A Phase 2, Multicenter, Open-label Study to Evaluate the Pharmacokinetics and Safety of RLYB212 in Pregnant Women at Higher Risk for HPA-1a Alloimmunization.

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Parexel International

Statistical Analysis Plan

Rallybio IPA, LLC

IPA2202

A Phase 2, Multicenter, Open-label Study to Evaluate the Pharmacokinetics and Safety of RLYB212 in Pregnant Women at Higher Risk for HPA-1a Alloimmunization

Statistical Analysis Plan

Version: 2.0

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Sponsor Signature Page

This document has been approved and signed electronically on the final page by the following:

Approved by: _[redacted]_ _____

[redacted] Date

Chief Medical Officer

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Parexel Signature Page

Signature(s) below confirm that the Statistical Analysis Plan was developed in accordance with SOP-GDO-WW-019 and that it is approved for release.

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Table of Contents

Version History

SAP Version	Date	Change	Rationale
1.0	Date of last signature	New document	
2.0 (Amendment)	26AUG2025	Added section 4.9 "Changes in the Conduct of the Study or Planned Analyses" describing early termination and use of participant level listings only. Statistical analyses and TLFs described in the original SAP will not be performed. Corrected typos and updated lab table 5 based on protocol version 4.0.	Early termination of the study due to Phase 2 PK data indicating that the RLYB212 dose regimen could not achieve predicted target concentration or the minimum concentration required for efficacy; only one participant enrolled. Strategic reduction in scope of TLFs for final analysis.

1. Introduction

RLYB212 is a recombinant human monoclonal anti-human platelet antigen (HPA)-1a immunoglobulin G (IgG)1κ antibody designed to selectively bind to HPA-1a positive fetal-derived cells or cell fragments present in the maternal circulation. The therapeutic goal of RLYB212 is to drive rapid and complete elimination of HPA-1a positive fetal antigen from the maternal circulation in HPA-1b/b pregnant women and prevent maternal HPA-1a alloimmunization (see protocol section 2.1).

This is a Phase 2, multicenter, open-label study to evaluate the pharmacokinetics and safety of RLYB212 in HPA-1b/b pregnant women at higher risk for HPA-1a alloimmunization and FNAIT.

A non-interventional (observational) sub-study (IPA2202A) is planned based on the phased approach to participant enrollment that results from the sequential cohort design. Because of the rarity of the potential occurrence of HPA-1a alloimmunization, the non-interventional (observational) sub-study will serve to augment an ongoing FNAIT Natural History Study (NCT05345561), ie, generating natural history data on the occurrence of HPA-1a alloimmunization and pregnancy/neonatal outcomes in women at higher risk for HPA-1a alloimmunization.

The analyses described in this SAP are based upon the following study documents:

- Clinical Study Protocol v 4.0 October 14, 2024 English IPA2202.
- 284014 Unique CRF v 1.0 27 Sep 2024.

1.1. Objectives, and Endpoints

1.1.1. Objectives and Endpoints (Interventional/Study IPA2202)

Objectives	Endpoints
Primary	
To evaluate the PK profile of RLYB212 during pregnancy following repeat SC administration	Maternal PK parameters, e.g., • half-life of RLYB212 ($t_{1/2}$) • maximum RLYB212 concentration (C_{max}) • time to maximum RLYB212 concentration (t_{max}) • apparent clearance (CL/F) of RLYB212 • apparent volume of distribution (Vd) • area under the RLYB212 concentration versus time curve (AUC)
To assess maternal and fetal safety of RLYB212 during pregnancy	• Type, seriousness, and incidence of AEs • Physical examination findings • Vital signs • Maternal clinical laboratory values • ECG • Obstetric/fetal doppler ultrasound

Secondary	
To evaluate RLYB212 exposure in the neonate at delivery	• Concentration of RLYB212 in cord blood
To assess the safety of RLYB212 in the HPA-1a positive neonate	• Type, seriousness, and incidence of AEs, including fetal/neonatal AEs • Physical examination findings, including APGAR score • Vital signs
To assess the immunogenicity of RLYB212	• Development of ADAs
To assess pregnancy and neonatal outcomes following antenatal RLYB212 administration	• Number of spontaneous abortions • Number of elective abortions • Number of stillbirths • Number of premature births • Number of full-term births (≥37 completed weeks of gestation) • Overall health and development of infants at 4-6 weeks and 12 months of age
To assess the occurrence of neonatal thrombocytopenia following antenatal RLYB212 administration	• Neonatal thrombocytopenia[a] and severe neonatal thrombocytopenia
To assess the occurrence of HPA-1a alloimmunization	• Presence of maternal anti-HPA-1a alloantibodies at Week 10 post pregnancy[b]

[a]Evaluation of neonatal thrombocytopenia will be based on the umbilical cord sample taken at parturition.
[b]For pregnancies that do not result in a live birth, the assessment of alloimmunization will be at 10 weeks from the date of the pregnancy-terminating event (ie, abortion [spontaneous/elective] or stillbirth).

RLYB212 drug concentrations will be summarized and listed in CSR. Maternal PK parameters, not part of the CSR will be explained outside of this SAP.

1.1.2. Objectives and Endpoints (Non-interventional [Observational])/Study IPA2202A

Objective	Endpoint
• To inform the frequency of HPA-1a alloimmunization among pregnant women identified at higher FNAIT risk.	• Occurrence of anti-HPA-1a maternal alloimmunization at Week 10 postpartum[a]
• To inform the frequency of pregnancy outcomes among pregnant women identified at higher FNAIT risk.	• Rate of spontaneous abortion, defined as non-deliberate fetal death which occurs prior to 19 weeks of gestation. • Rate of elective abortion, defined as deliberate termination of pregnancy at any time in gestation • Rate of stillbirth, defined as non-deliberate fetal death anytime in gestation on or after 19 weeks of gestation • Rate of premature birth, defined as live birth prior to 37 completed weeks of gestation • Rate of full-term birth (≥ 37 completed weeks of gestation)
• To inform the frequency, where data are available, of neonatal thrombocytopenia in infants born to women who have alloimmunized, as determined by detectable anti-HPA-1a antibody at Week 10 postpartum[a].	• Neonatal thrombocytopenia and severe neonatal thrombocytopenia, as determined by a platelet count $< 150 \times 10^9$/L and $< 50 \times 10^9$/L, respectively, where data are available

[a]For pregnancies that do not result in a live birth, the assessment of alloimmunization will be at 10 weeks from the date of the pregnancy-terminating event (ie, abortion [spontaneous/elective] or stillbirth).

The purpose of the IPA2202 study is to follow the PK and Safety of 8 participants that receive RLYB212. The participants that are identified at higher risk for FNAIT that do not enter the interventional study will be asked to consent for the non-interventional (observational) sub-study (IPA2202A). These observational participants will be followed per protocol through parturition and assessed 10 weeks postpartum (or end of the pregnancy) for the occurrence of

alloimmunization. The data from these observational participants will be merged with the IPA2002 study dataset and analyzed as one. Only IPA2202A participants' disposition will be summarized along with IPA2202 study summary. Hence objectives and endpoints of IPA2202A participants will not be discussed in this document.

1.2. Study Design

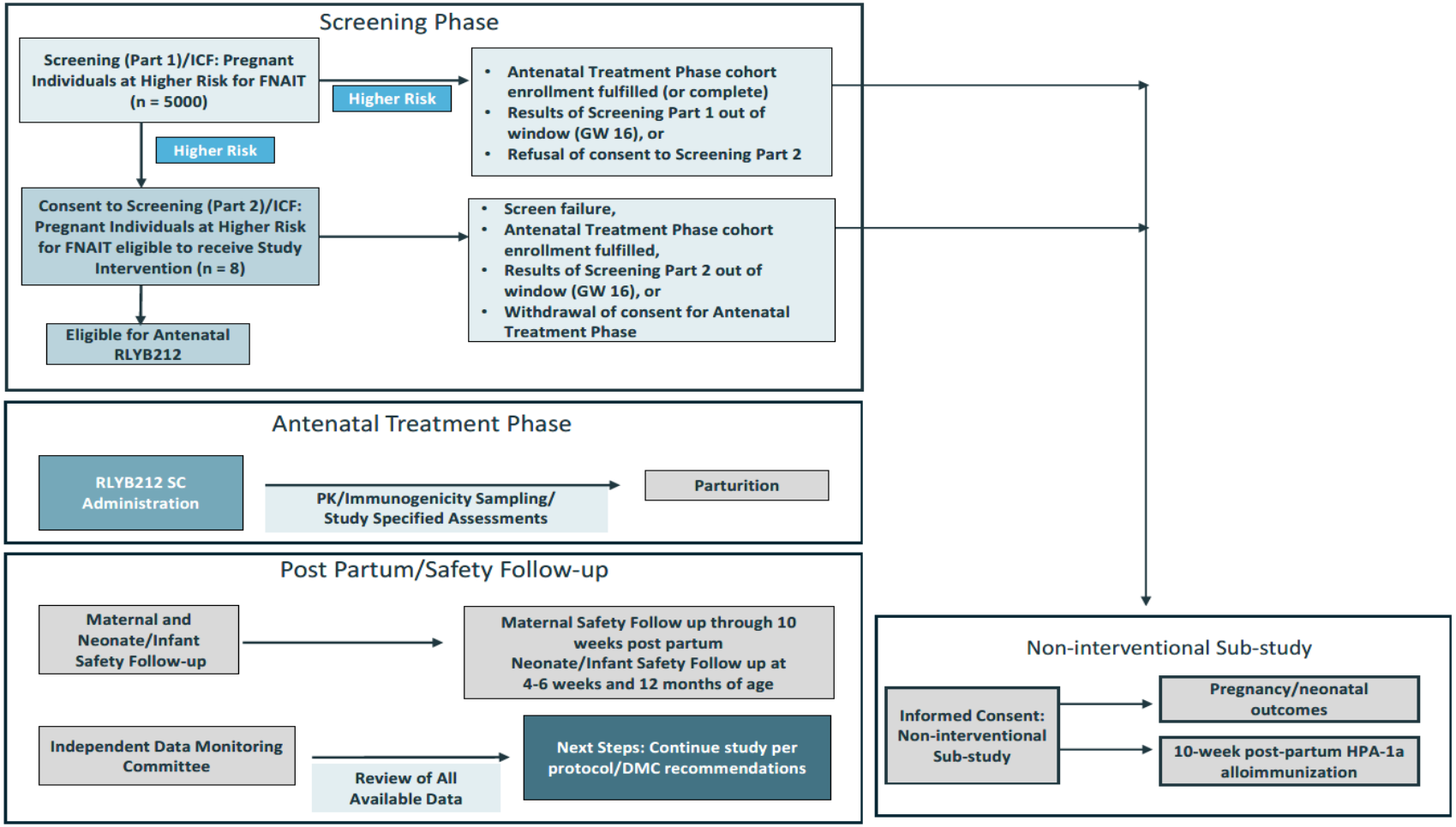
This study is a single-arm, open-label, multicenter study of RLYB212 in HPA-1b/b pregnant participants at higher risk for the occurrence of HPA-1a alloimmunization and FNAIT. A laboratory testing paradigm will be applied at screening to identify women at higher risk for HPA-1a alloimmunization. Study IPA2202 is comprised of three phases: a two-part screening phase, an antenatal treatment phase, and a postpartum follow-up phase (Figure 1). Study duration for each participant is anticipated to be around 44 weeks, inclusive of the screening visits through the Week 10 postpartum visit. For each child born during the study, the study duration is anticipated to be around 12 months.

For the non-interventional (observational) sub-study (IPA2202A), the same two-part screening phase for the intervention, as applicable, is followed by a postpartum follow-up phase. The sub-study duration is anticipated to be around 44 weeks, inclusive of the screening visits through the Week 10 postpartum visit.

