Statistical analysis plan

A prospective, observational long-term follow up study of patients treated with imlifidase (IdeS) prior to kidney transplantation

Sponsor:	**Hansa Biopharma AB**
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Signature page

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List of abbreviations and definition of terms

ADA	Anti-drug antibody
ADaM	Analysis data model
AE	Adverse event
AMR	Antibody mediated rejection
CI	Confidence interval
CRF	Case report form
DSA	Donor specific antibodies, anti-human leukocyte antigen (HLA) donor-specific antibodies
EQ-5D-5L	EuroQol group 5 dimensions-5 levels
FAS	Full analysis set
KDQOL-SF 1.3	Kidney disease quality of live instrument – short form version 1.3
MedDRA	Medical Dictionary for Regulatory Activities
PT	Preferred term
QOL	Quality of live
SAB-HLA	Single antigen beads - human leukocyte antigen
SAE	Serious adverse event
SAP	Statistical analysis plan
SOC	System organ class
STDM	Study data tabulation model
TLF	Tables, listings and figures

1 Introduction

This document describes the planned processing and presentation of data and the statistical analyses for the study 17-HMedIdeS-14. This is a prospective long-term follow-up study including patients that have been treated with imlifida se in four previous studies – called the feeder studies. The feeder studies are: 13-HMedIdeS-02, 13-HMedIdeS-03, 14-HMedIdeS-04 and 15-HMedIdeS-06. There is no treatment with imlifidase in the current study.

The SAP is based on the protocol version 4.0 including amendment 03 dated 22 November 2021.

Because of the long-term follow-up nature of the study it is planned that yearly summary analyses of the data will be performed. A summary analysis can also be done ad hoc during the study.

1.1 Study objectives and endpoints

1.1.1 Objectives

The primary objective of this study is:

The primary objective of this study is to evaluate graft survival in subjects who have undergone kidney transplantation after imlifidase administration.

The secondary objectives of this study are:

- Evaluation of long-term clinical outcomes of transplanted subjects treated with imlifidase in terms of patient survival, kidney function, comorbidity, treatments and quality of life.
- Assessment of safety blood sampling in transplanted subjects treated with imlifidase
- Assessment of donor specific antibodies (DSA) in transplanted subjects treated with imlifidase
- Assessment of immunogenicity (anti-drug antibodies, ADA) in transplanted subjects treated with imlifidase

1.1.2 Endpoints

The primary endpoint of this study is:

The primary endpoint of this study is to determine overall graft survival, defined as time from transplantation to graft loss at 1, 2, 3 and 5 years after first dose of imlifidase. Graft loss is defined as: Permanent return to dialysis for at least 6 weeks, re-transplantation, or nephrectomy. If dialysis is used to define graft loss, the date of graft loss will be the first day of the last ongoing dialysis period reported (EMA Guideline on clinical investigation of immunosuppressants for solid organ transplantation 2008).

The secondary endpoints of this study are:

The following secondary endpoints will be evaluated after the first dose of imlifidase at the time points 1, 2, 3 and 5 years:

- Graft loss not censored for death (graft survival free of graft loss and death)
- Overall patient survival defined as time from transplantation to death for any cause

- Kidney function as evaluated by eGFR, P-creatinine, proteinuria
- Number of graft rejection episodes (classified by Banff, (Haas et al. 2018))
- Safety laboratory tests (haematology, total IgG)
- Treatment of graft rejection episodes
- Comorbidity
- DSA levels as evaluated by SAB-HLA analysis
- Presence of BK virus
- ADA as evaluated by anti-imlifidase IgG
- Health related quality of life (HR-QoL) as evaluated by patient questionnaires EQ-5D-5L and KDQOL-SF.

2 Study design

2.1 Overview of study procedures

Visit post imlifidase dosing	1 year[1]	2 years	3 years	5 years
Visit window	(+/- 2 months)	(+/- 4 months)	(+/- 4 months)	(+/- 6 months)
Informed consent	x[2]			
Eligibility	x[2]			
Enrollment and allocation of patient number	x[2]			
QoL questionnaires (EQ-5D-5L, KDQOL-SF)	x	x	x	x
Patient survival status	x[3]	x	x	x
Graft survival status	x[3]	x	x	x
Graft rejection episodes[4]	x	x	x	x
Kidney biopsy reports [5]	x	x	x	x
P-creatinine, eGFR calculation (performed by Sponsor)	x	x	x	x
Proteinuria (dipstick)	x	x	x	x
Hematology (Hemoglobin, Diff of leukocytes, Thrombocytes)	x	x	x	x
Total IgG	x	x	x	x
BK test	x	x	x	x
DSA (HLA antibody, Luminex) *central lab*	x	x	x	x
DSA (HLA antibody, Luminex)) *local lab*	x	x	x	x
ADA (Anti-imlifidase IgG) *central lab*	x	x	x	x
Comorbidity[6]	x	x	x	x
Current immunosuppressive medication	x	x	x	x
Treatment of graft rejection episode (PE, IVIg, dialysis, other)	x	x	x	x
Adverse events[7]	x	x	x	x

