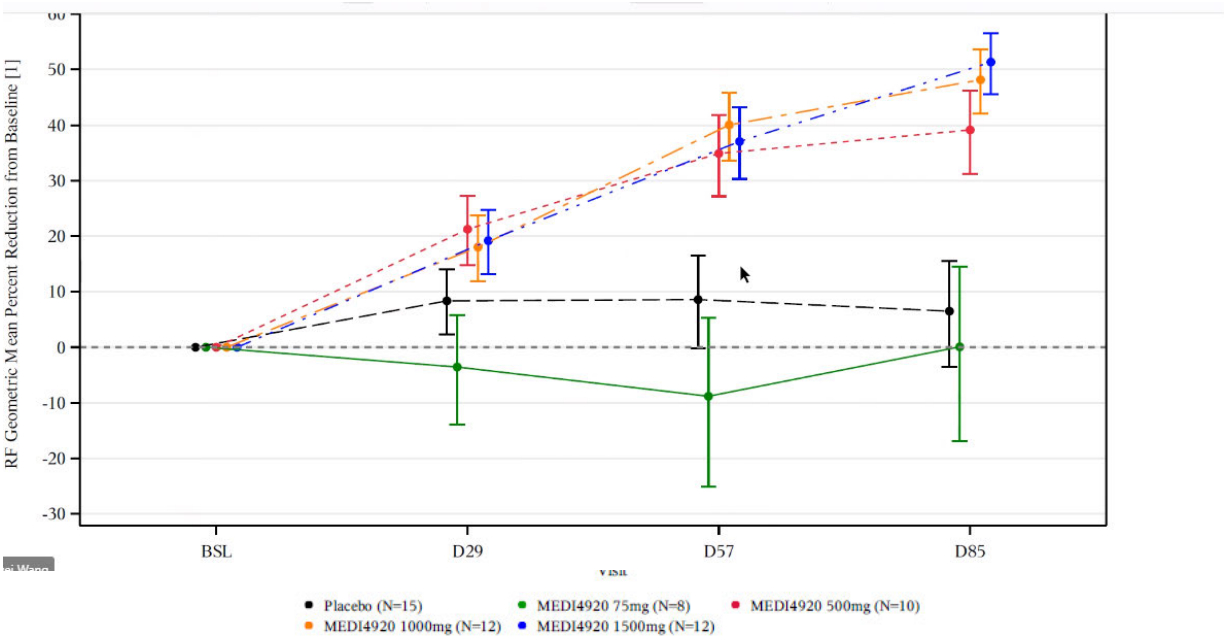

Figure 1. Geometric mean percent reduction from baseline in rheumatoid factor (Phase 1b study of VIB4920)

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Approval	[redacted] 07-Jun-2021 18:31:02 GMT+0000

Approval	[redacted] 07-Jun-2021 18:43:19 GMT+0000

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