The overall design of the Phase 2 study, including the non-interventional (observational) sub-study, is presented in Figure 1.

The study intervention, RLYB212, will be administered to participants via SC injection using vial and syringe in accordance with the study protocol. The RLYB212 dose regimen is comprised of an initial (loading) dose of 0.12 mg no later than GW 16 followed by maintenance (repeat) doses of 0.06 mg every 4 weeks (Q4W) ±3 days throughout the pregnancy and with a final 0.06 mg dose within 24 hours (±24 hours) of parturition. The dose regimen may be adjusted empirically as additional participants are enrolled in the study, as described in the study protocol.

Figure 1 Overall Study Design (Interventional and Non-interventional [Observational])



FNAIT = fetal and neonatal alloimmune thrombocytopenia; ICF = informed consent form; PK = pharmacokinetic; SC = subcutaneous. For Screening (Part 2)/ICF: Enrollment planned for 8 eligible participants for whom the pregnancy results in a live birth and who are evaluable for PK and safety assessments

2. Statistical Hypotheses

This study will be descriptive in nature. No statistical hypothesis testing is proposed. No formal interim analyses will be conducted. Preliminary data may be used for summary purposes and for communication with health authorities.

2.1. Multiplicity Adjustment

No hypotheses are planned to be formally tested using inferential statistics in this study; hence multiplicity is not a concern.

3. Analysis Sets

For purposes of analysis, the following populations are defined:

Table 1: Analysis sets

Population	Description
Full Analysis Set (FAS)	All participants that fulfill the criteria for screening part 1 and part 2, and received one or more full doses of RLYB212.
Neonate Full Analysis Set (NFAS)	Neonates born to participants that fulfill the criteria for screening part 1 and part 2 and received one or more doses of RLYB212.
Safety Analysis Set (SAS)	All participants in the study who received any dose of RLYB212.
RLYB212 PK Analysis Set	All participants received at least one dose of RLYB212 and at least one RLYB212-PK sample has been analyzed will be included.
Immunogenicity Analysis Set (IMAS)	All participants that fulfill the criteria for screening part 1 and part 2, received one or more doses of RLYB212 and had detection and categorization of ADA.

Population	Description
Alloimmunization Analysis Set (AAS)	All participants who had at least one screening (Screening Part 1 or 2) or baseline (Visit 2) determination of anti-HPA-1a activity and a subsequent determination of anti-HPA-1a activity postpartum.

4. Statistical Analyses

4.1. General Considerations

Continuous data will be summarized using descriptive statistics (the number of participants[n], mean, SD, median, 25th and 75th percentiles [where appropriate], minimum and maximum unless otherwise stated). For log transformed data, gmean, geometric CVmedian, minimum and maximum will be presented.

For continuous data including derived data, the minimum and maximum will be reported to the same number of decimal places as the raw data recorded in the database. The mean, median, lower quartile and upper quartile will be reported to 1 more decimal place than the raw data recorded in the database. The SD and geometric CV will be rounded to 2 additional decimal places compared to the original data. In general, the maximum number of decimal places reported will not exceed four decimal places for any summary statistic. If for any summary table, n is less than three, then only n, minimum, and maximum should be presented, and other summary statistics will be left blank.

Categorical data will be summarized in terms of the number of participants providing data at the relevant time point (n), frequency counts and percentages. Percentages will not be presented for 0 (zero) counts. Unless otherwise stated, percentages will be calculated using the number of participants included in the analysis set for that treatment group as denominator and presented to 1 decimal place.

Date variables are formatted as YYYY-MM-DD for presentation. Time is formatted in a 24 hour clock time as HH:MM for presentation.

For assessments on the day of first dose where time is not captured, a nominal pre-dose indicator, if available, will serve as evidence that the assessment occurred prior to first dose. Assessments

on the day of first dose where neither time nor a nominal pre-dose indicator are captured will be considered prior to first dose if such procedures are required by the protocol to be conducted before first dose.

Wherever possible, data will be decimal aligned.

4.1.1. Data Quality Assurance

All tables, figures, and data listings will be independently checked for consistency, integrity, and in accordance with standard Parexel procedures.

4.1.2. Software

All outputs will be produced using SAS® Version 9.4 or later in a secure and validated environment.

4.1.3. General Variables

4.1.3.1. Baseline

For all laboratory variables, vital signs, and -pharmacodynamic variables, the baseline will be the latest recorded measurement prior to the first dose of the study drug. Unless otherwise specified, any information taken after first dose/administration of study medication will be regarded as post baseline information. When time is not available, any observation on the same day as first dose will be assumed to be before first dose and may qualify as the baseline value. If more than 1 measurement is taken on the same day for a particular laboratory or vital signs parameter, the value with the later time (if available) will be considered as baseline. Otherwise, the average of the measurements taken on the same day will be used as the baseline.

In all summaries:

Change from baseline = post-baseline value - baseline value.

$$\text{Percent change from baseline} = \frac{\text{post-baseline value - baseline value}}{\text{baseline value}} \times 100.$$

4.1.3.2. Relative Day

Wherever data are summarized over time, study day will be calculated in relation to date of first treatment. If no value exists before the first dose/administration, then the baseline value will be treated as missing. Unless time variables indicate otherwise, AEs occurring on the day of first dose will be assumed to have occurred after first dose and will be assumed to be TE. The relative day for an assessment will be calculated from the first dosing date of the study drug and derived as follows:

- For days prior to the first dose = Assessment Date – first dosing date.
- For post-dose relative days = Assessment Date – first dosing date +1.

The relative day will be included in relevant listings.

4.1.3.3. Analysis Visit Window

The protocol specified visit windowing will be followed for all assessments (see Table 3 and Table 4). If multiple visits occur in a time window, the one closest to the target visit will be used for analyses. If the two visits have the same distance from a target window, the later one will be used. If two or more visits have the same date and time (or a date but no time) then the average of these visits will be used. Both unscheduled and scheduled visit values will be considered (with no preference) for use in the analyses using the rules above.

4.1.3.4. Handling of Missing Data

Missing or below lower limit of quantitation (BLQ) PK results prior to the first dose of RLYB212 will be imputed as zero for graphing and descriptive statistics of concentrations. RLYB212 concentrations with missing time or date information will be considered non-evaluable, will be flagged in the data set. No formal analysis of "outliers" is planned.

No imputation of missing data will be performed except the partial date imputations specified as below:

Missing or Partial Dates

All listings will report dates as collected on the eCRF and will not include imputed dates.

Imputation Rules for Prior or Concomitant Medication Dates

Missing Medication Start Date

- If the medication start date is missing, and the medication stop date is on or after the first dose of study medication, then the medication start date will be imputed as the date of the first dose of study medication.

If the medication start date is missing, and the medication stop date is not missing and before the first dose of study medication, then the medication start date will be imputed as the medication stop date.

Partial Medication Start Date

Missing Day and Month

- If the year of the incomplete start date is the same as the year of the date of the first dose of study medication, then the day and month of the date of the first dose of study medication will be assigned to the missing fields.
- If the year of the incomplete start date is before the year of the date of the first dose of study medication, then December 31 will be assigned to the missing fields.
- If the year of the incomplete start date is after the year of the date of the first dose

Missing Month Only

- The day will be treated as missing and both month and day will be replaced according to the above procedure.

Missing Day Only

- If the month and year of the incomplete start date are the same as the month and year of the date of the first dose of study medication, then the day of the first dose of study medication will be assigned to the missing day.
- If either the year is before the year of the date of the first dose of study medication or if both years are the same, but the month is before the month of the date of the first dose of study medication, then the last day of the month will be assigned to the missing day.
- If either the year is after the year of the date of the first dose of study medication or if both years are the same, but the month is after the month of the date of the

first dose of study medication, then the first day of the month will be assigned to the missing day.

Missing Medication Stop Date

- If a medication stop date is missing and the ongoing status is also missing, then the medication is assumed to be ongoing.
- If the imputed medication stop date is before the study medication start date (whether imputed or non-imputed), then the imputed medication stop date will be equal to the study medication start date.

Partial Medication Stop Date

Missing Day and Month

- If the year of the incomplete stop date is the same as the year of the date of the last dose of study medication, then the day and month of the date of the last dose of study medication will be assigned to the missing fields.
- If the year of the incomplete stop date is before the year of the date of the last dose of study medication, then December 31 will be assigned to the missing fields.
- If the year of the incomplete stop date is after the year of the date of the last dose of study medication, then January 1 will be assigned to the missing fields.

Missing Month Only

- The day will be treated as missing and both month and day will be replaced according to the above procedure.

Missing Day Only

- If the month and year of the incomplete medication stop date are the same as the month and year of the date of the last dose of study medication, then the day of the last dose of study medication will be assigned to the missing day.
- If either the year is before the year of the date of the last dose of study medication or if both years are the same, but the month is before the month of the date of the

last dose of study medication, then the last day of the month will be assigned to the missing day.

If either the year is after the year of the date of the last dose of study medication or if both years are the same, but the month is after the month of the date of the last dose of study medication, then the first day of the month will be assigned to the missing day.

Imputation Rules for Adverse Event (AE) Dates

Missing AE Start Date

- If the AE start date is missing, and the AE stop date is on or after the first dose of study medication, then the AE start date will be imputed as the date of the first dose of study medication.
- If the AE start date is missing, and the AE stop date is not missing and before the first dose of study medication, then the AE start date will be imputed as the stop date.

Partial AE Start Date

Missing Day and Month

- If the year is the same as the year of the date of the first dose of study medication, then the day and month of the date of the first dose of study medication will be assigned to the missing fields.
- If the year is before the year of the date of the first dose of study medication, then December 31 will be assigned to the missing fields.
- If the year is after the year of the date of the first dose of study medication, then January 1 will be assigned to the missing fields.

Missing Month Only

- The day will be treated as missing and both month and day will be replaced according to the above procedure.

Missing Day Only

- If the month and year are the same as the month and year of the date of the first dose of study medication, then the day of the first dose of study medication will be assigned to the missing day.
- If either the year is before the year of the date of the first dose of study medication or if both years are the same, but the month is before the month of the date of the first dose of study medication, then the last day of the month will be assigned to the missing day.
- If either the year is after the year of the date of the first dose of study medication or if both years are the same, but the month is after the month of the date of the first dose of study medication, then the first day of the month will be assigned to the missing day.
- If the imputed AE start date is after the AE stop date, then the imputed AE start date will be populated to the AE stop date.

All listings will report dates as reported on the eCRF and will not include imputed dates.

4.1.4. Study Participants

4.1.4.1. Disposition of Participants

A clear accounting of the disposition of all participants who enter the study will be provided, from the time of informed consent to study completion. Only the pooled numbers will be provided for screened, screen failures, and reasons for screen failures.

The number and percentage of the participants in the following categories will be summarized separately by study part (interventional and non-interventional [observational]) for all participants signed the ICF:

- Participants signed ICF.
- Participants screened for Screening part 1.
- Participants screened for Screening part 2.
- Participants with screen failure and reasons for screen failures in each screening part.
- Did not receive treatment with reasons for not receiving the treatment (only for interventional part).
- Completed study treatment (only for interventional part).

- Did not complete study treatment with reasons for premature discontinuation of study drug (only for interventional part).
- Completed study.
- Did not complete the study with reasons for premature discontinuation of study.

The denominator for the percentage calculation will be the total number of participants in the Full Analysis Set.

A by-participant listing of all screen failures and study eligibility details will be presented for the screened population. The reasons for premature study discontinuation will be listed by PID. The reasons for screen failure will also be provided by study part, by PID number in ascending order.

4.1.4.2. Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol, ICH GCP, or SOP requirements. The noncompliance may be either on the part of the participant, on the Investigator, or on the study site staff. Protocol deviations occurring after participants entered the study are documented during the routine monitoring. These protocol deviations will be classified as "major" or "minor" on a case-by-case basis by the clinical study team and sponsor.

Major protocol deviations are defined as those deviations from the protocol likely to have an impact on the participant's right, safety, well-being, and/or validity of the data for analysis. Minor protocol deviations included all deviations from the protocol excluding the major protocol deviations. Major protocol deviations and any action to be taken regarding the exclusion of participants or affected data from specific analysis are defined in the Protocol Deviation Assessment Plan (PDAP).

Deviations considered to be major will be listed. All decisions on importance will be made ahead of database lock for the primary analysis and will be documented prior to the primary analysis being conducted.

A summary of major protocol deviations for FAS, by deviation category will be provided.

4.1.4.3. Analysis Sets

The number and percentage of participants in each analysis set and reasons for exclusions from each analysis set will be summarized for FAS. The participants included and excluded in each analysis set will be listed for FAS.

4.1.4.4. Demographics and Baseline Characteristics

The maternal demographic and baseline data will be collected at the screening visits.

The demographic characteristics (e.g., age, race, ethnicity, sex, height, body weight, body mass index [BMI]) and baseline viral serology (Hepatitis B virus surface [negative/positive], Hepatitis C virus antibody [negative/positive], Human Immunodeficiency Virus antibody [negative/positive]]), FNAIT status (maternal HPA-1 genotype [HPA-1b/b, HPA-1a/a, HPA-1 a/b], maternal HLA-DRB3*01:01 genotype [positive, negative], maternal anti-HPA-1a antibody [positive, negative], fetal HPA-1 genotype [HPA-1a/b, HPA-1b/b])) results will be summarized and listed for FAS.

4.1.4.5. Medical History

Medical history collected at screening will be coded using MedDRA version 27.0 or later.

Medical history will be summarized by SOC and by preferred term for FAS. Participants who report two or more medical history items that are coded to the same SOC and preferred term will be counted only once by the unique coded term in the summary.

A listing of medical history will be provided for FAS.

4.1.4.6. Obstetrics History

The obstetrics history (participants with previous pregnancies [Yes, No], and for each prior pregnancy - mode of delivery [vaginal, cesarean section], gestational age of delivery, outcome of delivery [premature birth, live birth, still birth, spontaneous abortion, elective abortion]) collected at screening will be summarized and listed for FAS.

4.1.4.7. Prior and Concomitant therapy

Standard treatments given during obstetric care are allowed during the study. Any medication (including over-the-counter or prescription medicines, recreational drugs, vitamins, and/or herbal

supplements) or other specific categories of interest that the participant is receiving at the time of enrollment or receives during the study will be recorded along with:

- Reason for use
- Dates of administration including start and end dates
- Dosage information including dose and frequency

Concomitant medications will be considered on a case-by-case basis by the investigator in consultation with the medical monitor.

For the purpose of inclusion in prior and/or concomitant medication summaries, incomplete medication start and stop dates will be imputed as detailed in section 4.1.3.4.

- Prior medications: Medications taken prior to study treatment with a stop date prior to first dose of study treatment.
- Concomitant medications: Medications with a stop date on or after the first dose date of study treatment (and could have started prior to or during treatment).

Prior and concomitant therapies will be summarized and listed separately for FAS. Both prior and concomitant therapy will be summarized by ATC drug class level 4 and by ATC drug class level 1 for preferred name using the number and percentage of participants. A participant reporting the same medication more than once will be counted once within each preferred name. The summary will be ordered alphabetically by ATC 4 drug class, and by preferred drug name in order of descending frequency within each ATC 1 drug class. For drugs with the same frequency, sorting will be done alphabetically.

4.2. Primary Endpoint Analysis

4.2.1. PK Profile of RLYB212 During Pregnancy Following Repeat SC Administration

4.2.1.1. Maternal RLYB212 Concentrations

Serum samples will be collected from participants for measurement of concentrations of RLYB212 at regular intervals as specified in Table 3.

The RLYB212 concentration data will be reviewed combined with dosing, concomitant medication and AE data on a case-by-case basis to determine whether any exclusion from the PK analysis set is deemed necessary.

Serum concentration-time data will be summarized for RLYB212 PK analysis set for interventional participants, by analysis visit, by means of descriptive statistics as follows:

- Geometric mean (gmean, calculated as exp[μ], where μ is the mean of the data on a logarithmic scale).
- Coefficient of variation (gCV%, calculated as 100 ($\sqrt{\exp(^2)} - 1$) where s is the standard deviation of the data on a log scale).
- Gmean ± geometric standard deviation (gmean+gSD and gmean-gSD), calculated as exp[μ ± s]).
- Arithmetic Mean.
- SD.
- Median.
- Minimum (min).
- Maximum (max).
- Number of observations (n).
- n > LLOQ.

Individual serum concentration versus actual elapsed times will be presented by scatter plot on both the linear and semilogarithmic scale for RLYB212 PK analysis set.

Individual concentrations below the LLOQ of the bioanalytical assay will be reported as NQ (Not Quantifiable) in the listings with the LLOQ defined in the footnotes of the relevant TFLs. Individual serum concentrations that are 'Not Reportable' will be reported as NR and those that are missing will be reported as NS (No Sample) in the listings. Serum concentrations that are NQ, NR, or NS will be handled as follows for the provision of descriptive statistics:

- Missing or below LLOQ (BLQ) PK results prior to the first dose of RLYB212 will be imputed as zero for graphing and descriptive statistics of concentrations. Post-dose concentration values that are BLQ or missing values (e.g., no sample collected, or no value reported from bioanalytical assay) will be treated as missing.

- At a time point where less than or equal to 50% of the concentration values are NQ, all NQ values will be substituted with the LLOQ concentration, and all descriptive statistics will be calculated accordingly.
- At a time point where more than half (but not all) of the values are NQ, mean, gmean, gCV%, +gSD and SD will be set to NC (Not Calculated). The maximum value will be reported from the individual data and the minimum and median will be set to NQ.
- If all concentrations are NQ at a time point, the mean, gmean, min, median and max will be reported as NQ and the +gSD, gCV%, and SD will be reported as NC.
- The number of values above LLOQ (n > LLOQ) will be reported for each time point together with the total number of collected values.
- Three observations > LLOQ will be required as a minimum for PK serum concentrations to be summarized. Two values will be presented as minimum and maximum with the other summary statistics as NC.

RLYB212 concentrations below BLQ will be reported as 0 for all descriptive statistics summaries.

PK concentration data will be listed for each participant who receives study intervention (RLYB212), together with the flag.

4.2.1.2. Maternal Pharmacokinetics Parameters

Maternal pharmacokinetics parameters are not part of the CSR and will be presented in a supplementary report.

4.2.2. Maternal and Fetal Safety of RLYB212 During Pregnancy

4.2.2.1. Type, Seriousness, and Incidence of Maternal AEs

An adverse event is any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study intervention.

Adverse Events will be collected throughout the study from the time of screening part 2 and beyond until the end of study visit (10 weeks postpartum for the maternal participant and 4-6 weeks of age for the neonate/infant). MedDRA version 27.0 or above will be used to code the

AEs. All maternal AEs will be graded according to the National Cancer Institute of Common Terminology Criteria for AEs (CTCAE version 5.0 or higher) and Maternal and Fetal Adverse Event Terminology (MFAET version 1.0 or higher).

Serious adverse events are collected from Screening part 2 of the study and onward. Serious adverse events are identified as serious via the eCRF.

- All AEs: An AE that newly occurs or worsen in severity from the time of screening part 2.
- TEAEs: An AE that newly occurs or worsen in severity on or after the first dose of the study drug.
- SAE: An AE occurring during any study phase, that fulfils one or more of the following criteria:
    - Results in death.
    - Is life-threatening.
    - Requires in-participant hospitalization or prolongation of existing hospitalization.
    - Results in persistent or significant disability or incapacity.
    - Is a congenital anomaly or birth defect.
    - Is an important medical event that may jeopardize the participant or may require medical treatment to prevent one of the outcomes listed above.

All reported AEs, SAEs will be listed along with the actual dose received at the time of onset, date of onset, date of resolution (if AE is resolved), investigator's assessment of CTCAE grade, MFAET grading, relationship to study treatment, action taken and outcome. The numbers and percentage of participants (with 95% Clopper-Pearson confidence interval) experiencing AEs/TEAEs will be summarized separately (AEs and TEAEs will be summarized separately) for the SAS, including but are not limited to:

- All AEs (*).
- All AEs related to study treatment (*).
- All AEs related to study procedure (*).
- All AEs with outcome of death.
- All AEs with outcome of death, related to study treatment.
- All AEs with outcome of death, related to study procedure.
- All AEs leading to drug interruption (*).
- All AEs leading to drug interruption, related to study treatment.

- All AEs leading to drug interruption, related to study procedure.
- All AEs leading to drug discontinuation (*).
- All AEs leading to drug discontinuation, related to study treatment.
- All AEs leading to drug discontinuation, related to study procedure.
- All AEs leading to study discontinuation (*).
- All AEs leading to study discontinuation, related to study treatment.
- All AEs leading to study discontinuation, related to study procedure.
- AEs of CTCAE grade 3 or higher (*).
- AEs of CTCAE grade 3 or higher, related to treatment.
- AEs of CTCAE grade 3 or higher, related to study procedure.
- AEs of MFAET grade 3 or higher.
- AEs of MFAET grade 3 or higher, related to treatment.
- AEs of MFAET grade 3 or higher, related to study procedure.
- All SAEs (*).
- All SAEs, related to study treatment (*).
- All SAEs, related to study procedure.
- All SAEs with outcome of death.
- All SAEs with outcome of death, related to study treatment.
- All SAEs with outcome of death, related to study procedure.
- All SAEs leading to drug interruption (*).
- All SAEs leading to drug interruption, related to study treatment.
- All SAEs leading to drug interruption, related to study procedure.
- All SAEs leading to drug discontinuation (*).
- All SAEs leading to drug discontinuation, related to treatment.
- All SAEs leading to drug discontinuation, related to study procedure.
- All SAEs leading to study discontinuation (*).
- All SAEs leading to study discontinuation, related to study treatment.
- All SAEs leading to study discontinuation, related to study procedure.

The categories marked above in * will be summarized by MedDRA System Organ Class and Preferred Term (PT). The following maternal and fetal AEs by MedDRA preferred term will be summarized separately for SAS (*Spencer R, Hecher K, Norman G, Marsal K, Deprest J, Flake A, et al.)*.

Maternal AEs:

- Haemorrhage in pregnancy
- Preterm premature rupture of membranes
- Chorioamnionitis
- Anaemia of pregnancy
- Gestational hypertension
- Pre-eclampsia
- Eclampsia
- Premature labour
- Puerperal infection
- Postpartum haemorrhage (primary)
- Retained placenta or membranes
- Amniotic fluid embolism

Fetal AEs:

- Haemorrhage in pregnancy
- Preterm premature rupture of membranes
- Chorioamnionitis
- Anaemia of pregnancy
- Fetal fluid collection
- Fetal bradycardia: non-labour
- Fetal tachyarrhythmia
- Cardiac function abnormalities
- Fetal brain scan abnormal
- Fetal gastrointestinal tract imaging abnormal
- Fetal musculoskeletal imaging abnormal
- Fetal renal imaging abnormal
- Fetal movement disorders
- Fetal neoplasm
- Fetal structural abnormalities: not otherwise classified
- Abnormal fetal growth
- Fetal intraoperative injury
- Procedure haemorrhage
- Post-procedural haemorrhage

4.2.2.2. Maternal Physical Examination Findings

A complete physical examination including the following observations/measurements will be done at the time of screening part 2: height, weight, general appearance, skin, head, eyes, ears, nose, and throat, lymph nodes, heart, lungs, abdomen, extremities/joints, neurological, and mental status. Any significant abnormalities observed at screening will be recorded as medical history.

A brief physical and obstetric examination (heart, lungs, abdomen) will also be performed throughout pregnancy and the postpartum period. All physical examination findings will be summarized and listed for the SAS.

4.2.2.3. Vital Signs

Systolic and diastolic blood pressures (mmHg), heart rate (beats/minute), respiratory rate (breaths/min) and temperature (°C) will be recorded in supine position for participants from screening. Any clinically significant abnormal findings will be recorded as AEs except events identified at the Screening Part 2 visit.

Changes from baseline in vital signs to each post-baseline assessment will be calculated. Absolute values, changes from baseline and percentage change from baseline will be summarized for the SAS. Individual vital signs results will be listed for the SAS too.

4.2.2.4. Maternal Clinical Laboratory Values

Summaries for safety laboratory will be presented for the SAS, which will only include the parameters specified in Table 5.

All values will be classified as low (below range), normal (within range), or high (above range) based on laboratory reference ranges. Results will be presented in PAREXEL standard units as specified in Table 6 and all the clinical laboratory parameter values in collected lab units will converted to PAREXEL standard units using the corresponding conversion factors as shown in Table 7. For all continuous laboratory assessments, absolute value, will be summarized using descriptive statistics at each scheduled assessment timepoint.

If the same parameter is found as measured in serum and in plasma, then the summaries will not distinguish between them (e.g. values from plasma albumin and serum albumin will be summarized under albumin). If the same parameter is found as measured in serum and in plasma

for the same participant (which would be a rare case), then the change from baseline will only be calculated for those post-baseline values using the same source, i.e., only within plasma or serum.

For clinical chemistry, hematology and coagulation, shift tables will be presented from baseline to worst value on-treatment (defined from start of treatment to parturition) according to reference range classification (HIGH, LOW, NORMAL). A shift table from baseline to maximum value will be summarized for urine dipstick variables.

Spaghetti plots of absolute values for all hematology, coagulation and clinical chemistry parameters will also be presented.

Liver biochemistry test results over time for participants who show elevated ALT or AST (≥ 3 x ULN) and elevated bilirubin (≥ 2 x ULN) (elevated results do not need to be present at the same visit) or ALT or AST of ≥ 5 x ULN, will be tabulated and plotted. Plots for both maximum post-baseline alanine transaminase (ALT) and aspartate transaminase (AST) versus the maximum post-baseline total bilirubin (expressed as multiples of their upper limit of normal [ULN] reference range) will be produced with reference lines at 3 x ULN for ALT and AST and 2 x ULN for total bilirubin (eDISH plot).

All laboratory results collected will be listed.

4.2.2.5. Maternal ECG

12-leads ECGs including heart rate, PR interval, QRS duration, QT interval, PR segment, RR interval, RR segment and QTc interval will be summarized for the SAS. In the summary table, baseline value and change from baseline at each post-baseline visit will also be provided. A listing for ECG assessment results with interpretation will be presented. The clinically significant abnormal results will be flagged in the listing.

4.2.2.6. Obstetric/Fetal Doppler Ultrasound

Obstetric and fetal doppler ultrasound monitoring will be performed as outlined in the SoA (Table 2) and at regular intervals during the study and consistent with local obstetric standard of care, to detect any evidence of placental structural abnormality, organ pathology, hemorrhage, or delayed growth in the fetus, or any doppler velocimetry effects indicative of placental insufficiency or fetal anemia.

The maternal ultrasound results (indication, fetal position, fetal anatomy with clinical significance and fetal AE, fetal cardiac activity with clinical significance and fetal AE, placenta position with clinical significance and fetal AE , placenta anatomy with clinical significance and fetal AE, amniotic fluid volume with clinical significance and fetal AE, retroplacental hemorrhage (Yes, No) with clinical significance and fetal AE, fetal growth restriction (Yes, No) with clinical significance and fetal AE, fetal macrosomia (Yes, No) with clinical significance and fetal AE and fetal doppler ultrasound findings (anatomic area, pulsatility index, resistance index, end-diastolic flow, systolic/diastolic ratio, overall impression with clinical significance, fetal AE and intervention status) will be listed only for the SAS.

4.2.3. Sensitivity Analysis

Not applicable

4.2.4. Supplementary Analyses

Not applicable

4.3. Secondary Endpoint Analysis

4.3.1. RLYB212 Exposure in the Neonate at Delivery

4.3.1.1. Concentration of RLYB212 in Cord Blood

A cord blood sample will be collected at parturition to assess neonate exposure to RLYB212. Neonate serum concentration will be listed only for all newborns for the RLYB212 PK analysis set. Serum concentrations below BLQ will be imputed as 0.

4.3.2. Safety of RLYB212 in the HPA-1a Positive Neonate

4.3.2.1. Type, Seriousness, and Incidence of AEs

The neonatal adverse events will be collected from the time of birth till 4 to 6 weeks of age. MedDRA version 27.0 or above will be used to code the AEs. All neonatal AEs will be graded according to neonatal adverse event severity scale (NAESS version 1.0 or higher).

The following summaries of neonates will be provided for NFAS (the number and percentage of participants) including but not limited to:

- All AEs (*).
- All AEs related to study treatment (*).
- All AE leading to worsening of a pre-existing condition (*).
- All AEs with outcome of death.
- All AEs with outcome of death, related to study treatment.
- AEs of NAESS grade 3 or higher.
- AEs of NAESS grade 3 or higher, related to treatment.
- All SAEs (*).
- All SAEs, related to study treatment.
- All SAE leading to worsening of a pre-existing condition (*).
- All SAEs with outcome of death.
- All SAEs with outcome of death, related to study treatment.

The incidences of above adverse events will also be summarized by the number of participants reporting at least one event, percentage of participants with the 95% exact Clopper-Pearson confidence interval for the percentage.

The selected summaries (marked above in *) will be presented by MedDRA System Organ Class (SOC) and Preferred Term (PT). Frequencies and percentages of participants reporting each preferred term will be presented (i.e., multiple events per participant will not be accounted for, except for event level summaries). All AEs, SAES, all AEs with outcome of death, all SAEs with outcome of death, all AEs leading to study discontinuation, all SAEs leading to study discontinuation will be summarized for neonates. The selected summaries (marked in above) will be presented by MedDRA System Organ Class (SOC) and Preferred Term (PT).

All reported neonatal AEs will be listed along with date of onset, date of resolution (if AE is resolved), investigator's assessment of NAESS grading, relationship to study treatment, action taken and outcome, SAE status MDR and concomitant of additional treatment given to due to AE).

4.3.2.2. Newborn Physical Examination Findings, Including APGAR Score

Newborn physical examination findings (gender, birth weight, length, head circumference, APGAR score taken at 1 min and 5 min after birth) will be summarized for NFAS.

Newborn physical examination findings will be listed for NFAS, by newborn participant id.

4.3.2.3. Vital signs

All available vital signs collected from live births will be listed for NFAS, by newborn id and by visit.

4.3.3. Immunogenicity of RLYB212

To assess the immunogenicity of RLYB212, anti-drug antibody in serum will be evaluated as described in SoA. Serum samples should also be collected at the final visit from participants who discontinue study intervention or are withdrawn from the study.

Serum ADA findings will be summarized for IMAS, by study visits. The number and percentage of participants with both positive and negative ADA samples as well as the titers, persistence or transience of positive ADA samples will be summarized, and a by- participant listing will be presented for all immunogenicity assessments using the IMAS. Definition of common terms applied in the descriptions of immunogenicity are as below:

- Pre-existing ADA: refers to antibodies reactive with the biologic drug that are present in participants before treatment (or before initiation of the clinical study).
- Treatment-emergent ADA: ADA developed de novo (seroconversion) following biologic drug administration.
- Treatment-boosted ADA: Pre-existing ADA that were boosted to a higher level following biologic drug administration.
- Titer: a quasi-quantitative expression of the level of ADA in a sample; magnitude of the ADA response.
- Transient ADA: Treatment-induced ADA detected at sampling time points during the treatment (including follow-up period if any), where the first and last ADA-positive samples (irrespective of any negative samples in between) are separated by a period less than 16 weeks, and the participant's last sampling time point is ADA-negative.
- Persistent ADA: Treatment-induced ADA detected at two or more sampling time points during the treatment, where the first and last ADA-positive samples (irrespective of any negative samples in between) are separated by a period of 16 weeks or longer or treatment-induced ADA is detected in the last sampling time point.

ADA impact assessment

Individual serum RLYB212 concentration-time (hour) profiles following administration of RLYB212 SC by participant ID and ADA status shall be presented in a figure, on a semi-log scale. ADA positive vs. negative participants shall be highlighted in the figure for visual comparison.

The results will be listed for each participant by visit.

4.3.4. Pregnancy and Neonatal Outcomes

The following pregnancy and neonatal outcomes will be summarized by the frequency of participants with the specified outcome and percentage with 95% Clopper-Pearson exact confidence interval for the FAS.

- Number of spontaneous abortions.
- Number of elective abortions.
- Number of stillbirths.
- Number of premature births.
- Number of full-term births (≥37 completed weeks of gestation).

4.3.5. Overall Health and Development of Infants at 4-6 Weeks and 12 Months of Age

For NFAS, general health assessment of livebirths will be collected at birth, at 4- 6 weeks; and a developmental assessment will be conducted at 12 months of age. All available, health status will be summarized and listed. Any abnormality in the health assessment will be flagged in the listing.

The development assessment at 12-months will consist of the parent-reported ASQ-3 data. Raw questionnaire data will be centrally scored and analyzed according to published methods for the instrument (*Ghimire, S., Ang, E., Deibert, M., Hartvich, E., & Fucile, S. (2024*)).

4.3.6. Neonatal Thrombocytopenia

A cord blood sample will be collected at delivery to assess the possible occurrence of neonatal thrombocytopenia and severe neonatal thrombocytopenia, as determined by a cord blood platelet count $< 150 \times 10^9$/L and $< 50 \times 10^9$/L respectively.

All available data will be summarized and listed for all newborns. The incidence of Neonatal thrombocytopenia and severe neonatal thrombocytopenia will also be summarized by frequency and percentage with 95% Clopper-Pearson exact confidence interval.

4.3.7. Post Pregnancy HPA-1a Alloimmunization

Serum samples will be tested at the Week 10 postpartum timepoint to assess for the occurrence of HPA-1a alloimmunization during the pregnancy and early postpartum period.

The presence of post pregnancy maternal anti-HPA-1a alloantibodies will be summarized by frequency and percentage with 95% Clopper-Pearson exact confidence interval for AAS.

4.3.8. Sensitivity Analysis

Not Applicable

4.3.9. Supplementary Analyses

Not Applicable

4.4. Exploratory Endpoint Analysis

Not applicable

4.5. Other Analyses

4.5.1. Extent of Exposure

Study drug exposure will be summarized for participants who received RLYB212 for the safety analysis set, for duration of exposure, number of doses, cumulative dose, and number of missed doses.
Duration of exposure (in Weeks) is defined as: (date of the last dose – the date of the first dose + 1)/7.

- Number of doses: Total number of non-zero doses administered during study.
- Cumulative dose (in mg) is defined as the cumulative amount of study drug administered during the treatment period.
- Number of missed doses is defined as: Total number of completely missed doses across study dosing period.

A by-participant listing of exposure to study drug will be generated for the FAS. The listing will include participant identifier, age, gestational age at each visit, treatment status (drug given [Yes, No]), planned dose, dose administered, anatomical location, laterality, route, dose form and date and time of administration.

4.6. Independent Data Monitoring Committee (DMC)

A DMC will monitor safety outcomes and study conduct and will provide recommendations for consideration by the sponsor regarding the continuation of the interventional study, dosing of further participants in the study or stopping the study for all interventional participants or subgroups of interventional participants all along the study. Safety data will include, but not be limited to, those outcomes listed as primary and secondary endpoints.

A detailed DMC charter and operating rules will be prepared and signed by DMC members before the sentinel participant is dosed. The DMC will review study data at regular intervals as described in the DMC charter. These sessions could be regular sessions or ad-hoc sessions. Ad-hoc sessions can be requested by the sponsor, or the DMC as needed and at any time during the study. A total of three (3) scheduled DMC safety reviews will occur. During the scheduled data review meetings, the DMC will receive an update on the study and will review data packages prepared in advance. In addition, the DMC will consider any specific items or issues brought to its attention by the Sponsor. The study has been designed to enroll an initial sentinel participant followed by staged enrollment of participants to two sequential cohorts.

- The first DMC data review meeting will be held when the single sentinel participant has been enrolled and received subcutaneous(ly) (SC) administered RLYB212 for the scheduled duration of their pregnancy. The DMC will review all available data through parturition for this sentinel participant, together with available RLYB212 exposure data and safety data in the neonate. This review will be performed before commencing dosing in subsequent participants.
- The second DMC data review meeting will be held for participants in a cohort of up to three (3) additional participants receiving SC administration of RLYB212. The DMC will review all available data through parturition for the additional three (3) participants, performed before commencing dosing to the next cohort.

- The third DMC data review meeting will be held for participants in a cohort of the final four (4) participants receiving SC administration of RLYB212. The DMC will review all available data through parturition for the final 4 participants, together with RLYB212 exposure data and safety data in the neonates.

4.7. Interim Analysis

No formal interim analyses will be conducted for this study. Preliminary data may be used for summary purposes and for communication with health authorities.

4.8. Changes to Protocol-planned Analyses

Since there is a formal possibility of (all) samples reading below LLOQ, and that is important information. The description of RLYB212 PK analysis set has been re-defined as "all participants who received at least one dose of RLYB212 and at least one RLYB212-PK sample has been analyzed".

The description of safety analysis set is re-defined as all participants in the study who received any dose of RLYB212 to include participants receiving any amount of the prescribed intervention.

The following analysis sets are added to accommodate summary or listing requirements (see Table 1 for detailed description each analysis set).

- Neonate Full Analysis Set (NFAS)
- Immunogenicity Analysis Set (IMAS)
- Full Analysis Set (FAS)

4.9. Changes in the Conduct of the Study or Planned Analyses

In response to a directive from the Sponsor, Rallybio IPA, LLC, a strategic reduction in the scope of the Tables, Listings, and Figures (TLFs) described in the current SAP was implemented for the final analysis.

The study was terminated early. The decision was based on pharmacokinetic (PK) data from the Phase 2 trial demonstrating the inability of the RLYB212 dose regimen to achieve the predicted

target concentration range, as well as the minimum concentration required for efficacy. As a result, the Sponsor discontinued further development of RLYB212.

Given the early termination and the limited sample size (only one participant enrolled), the originally planned statistical analyses and TLFs will not be produced. Instead, participant-level listings will be generated to present the data collected up to the time of study termination. These listings will include participant disposition, inclusion/exclusion criteria, protocol deviations, demographics characteristics, pregnancy outcome, newborn and infant general status, medical and obstetric history, prior and concomitant medication, study drug exposure, adverse events, laboratory results, vital signs, ECG, and relevant efficacy assessments.

No tables, figures, or inferential statistical analyses will be performed. The listings will be descriptive in nature and will serve as the sole presentation of the study data.

5. Sample Size Determination

The primary objectives of the study are to characterize the safety and PK of RLYB212 in HPA-1b/b pregnant women at risk of HPA-1a alloimmunization. Empiric PK data from this study will be used to supplement the parameters for the current clinical pharmacology model, including the impact of target-mediated drug disposition, if necessary. The PK characterization of RLYB212 in this study is intended to be exploratory, rather than to meet a pre-specified statistical objective. The proposed sample size of 8 is consistent with other studies reported in literature intended to characterize the PK of monoclonal antibodies in an exploratory manner and has been determined to be adequate from a PK perspective based on the following (refer to protocol section 9.2 for details).

- Low to moderate variability observed in RLYB212 PK.
- Antibody PK in pregnancy.
- Conservative dose selection approach.

It is anticipated that approximately 5,000 participants will be screened to identify 8 pregnant women who both meet the study-specific screening test requirements (ie, genotype HPA-1b/b, genotype HLA-DRB3*01:01 positive, anti-HPA-1a antibody negative, and carrying an HPA-1a positive fetus) and who meet all other inclusion/exclusion criteria to be eligible to receive the study intervention (RLYB212). Women in their first or subsequent pregnancy may be included in

this study. Replacement of participants is permitted to achieve 8 participants for whom the pregnancy results in a live birth and who are evaluable for PK and safety assessments.

6. Supporting Documentation

6.1. Appendix 1: List of Abbreviations

Abbreviation / Acronym	Definition / Expansion
ADA	Anti-drug antibody
AE	Adverse event
ALT	Alanine aminotransferase
APGAR	Appearance, Pulse, Grimace, Activity, and Respiration
AST	Aspartate transaminase
ATC	Anatomical Therapeutic Chemical
AUC	Area under the curve
BMI	Body Mass Index
BUN	Blood urea nitrogen
CI	Confidence interval
CL/F	Apparent clearance
CRP	C-reactive protein
CSR	Clinical study report
CTCAE	Common terminology criteria for adverse events
CV	Coefficient of variation
DMC	Data Monitoring Committee
ECG	Electrocardiogram
eCRF	Electronic case report form
eDISH	Evaluation of drug-induced serious hepatotoxicity
EOS	End-of-study
FAS	Full analysis set
FNAIT	Fetal and neonatal alloimmune thrombocytopenia
GCP	Good Clinical Practice
GGT	Gamma glutamyl transferase
GMR	Geometric mean ratio
GW	Gestational Week
HLA	Human leukocyte antigen
HPA	Human platelet antigen
ICF	Informed consent form
ICH	International Council for Harmonisation
IgG	Immunoglobulin
LLOQ	Lower limit of quantification
MCH	Mean corpuscular hemoglobin
MCHC	Mean corpuscular hemoglobin concentration
MCV	Mean corpuscular volume
MedDRA	Medical Dictionary for Regulatory Activities
MFAET	Maternal and fetal adverse event terminology

Abbreviation / Acronym	Definition / Expansion
NAESS	Neonatal Adverse Event Severity Scale
PD	Protocol deviation
PID	Participant ID
PK	Pharmacokinetics
PT	Preferred Term
RBC	Red blood cells
SAE	Serious Adverse Event
SAS	Safety Analysis Set
SC	Subcutaneous
SD	Standard deviation
SGOT	Serum glutamic oxaloacetic transaminase
SGPT	Serum glutamic pyruvic transaminase
SBP	Systolic blood pressure
SOC	System Organ Class
SoA	Schedule of Activities
t1/2	Half-life
TEAE	Treatment-emergent adverse event
tmax	Time to maximum concentration
ULN	Upper limit of normal
Vd	Volume of distribution
WBC	White blood cell
WHO-DD	World Health Organization - Drug Dictionary

6.2. Appendix 2: Schedule of Activities

Table 2: Schedule of Activities: Screening Part 1 and Screening Part 2

Assessments	Notes
Screening Part 1	
Informed consent (SCR)	Consent for blood samples to be collected to determine higher risk for occurrence of HPA-1a alloimmunization and FNAIT during the pregnancy.
Demographics	Year of birth, self-characterized race, ethnicity, and obstetric history. Gestational age in weeks as estimated by the principal investigator or qualified staff.
Blood samples for FNAIT laboratory testing	Pregnant participant presenting at GW 6 or after the pre-natal visit will be determined to be eligible if they are: HPA-1b/b genotype (HPA-1a negative), HLA-DRB3*01:01 positive genotype, anti-HPA-1a alloantibody negative, and fetal HPA-1a/b genotype (ie, HPA-1a positive)[a].
Screening Part 2 (After Screening Part 1 and by ~GW 16)	Consent for further assessments to confirm participants meet all inclusion/exclusion criteria and are eligible for treatment with RLYB212 and for their pregnancy to be followed according to the requirements of the protocol. Note: This is the same as "Visit 2" in Table 1-3.

FNAIT = fetal and neonatal alloimmune thrombocytopenia; GW = gestational week; SCR = screening.
[a] Two distinct samples and analyses are performed, per industry practice, to confirm absence of the HPA-1b allele in the fetus, with timing between sampling ~2 weeks.

Table 3: Schedule of Activities of Participants Eligible for RLYB212 Interventional Treatment and Postnatal Follow-up

Study Period	Eligibility, Treatment, and Follow-up Period[a]																Notes
	SV Pt 1	SV Pt 2 (B)	Initial Dose		Dose 2	Dose 3		Dose 4		Dose 5		Dose 6		Dose 7		EOS	Infant EOS	Gestational Week presented for Screening Visits, Parturition and Postpartum. Weeks since Initial Dose presented for subsequent dosing and PK sampling; visit window for Visits 4-13 are ±3 days; and ±7 for Visits 15-16
Gestational Week	<14	<16	by 16	-18	-20	-24	-26	-28	-30	-32	-34	-36	-38	P[b]	PP4	PP10		
Week Since Initial Dose			0	2	4	8	10	12	14	16	18	20	22					
Visit Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
General and Safety Assessments																		
Informed consent, eligibility confirmation, demographics, and medical history	X	X																Including obstetric history. Gestational age in weeks is confirmed by the principal investigator or qualified staff
Brief physical exam (height, weight, BMI)	X	X*			X	X			X				X	X*	X	X*		X* = full physical exam Should be symptom directed
Vital signs		X	X			X				X				X		X		
12-lead ECG		X												X		X		ECG to be performed pre-dose, where applicable

Study Period	Eligibility, Treatment, and Follow-up Period[a]																Notes
	SV Pt 1	SV Pt 2 (B)	Initial Dose		Dose 2	Dose 3		Dose 4		Dose 5		Dose 6		Dose 7		EOS	Infant EOS	Gestational Week presented for Screening Visits, Parturition and Postpartum. Weeks since Initial Dose presented for subsequent dosing and PK sampling; visit window for Visits 4-13 are ±3 days; and ±7 for Visits 15-16
Gestational Week	<14	<16	by 16	-18	-20	-24	-26	-28	-30	-32	-34	-36	-38	P[b]	PP4	PP10		
Week Since Initial Dose			0	2	4	8	10	12	14	16	18	20	22					
Visit Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
AE/SAE review		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Concomitant medication review		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		
Obstetric and fetal doppler ultrasound		X			X	X		X		X		X	Y	X				Y = Week 38 is for high-risk pregnancies as assessed by the PI
Laboratory Assessments																		
Viral serology		X																HIV, hepatitis B and C
Hematology, chemistry, coagulation, CRP		X*			X*			X*		X*				X*	X	X		X*: Collection of sample up to 1 hour prior to study drug administration
Urinalysis		X*			X*			X*		X*				X*	X	X		X*: Collection of sample up to 1 hour prior to study drug administration

Study Period	Eligibility, Treatment, and Follow-up Period[a]																Notes
	SV Pt 1	SV Pt 2 (B)	Initial Dose		Dose 2	Dose 3		Dose 4		Dose 5		Dose 6		Dose 7		EOS	Infant EOS	Gestational Week presented for Screening Visits, Parturition and Postpartum. Weeks since Initial Dose presented for subsequent dosing and PK sampling; visit window for Visits 4-13 are ±3 days; and ±7 for Visits 15-16
Gestational Week	<14	<16	by 16	-18	-20	-24	-26	-28	-30	-32	-34	-36	-38	P[b]	PP4	PP10		
Week Since Initial Dose			0	2	4	8	10	12	14	16	18	20	22					
Visit Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
RLYB212 PK			X*	Y	X*	X*	Y	X*	Y	X*	Y	X*	Y	X*	X			X*: Collection of sample up to 1 hour prior to study drug administration. Y: Sample window of ±7 days
ADA			X*		X*	X*		X*		X*		X*		X*	X			X*: Collection of sample up to 1 hour prior to study drug administration
Study Intervention																		
Study drug administration			X		X	X		X		X		X		X*				Proposed dosing window of ±3 days X*: Dosing within 24 hours (±24 hours) of parturition
Other Assessments																		

Study Period	Eligibility, Treatment, and Follow-up Period[a]																Notes
	SV Pt 1	SV Pt 2 (B)	Initial Dose		Dose 2	Dose 3		Dose 4		Dose 5		Dose 6		Dose 7		EOS	Infant EOS	Gestational Week presented for Screening Visits, Parturition and Postpartum. Weeks since Initial Dose presented for subsequent dosing and PK sampling; visit window for Visits 4-13 are ±3 days; and ±7 for Visits 15-16
Gestational Week	<14	<16	by 16	-18	-20	-24	-26	-28	-30	-32	-34	-36	-38	P[b]	PP4	PP10		
Week Since Initial Dose			0	2	4	8	10	12	14	16	18	20	22					
Visit Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
HPA-1a alloantibodies	X															X		
Pregnancy outcome														X				
Cord blood sample[c]														X				Platelet and hematocrit, hemoglobin, reticulocytes, total bilirubin, RLYB212 concentration If neonatal thrombocytopenia is present, follow-up to resolution is required through normalization of platelet count as per standard of care
Newborn general status[d]														X				

Study Period	Eligibility, Treatment, and Follow-up Period[a]																Notes
	SV Pt 1	SV Pt 2 (B)	Initial Dose		Dose 2	Dose 3		Dose 4		Dose 5		Dose 6		Dose 7		EOS	Infant EOS	Gestational Week presented for Screening Visits, Parturition and Postpartum. Weeks since Initial Dose presented for subsequent dosing and PK sampling; visit window for Visits 4-13 are ±3 days; and ±7 for Visits 15-16
Gestational Week	<14	<16	by 16	-18	-20	-24	-26	-28	-30	-32	-34	-36	-38	P[b]	PP4	PP10		
Week Since Initial Dose			0	2	4	8	10	12	14	16	18	20	22					
Visit Number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16		
Infant general status															X*		Y	X*: if infant present at 4-6 weeks. Y: 12 months (±2 weeks)

After Visit 3, windows for administering RLYB212 and other maternal assessments are ±3 days, with the exception of PK assessments at Weeks 30 and 38 which are ±7 days. The last dose of RLYB212 is to be administered within 24 hours (±24 hours) of parturition. ADA = anti-drug antibody; AE = adverse event; BMI = body mass index; CRP = C-reactive protein; D = day; ECG = electrocardiogram; EOS = end of study; GW = gestational week; h = hour; HPA = human platelet antigen; m = minute; P = Parturition; PI = principal investigator; PK = pharmacokinetic(s); PP = postpartum; SAE = serious adverse event; SV = study visit; Tx = treatment.

[a] Screening Part 1 (presenting at GW 6 or after) women will consent to screening blood tests for HPA-1a genotyping and, if have an HPA-1b/b genotype, testing for HLA-DRB3*01:01, anti-HPA-1a alloantibody negative, and confirmation of fetal HPA-1a/b genotype via two distinct samples/analyses (as outlined in Table 1-2). At Screening Part 2, targeted after the Screening Part 1 visit, and by ~GW 16, those participants who are HPA-1b/b and HLA-DRB3*01:01 positive genotype, anti-HPA-1a alloantibody negative, and fetal HPA-1a/b genotype will be consented to further assessments to confirm they meet all inclusion/exclusion criteria and are eligible for treatment with RLYB212 and for their pregnancy to be followed according to the requirements of the protocol.

[b] Assumption is that the full term birth is at 40 weeks. If this occurs earlier than 40 weeks, the assessments planned for Week 40 will be conducted at parturition.

[c] Evaluation of neonatal thrombocytopenia will be based on the umbilical cord sample taken at parturition.

[d] Newborn general status to include Appearance, Pulse, Grimace, Activity, and Respiration (APGAR) score. The APGAR score is to be captured twice: once at 1 minute after birth and again at 5 minutes after birth. The physical examination of the newborn is the routine clinical examination performed at birth.

6.3. Appendix 3: Data Handling Conventions

Table 4: Analysis Visit Windowing

Assessment	Analysis Visit (Target Week[l])	Target Day*	Protocol Specified Visit window	Analysis Visit Windowing	
				Lower Limit	Upper Limit
Brief physical exam (height, weight, BMI)	Screening Visit 1	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Screening Visit 2	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 6 (Week 8)	Day 56	± 3 days	Day 53	Day 59
	Visit 9 (Week 14)	Day 98	± 3 days	Day 95	Day 101
	Visit 13 (Week 22)	Day 154	± 3 days	Day 151	Day 157
	Visit 14 (Day of Parturition)	Day of parturition[t]	± 3 days	Day of parturition – 3	Day of parturition + 3
	Visit 15 (4 weeks from Parturition)	Day 28 from Day of parturition	± 7 days	Day of Parturition + 20	Day of Parturition + 34
	Visit 16 (10 weeks from parturition)	Day 70 from Day of parturition	± 7 days	Day of Parturition + 62	Day of Parturition + 76

Assessment	Analysis Visit (Target Week[‡])	Target Day*	Protocol Specified Visit window	Analysis Visit Windowing	
				Lower Limit	Upper Limit
Vital signs	Screening Visit 2	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 3 (Week 0)	Day 1	0	Day 1	Day 1
	Visit 6 (Week 8)	Day 56	± 3 days	Day 53	Day 59
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 14 (Day of Parturition)	Day of parturition[†]	± 3 days	Day of parturition – 3	Day of parturition + 3
	Visit 16 (10 weeks from parturition)	Day 70 from Day of parturition	± 7 days	Day of Parturition + 62	Day of Parturition + 76
12-lead ECG	Screening Visit 2	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 14 (Day of Parturition)	Day of parturition[†]	± 3 days	Day of parturition – 3	Day of parturition + 3
	Visit 16 (10 weeks from parturition)	Day 70 from Day of parturition	± 7 days	Day of Parturition + 62	Day of Parturition + 76
Obstetric and fetal doppler ultrasound	Screening Visit 2	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 6 (Week 8)	Day 56	± 3 days	Day 53	Day 59
	Visit 8 (Week 12)	Day 84	± 3 days	Day 81	Day 87
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 12 (Week 20)	Day 140	± 3 days	Day 143	Day 137

Assessment	Analysis Visit (Target Week[‡])	Target Day*	Protocol Specified Visit window	Analysis Visit Windowing	
				Lower Limit	Upper Limit
	Visit 13 (Week 22)	Day 154	± 3 days	Day 151	Day 153
	Visit 14 (Day of Parturition)	Day of parturition[†]	± 3 days	Day of parturition – 3	Day of parturition + 3
Hematology, chemistry, coagulation, CRP	Screening Visit 2	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 8 (Week 12)	Day 84	± 3 days	Day 81	Day 87
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 14 (Day of Parturition)	Day of parturition[†]	± 3 days	Day of parturition – 3	Day of parturition + 3
	Visit 15 (4 weeks from Parturition)	Day 28 from Day of parturition[†]	± 7 days	Day of Parturition + 20	Day of Parturition + 34
	Visit 16 (10 weeks from parturition)	Day 70 from Day of parturition[†]	± 7 days	Day of Parturition + 62	Day of Parturition + 76
Urinalysis	Screening Visit 2	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 8 (Week 12)	Day 84	± 3 days	Day 81	Day 87
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 14 (Day of Parturition)	Day of parturition[†]	± 3 days	Day of parturition – 3	Day of parturition + 3

Assessment	Analysis Visit (Target Week[l])	Target Day*	Protocol Specified Visit window	Analysis Visit Windowing	
				Lower Limit	Upper Limit
	Visit 15 (4 weeks from Parturition)	Day 28 from Day of parturition	± 7 days	Day of Parturition + 20	Day of Parturition + 34
	Visit 16 (10 weeks from parturition)	Day 70 from Day of parturition	± 7 days	Day of Parturition + 62	Day of Parturition + 76
Study drug administration	Visit 3 (Week 0)	Day 1	0	Day 1	Day 1
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 6 (Week 8)	Day 56	± 3 days	Day 53	Day 59
	Visit 8 (Week 12)	Day 84	± 3 days	Day 81	Day 87
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 12 (Week 20)	Day 140	± 3 days	Day 143	Day 137
	Visit 14 (Day of Parturition)	Day of parturition[†,‡]	± 24 hours [‡]	Day of parturition – 1	Day of parturition + 1
ADA	Visit 3 (Week 0)	Day 1	0	Day 1	Day 1
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 6 (Week 8)	Day 56	± 3 days	Day 53	Day 59
	Visit 8 (Week 12)	Day 84	± 3 days	Day 81	Day 87
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 12 (Week 20)	Day 140	± 3 days	Day 143	Day 137
	Visit 14 (Day of Parturition)	Day of parturition[†,‡]	± 24 hours [‡]	Day of parturition – 1	Day of parturition + 1

Assessment	Analysis Visit (Target Week[l])	Target Day*	Protocol Specified Visit window	Analysis Visit Windowing	
				Lower Limit	Upper Limit
	Visit 15 (4 weeks from Parturition)	Day 28 from Day of Parturition[†]	± 7 days	Day of Parturition + 20	Day of Parturition + 34
RLYB212 PK	Visit 3 (Week 0)	Day 1	0	Day 1	Day 1
	Visit 4 (Week 2)	Day 14	± 7 days	Day 8	Day 21
	Visit 5 (Week 4)	Day 28	± 3 days	Day 25	Day 31
	Visit 6 (Week 8)	Day 56	± 3 days	Day 53	Day 59
	Visit 7 (Week 10)	Day 70	± 7 days	Day 63	Day 77
	Visit 8 (Week 12)	Day 84	± 3 days	Day 81	Day 87
	Visit 9 (Week 14)	Day 98	± 7 days	Day 91	Day 105
	Visit 10 (Week 16)	Day 112	± 3 days	Day 109	Day 115
	Visit 11 (Week 18)	Day 126	± 7 days	Day 119	Day 133
	Visit 12 (Week 20)	Day 140	± 3 days	Day 143	Day 137
	Visit 13 (Week 22)	Day 154	± 7 days	Day 147	Day 164
	Visit 14 (Day of Parturition)	Day of parturition[†,‡]	± 24 hours [‡]	Day of parturition – 1	Day of parturition + 1
	Visit 15 (4 weeks from Parturition)	Day 28 from Day of parturition[†]	± 7 days	Day of Parturition + 20	Day of Parturition + 34
Pregnancy outcome	Visit 14 (Day of Parturition)	Day of parturition[†]	N/A	Day of Parturition	Day of Parturition
Cord blood sample	Visit 14 (Day of Parturition)	Day of parturition[†]	N/A	Day of Parturition	Day of Parturition
Newborn general status	Visit 14 (Day of Parturition)	Day of parturition[†]	N/A	Day of Parturition	Day of Parturition

Assessment	Analysis Visit (Target Week[ł])	Target Day*	Protocol Specified Visit window	Analysis Visit Windowing	
				Lower Limit	Upper Limit
Infant general status	Visit 15 (4 weeks from Parturition)	Day 28 from Day of parturition[†]	± 7 days	Day of Parturition + 20	Day of Parturition + 34
	Infant EOS	12 months from Day of parturition[†]	± 14 days	Day of Parturition + 351.25	Day of Parturition + 379.25
HPA-1a alloantibodies	Screening Visit 1	Day from initial dose	N/A	Day from initial dose	Day from initial dose
	Visit 16 (10 weeks from parturition)	Day 70 from Day of parturition[†]	± 7 days	Day of Parturition + 62	Day of Parturition + 76

[ł] Number of weeks since initial dose.

* Number of days since initial dose (initial dose day is considered as Day 1) = (date of target visit – date of initial dose) + 1.

[†] Day of Parturition = (date of Parturition – date of initial dose) + 1.

[‡]Analysis visit window should be calculated from Date and time of parturition.

Table 5: Clinical Laboratory Assessments

Laboratory Assessments	Parameters			
Hematology	Platelet count RBC count Hemoglobin Hematocrit	RBC indices: • MCV • MCH • MCHC • % reticulocytes		Platelet count WBC count with differential: • Neutrophils • Lymphocytes • Monocytes • Eosinophils • Basophils
Clinical Chemistry	Urea Albumin Creatinine Glucose (nonfasting)	Potassium Sodium Calcium C-reactive protein	ALT/SGPT AST/SGOT GGT	Total bilirubin (and direct and indirect bilirubin Total protein Alkaline phosphatase
Coagulation	Prothrombin time International normalized ratio Activated partial thromboplastin time			
Viral Serology	Hepatitis C virus antibody; Hepatitis B surface antigen (HBsAg); HIV antibody			
Routine Urinalysis	Specific gravity Dipstick for glucose, pH, nitrate, occult blood, ketones, bilirubin, urobilinogen, nitrite, and leukocyte esterase Microscopic examination (if blood or protein is abnormal)			
FNAIT Testing δ	FNAIT laboratory screening tests for maternal HPA-1a genotype, maternal HLA- DRB3*01:01 genotype, and maternal HPA-1 alloantibodyb, fetal HPA-1a genotype/cffDNA			

RLYB212 Specific [δ]	Immunogenicity data (ADA response and presence of neutralizing antibody) PK

ADA = anti-drug antibody; ALT = alanine aminotransferase; AST = aspartate aminotransferase; cffDNA = cell-free DNA; FNAIT = fetal and neonatal alloimmune thrombocytopenia; GGT = gamma glutamyl transferase; HBV = hepatitis B virus; HCV = hepatitis C virus; MCH = mean corpuscular hemoglobin; MCHC = mean corpuscular hemoglobin concentration; MCV = mean corpuscular volume; PK = pharmacokinetics; RBC = red blood cell; SGOT = serum glutamic-oxaloacetic transaminase; SGPT = serum glutamic-pyruvic transaminase; WBC = white blood cell.

[a] Direct and indirect bilirubin will only be assessed if total bilirubin is elevated.

[b] If a positive test result is observed for anti-HPA-1a maternal alloantibody test, the results should be discussed with the Sponsor (CSP Section 8.4.4).

[δ] FNAIT testing and RLYB212 specific tests are performed in central laboratories; all other tests are performed locally.

Table 6: Clinical Laboratory Parameters with Standard Unit of Presentation

Test Name	PAREXEL Standard Unit for presentation
Albumin	g/L
Alkaline Phosphatase	U/L
ALT (SGPT) - Alanine Aminotransferase	U/L
aPTT (Ratio)	Ratio
aPTT (seconds)	Seconds
AST (SGOT) - Aspartate Aminotransferase	U/L
Bands (%)	%
Bands (Absolute)	10^9/L
Basophils (%)	%
Basophils (Absolute)	10^9/L
C-reactive protein (CRP)	mg/L
Creatinine	µmol/L
Direct Bilirubin	µmol/L
Eosinophils (%)	%
Eosinophils (Absolute)	10^9/L
Gamma Glutamyl Transferase	U/L
Glucose	mmol/L
Hematocrit	%
Hemoglobin	g/L
Indirect Bilirubin	µmol/L
International normalized ratio	Ratio
Lymphocytes (%)	%
Lymphocytes (Absolute)	10^9/L
Mean Corpuscular Hemoglobin (MCH)	pg
Mean Corpuscular Hemoglobin Concentration (MCHC)	g/L
Mean Corpuscular Volume (MCV)	fL
Monocytes (%)	%
Monocytes (Absolute)	10^9/L
Neutrophils %	%
Neutrophils (Absolute)	10^9/L
Platelet Count	10^9/L
Potassium	mmol/L
PT (%)	Ratio

PT (seconds)	Seconds
RBC (Red Blood Cells)	10^{12}/L
Reticulocyte (%)	%
Reticulocyte Count (Absolute)	10^{9}/L
Sodium	mmol/L
Total Bilirubin	µmol/L
Total Calcium	mmol/L
Total Protein	g/L
Urea	mmol/L
WBC (White Blood Cells)	10^{9}/L

Table 7: Clinical Chemistry Parameters, Conversion Factor from Collected Unit to PAREXEL Standard Unit for Presentation

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Albumin	ALBUMIN	g/L	1.000	g/L
Albumin	ALBUMIN	g/dL	10.000	g/L
Albumin	ALBUMIN	mg/dL	0.010	g/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	IU/L	1.00000	U/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	U/L	1.00000	U/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	µkat/L	60.00000	U/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	nkat/L	0.06000	U/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	µmol/s*L	60.00000	U/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	µmol/min*L	1.00000	U/L
Alkaline Phosphatase (ALP)	ALK. PHOS.	µmol/h*L	0.01670	U/L
Alanine Aminotransferase	ALT / SGPT	IU/L	1.00000	U/L
Alanine Aminotransferase	ALT / SGPT	U/L	1.00000	U/L
Alanine Aminotransferase	ALT / SGPT	µkat/L	60.00000	U/L
Alanine Aminotransferase	ALT / SGPT	nkat/L	0.06000	U/L
Alanine Aminotransferase	ALT / SGPT	µmol/s*L	60.00000	U/L
Alanine Aminotransferase	ALT / SGPT	µmol/min*L	1.00000	U/L
Alanine Aminotransferase	ALT / SGPT	µmol/h*L	0.01670	U/L
Activated Partial Thromboplastin Time_Ratio	APTT_Ratio	%	0.01000	Ratio
Activated Partial Thromboplastin Time_Ratio	APTT_Ratio	Ratio	1.00000	Ratio
Activated Partial Thromboplastin Time	APTT_SEC	Sec	1.00000	Sec

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Aspartate Aminotransferase (AST)	AST / SGOT	IU/L	1.00000	U/L
Aspartate Aminotransferase (AST)	AST / SGOT	U/L	1.00000	U/L
Aspartate Aminotransferase (AST)	AST / SGOT	µkat/L	60.00000	U/L
Aspartate Aminotransferase (AST)	AST / SGOT	nkat/L	0.06000	U/L
Aspartate Aminotransferase (AST)	AST / SGOT	µmol/s*L	60.00000	U/L
Aspartate Aminotransferase (AST)	AST / SGOT	µmol/min*L	1.00000	U/L
Aspartate Aminotransferase (AST)	AST / SGOT	µmol/h*L	0.01670	U/L
Basophils (REL)	BASO%	%	1.00000	%
Basophils (REL)	BASO%	Proportion of 1.0	100.00000	%
Basophils (REL)	BASO%	Fraction	100.00000	%
Basophils (ABS)	BASOABS	/cumm	0.00100	10^9/L
Basophils (ABS)	BASOABS	/mm^3	0.00100	10^9/L
Basophils (ABS)	BASOABS	10^6/L	0.00100	10^9/L
Basophils (ABS)	BASOABS	/µL	0.00100	10^9/L
Basophils (ABS)	BASOABS	k/µL	1.00000	10^9/L
Basophils (ABS)	BASOABS	10^3/µL	1.00000	10^9/L
Basophils (ABS)	BASOABS	10^3/mm^3	1.00000	10^9/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Basophils (ABS)	BASOABS	10^9/L	1.00000	10^9/L
Basophils (ABS)	BASOABS	/nL	1.00000	10^9/L
Basophils (ABS)	BASOABS	Gpt/L	1.00000	10^9/L
Basophils (ABS)	BASOABS	Giga/L	1.00000	10^9/L
Direct Bilirubin	BILIRUBIN_DIRECT	mg/dL	17.103	µmol/L
Direct Bilirubin	BILIRUBIN_DIRECT	mg%	17.103	µmol/L
Direct Bilirubin	BILIRUBIN_DIRECT	mmol/L	1000.000	µmol/L
Direct Bilirubin	BILIRUBIN_DIRECT	mg/L	1.710	µmol/L
Direct Bilirubin	BILIRUBIN_DIRECT	µmol/L	1.000	µmol/L
Indirect Bilirubin	BILIRUBIN_INDIRECT	mg/dL	17.103	µmol/L
Indirect Bilirubin	BILIRUBIN_INDIRECT	mg%	17.103	µmol/L
Indirect Bilirubin	BILIRUBIN_INDIRECT	mmol/L	1000.000	µmol/L
Indirect Bilirubin	BILIRUBIN_INDIRECT	mg/L	1.710	µmol/L
Indirect Bilirubin	BILIRUBIN_INDIRECT	µmol/L	1.000	µmol/L
Bilirubin	BILIRUBIN_TOTAL	mg/dL	17.103	µmol/L
Bilirubin	BILIRUBIN_TOTAL	mg%	17.103	µmol/L
Bilirubin	BILIRUBIN_TOTAL	mmol/L	1000.000	µmol/L
Bilirubin	BILIRUBIN_TOTAL	mg/L	1.710	µmol/L
Bilirubin	BILIRUBIN_TOTAL	µmol/L	1.000	µmol/L
C Reactive Protein	C_REACTIVE_PROTEIN	mg/L	1.00000	mg/L
C Reactive Protein	C_REACTIVE_PROTEIN	mg/dL	10.00000	mg/L
C Reactive Protein	C_REACTIVE_PROTEIN	mg/100mL	10.00000	mg/L
C Reactive Protein	C_REACTIVE_PROTEIN	g/L	1000.00000	mg/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Calcium	CALCIUM	mmol/L	1.000	mmol/L
Calcium	CALCIUM	mEq/L	0.500	mmol/L
Calcium	CALCIUM	mg/L	0.025	mmol/L
Calcium	CALCIUM	mg/100mL	0.250	mmol/L
Calcium	CALCIUM	mg/dL	0.250	mmol/L
Creatinine	CREATININE	mg/dL	88.402	µmol/L
Creatinine	CREATININE	mg/100mL	88.402	µmol/L
Creatinine	CREATININE	mmol/L	1000.000	µmol/L
Creatinine	CREATININE	mg/L	8.840	µmol/L
Creatinine	CREATININE	µmol/L	1.000	µmol/L
Eosinophils (REL)	EOS%	%	1.00000	%
Eosinophils (REL)	EOS%	Proportion of 1.0	100.00000	%
Eosinophils (REL)	EOS%	Fraction	100.00000	%
Eosinophils (ABS)	EOSABS	/cumm	0.00100	10^9/L
Eosinophils (ABS)	EOSABS	/mm^3	0.00100	10^9/L
Eosinophils (ABS)	EOSABS	10^6/L	0.00100	10^9/L
Eosinophils (ABS)	EOSABS	/µL	0.00100	10^9/L
Eosinophils (ABS)	EOSABS	k/µL	1.00000	10^9/L
Eosinophils (ABS)	EOSABS	10^3/µL	1.00000	10^9/L
Eosinophils (ABS)	EOSABS	10^3/mm^3	1.00000	10^9/L
Eosinophils (ABS)	EOSABS	10^9/L	1.00000	10^9/L
Eosinophils (ABS)	EOSABS	/nL	1.00000	10^9/L
Eosinophils (ABS)	EOSABS	Gpt/L	1.00000	10^9/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Eosinophils (ABS)	EOSABS	Giga/L	1.00000	10^9/L
Gamma Glutamyl Transferase	GGT	IU/L	1.00000	U/L
Gamma Glutamyl Transferase	GGT	U/L	1.00000	U/L
Gamma Glutamyl Transferase	GGT	µkat/L	60.00000	U/L
Gamma Glutamyl Transferase	GGT	nkat/L	0.06000	U/L
Gamma Glutamyl Transferase	GGT	µmol/s*L	60.00000	U/L
Gamma Glutamyl Transferase	GGT	µmol/min*L	1.00000	U/L
Gamma Glutamyl Transferase	GGT	µmol/h*L	0.01670	U/L
Glucose	GLUCOSE	mg/L	0.0056	mmol/L
Glucose	GLUCOSE	mg%	0.056	mmol/L
Glucose	GLUCOSE	mg/dL	0.056	mmol/L
Glucose	GLUCOSE	mmol/L	1.000	mmol/L
Glucose	GLUCOSE	g/L	5.55060	mmol/L
Hematocrit	HCT	%	1.00000	%
Hematocrit	HCT	V/V	100.00000	%
Hematocrit	HCT	L/L	100.00000	%
Hemoglobin	HEMOGLOBIN	g/L	1.0000	g/L
Hemoglobin	HEMOGLOBIN	g/dL	10.0000	g/L
Hemoglobin	HEMOGLOBIN	mmol/l	16.049	g/L
INR (Intl. Normalized Ratio)	INR	NA	1.00000	Ratio
INR (Intl. Normalized Ratio)	INR	Ratio	1.00000	Ratio
Lymphocytes (REL)	LYM%	%	1.00000	%
Lymphocytes (REL)	LYM%	Proportion of 1.0	100.00000	%

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Lymphocytes (REL)	LYM%	Fraction	100.00000	%
Lymphocytes (ABS)	LYMPABS	/cμumm	0.00100	10^9/L
Lymphocytes (ABS)	LYMPABS	/mm^3	0.00100	10^9/L
Lymphocytes (ABS)	LYMPABS	10^6/L	0.00100	10^9/L
Lymphocytes (ABS)	LYMPABS	/μL	0.00100	10^9/L
Lymphocytes (ABS)	LYMPABS	k/μL	1.00000	10^9/L
Lymphocytes (ABS)	LYMPABS	10^3/μL	1.00000	10^9/L
Lymphocytes (ABS)	LYMPABS	10^3/mm^3	1.00000	10^9/L
Lymphocytes (ABS)	LYMPABS	10^9/L	1.00000	10^9/L
Lymphocytes (ABS)	LYMPABS	/nL	1.00000	10^9/L
Mean Corpuscular Hemoglobin (MCH)	MCH	pg	1.000	pg
Mean Corpuscular Hemoglobin (MCH)	MCH	μμg	1.000	pg
Mean Corpuscular Hemoglobin (MCH)	MCH	amol	0.065	pg
Mean Corpuscular Hemoglobin (MCH)	MCH	amolFe	0.016	pg
Mean Corpuscular Hemoglobin (MCH)	MCH	fmol	16.114	pg
Mean Corpuscular Hemoglobin (MCH)	MCH	fmolFe	16.250	pg
Mean Corpuscular Hemoglobin Concentration (MCHC)	MCHC	mmol/L	16.114	g/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Mean Corpuscular Hemoglobin Concentration (MCHC)	MCHC	%	10.000	g/L
Mean Corpuscular Hemoglobin Concentration (MCHC)	MCHC	g/dL	10.000	g/L
Mean Corpuscular Hemoglobin Concentration (MCHC)	MCHC	g%	10.000	g/L
Mean Corpuscular Hemoglobin Concentration (MCHC)	MCHC	g/L	1.000	g/L
Mean Corpuscular Volume (MCV)	MCV	fL	1.00000	fL
Mean Corpuscular Volume (MCV)	MCV	μm^3	1.00000	fL
Monocytes (REL)	MONO%	%	1.00000	%
Monocytes (REL)	MONO%	Proportion of 1.0	100.00000	%
Monocytes (REL)	MONO%	Fraction	100.00000	%
Monocytes (ABS)	MONOABS	Giga/L	1.00000	10^9/L
Monocytes (ABS)	MONOABS	/cumm	0.00100	10^9/L
Monocytes (ABS)	MONOABS	$/mm^3$	0.00100	10^9/L
Monocytes (ABS)	MONOABS	10^6/L	0.00100	10^9/L
Monocytes (ABS)	MONOABS	/µL	0.00100	10^9/L
Monocytes (ABS)	MONOABS	k/uL	1.00000	10^9/L
Monocytes (ABS)	MONOABS	10^3/µL	1.00000	10^9/L
Monocytes (ABS)	MONOABS	$10^3/mm^3$	1.00000	10^9/L
Monocytes (ABS)	MONOABS	10^9/L	1.00000	10^9/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Monocytes (ABS)	MONOABS	/nL	1.00000	10^9/L
Monocytes (ABS)	MONOABS	Gpt/L	1.00000	10^9/L
Monocytes (ABS)	MONOABS	Giga/L	1.00000	10^9/L
Neutrophils (REL)	NEUT%	%	1.00000	%
Neutrophils (REL)	NEUT%	Proportion of 1.0	100.00000	%
Neutrophils (REL)	NEUT%	Fraction	100.00000	%
Neutrophils (ABS)	NEUTABS	/cumm	0.00100	10^9/L
Neutrophils (ABS)	NEUTABS	/mm^3	0.00100	10^9/L
Neutrophils (ABS)	NEUTABS	10^6/L	0.00100	10^9/L
Neutrophils (ABS)	NEUTABS	/µL	0.00100	10^9/L
Neutrophils (ABS)	NEUTABS	k/µL	1.00000	10^9/L
Neutrophils (ABS)	NEUTABS	10^3/µL	1.00000	10^9/L
Neutrophils (ABS)	NEUTABS	10^3/mm^3	1.00000	10^9/L
Neutrophils (ABS)	NEUTABS	10^9/L	1.00000	10^9/L
Neutrophils (ABS)	NEUTABS	/nL	1.00000	10^9/L
Neutrophils (ABS)	NEUTABS	Gpt/L	1.00000	10^9/L
Neutrophils (ABS)	NEUTABS	Giga/L	1.00000	10^9/L
Neutrophils Band Form (REL)	NEUTROPHILS_BAND_%	%	1.00000	%
Neutrophils Band Form (REL)	NEUTROPHILS_BAND_%	Proportion of 1.0	100.00000	%
Neutrophils Band Form (REL)	NEUTROPHILS_BAND_%	Fraction	100.00000	%
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	/cumm	0.00100	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	/mm^3	0.00100	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	10^6/L	0.00100	10^9/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	/µL	0.00100	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	k/µL	1.00000	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	10^3/uL	1.00000	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	10^3/mm^3	1.00000	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	10^9/L	1.00000	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	/nL	1.00000	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	Gpt/L	1.00000	10^9/L
Neutrophils Band Form	NEUTROPHILS_BAND_ABS	Giga/L	1.00000	10^9/L
Platelet Count	PLT	/cumm	0.00100	10^9/L
Platelet Count	PLT	/mm^3	0.00100	10^9/L
Platelet Count	PLT	10^6/L	0.00100	10^9/L
Platelet Count	PLT	/µL	0.00100	10^9/L
Platelet Count	PLT	k/µL	1.00000	10^9/L
Platelet Count	PLT	10^3/µL	1.00000	10^9/L
Platelet Count	PLT	10^3/mm^3	1.00000	10^9/L
Platelet Count	PLT	10^9/L	1.00000	10^9/L
Platelet Count	PLT	/nL	1.00000	10^9/L
Platelet Count	PLT	Gpt/L	1.00000	10^9/L
Platelet Count	PLT	10^4/µL	10.00000	10^9/L
Platelet Count	PLT	10^5/µL	100.00000	10^9/L
Platelet Count	PLT	Giga/L	1.00000	10^9/L
Potassium (K)	POTASSIUM	mEq/L	1.000	mmol/L
Potassium (K)	POTASSIUM	mmol/L	1.000	mmol/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Total Protein	PROTEIN_TOTAL	g/L	1	g/L
Total Protein	PROTEIN_TOTAL	g/dL	10	g/L
Total Protein	PROTEIN_TOTAL	g%	10	g/L
Prothrombin Time_Ratio	Prothrombin Time_Ratio	Ratio	1.00000	Ratio
Prothrombin Time_Ratio	Prothrombin Time_Ratio	%	0.01000	Ratio
Prothrombin Time	Prothrombin Time_SEC	Sec	1.00000	Sec
Red Blood Cell	Red Blood Cell	/cumm	0.000001	10^{12}/L
Red Blood Cell	Red Blood Cell	/mm^3	0.000001	10^{12}/L
Red Blood Cell	Red Blood Cell	10^6/L	0.000001	10^{12}/L
Red Blood Cell	Red Blood Cell	/µL	0.000001	10^{12}/L
Red Blood Cell	Red Blood Cell	M/µL	1.00000	10^{12}/L
Red Blood Cell	Red Blood Cell	10^6/µL	1.00000	10^{12}/L
Red Blood Cell	Red Blood Cell	10^6/mm^3	1.00000	10^{12}/L
Red Blood Cell	Red Blood Cell	/pL	1.00000	10^{12}/L
Red Blood Cell	Red Blood Cell	Tpt/L	1.00000	10^{12}/L
Red Blood Cell	Red Blood Cell	T/L	1.00000	10^{12}/L
Red Blood Cell	Red Blood Cell	10^{12}/L	1.00000	10^{12}/L
Reticulocytes (REL)	RETIC%	%	1.00000	%
Reticulocytes (REL)	RETIC%	Proportion of 1.0	100.00000	%
Reticulocytes (REL)	RETIC%	Fraction	100.00000	%
Reticulocytes (REL)	RETIC%	Promille	0.1	%
Reticulocytes (REL)	RETIC%	‰	0.1	%
Reticulocytes (REL)	RETIC%	0/00	0.1	%

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Reticulocytes (ABS)	RETICUAB	/cumm	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	/mm^3	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	10^6/L	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	/µL	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	k/µL	1.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	10^3/µL	1.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	10^3/mm^3	1.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	10^9/L	1.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	/nL	1.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	Gpt/L	1.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	/cumm	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	/mm^3	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	10^6/L	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	/µL	0.00100	10^9/L
Reticulocytes (ABS)	RETICUAB	M/µL	1000.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	10^6/µL	1000.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	10^6/mm^3	1000.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	/pL	1000.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	Tpt/L	1000.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	T/L	1000.00000	10^9/L
Reticulocytes (ABS)	RETICUAB	Giga/L	1.00000	10^9/L
Sodium (NA)	SODIUM	mEq/L	1.000	mmol/L
Sodium (NA)	SODIUM	mmol/L	1.000	mmol/L

LAB TEST DESCRIPTION (SDTM Labtest)	QUESTION	Collected Unit	Conversion Factor	PAREXEL Standard Unit for Presentation
Urea	UREA	mg/dL	0.167	mmol/L
Urea	UREA	g/L	16.650	mmol/L
Urea	UREA	mmol/L	1.000	mmol/L
Urea	UREA	mg%	0.167	mmol/L
Urea	UREA	µmol/L	0.001	mmol/L
Urea	UREA	mg/L	0.0167	mmol/L
White Blood Cells	WBC	/cumm	0.00100	10^9/L
White Blood Cells	WBC	/mm^3	0.00100	10^9/L
White Blood Cells	WBC	10^6/L	0.00100	10^9/L
White Blood Cells	WBC	/µL	0.00100	10^9/L
White Blood Cells	WBC	k/µL	1.00000	10^9/L
White Blood Cells	WBC	10^3/µL	1.00000	10^9/L
White Blood Cells	WBC	10^3/mm^3	1.00000	10^9/L
White Blood Cells	WBC	10^9/L	1.00000	10^9/L
White Blood Cells	WBC	/nL	1.00000	10^9/L
White Blood Cells	WBC	10^2/µL	0.10000	10^9/L
White Blood Cells	WBC	Gpt/L	1.00000	10^9/L
White Blood Cells	WBC	Giga/L	1.00000	10^9/L

7. References

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