[1] Some subjects will not perform all 4 visits because the study start will be after the subject`s first visit should have taken place. If applicable, record creatinine and proteinuria results from planned time for 1- and 2 Years visits. End of Study (EOS) will occur 5 years (+/- 6M) after transplantation or earlier in the case of death, withdrawal of consent or lost to follow up.

[2] These activities shall be performed at subject`s first visit that can take place 1, 2, or 3 years post imlifidase dose depending on when the subject was transplanted in the feeder study.

[3] After informed consent is obtained, pre-study visit data such as information on graft survival and patient survival can be collected and entered in the CRF. If applicable, record cause and date of death.

[4] Record biopsy proven graft rejection episodes (classified by the Banff classification) and creatinine and proteinuria results from the episode.

[5] If standard of care kidney biopsies are performed for any reason, at any time-point, e.g. suspected rejections, record information in the CRF.

[6] Record comorbidities that are medically relevant and registered in the subject`s medical record. Medically relevant comorbidity are infections, malignancy, diabetes mellitus and cardiovascular events.

[7] Adverse events caused by a procedure in the protocol (blood sampling) or a clinically significant safety lab value are the only AEs that will be captured and reported. If the lab value is attributable to worsening renal function, graft rejection or natural progression of disease, it will not be reported as AE

2.2 Determination of sample size

As this is a non-interventional follow up study, no power calculation for sample size estimation was performed. All patients enrolled in the selected imlifidase kidney transplant studies will be considered for inclusion in this study. Up to 46 patients can be included, although the exact

number will depend on enrolment and patients' discontinuation figures in ongoing and/or selected clinical studies.

2.3 Blinding

This is an open study.

2.4 Data pre-processing

Data will be received from the data management database as SAS files in a raw data format and from the central laboratory in Excel files. Additionally, an excel file with acute rejection episodes during feeder studies will be provided by sponsor. All data will be converted to SDTM format using SDTM v1.4/SDTM IG v3.2 and will be documented by SDRG and define xml files. Further, SDTM data will converted to ADaM data using ADaM 1.0/ ADaM IG v1.0 from which the production of tables, listings and figures will take place.

A study day variable is needed in several presentations and analyses. This could be derived as number of days since first administration of imlifidase or as the number of days since transplantation. For each subject, these dates are typically at most several days apart and, as the time span of the study is 5 years, the distinction between these two definitions is not important. All derivations of study day will therefore take first administration of imlifidase as the start day.

As a follow-up study, data that were collected in the feeder studies will in general not be re-collected. Relevant data are therefore copied from the feeder studies to the current study and included in the SDTM and the ADaM data sets. This is particularly relevant for the demographic data. The following table presents an overview of data types that will be retrieved from feeder studies.

Data type	Variables	Comment
Age		For demography presentations age at baseline will be used. For calculation of eGFR age at collection date will be used.
Other demography	Sex, race, country, site	
Baseline characteristics	Height, weight, BMI	
Transplant characteristics	Cross-match (positive/negative), delayed graft function, living or deceased donor, cold ischaemia time, number of historical transplantations	
SAB-HLA at pre-dose and 6 months		
eGFR, creatinine, proteinuria at pre-dose and 6 months		
ADA		

EQ-5L-5D

The EQ-5D-5L questionnaire will be assessed at each visit. The EQ-5D-5L index value will be calculated according to User Guide EQ-5D-5L v2.1 April 2015 and based on the index value set as downloaded from https://euroqol.org/eq-5d-instruments/eq-5d-5l-about/valuation-standard-value-sets/crosswalk-index-value-calculator/ on 23JAN2019. The study will include data from patients in Sweden, France and the USA. The downloaded index value table covers amongst others USA, France and Denmark, while it does not cover Sweden. For the Swedish patients, index values for Denmark will be used. Therefore, with these index value tables, a general index value will be looked up for each patient and visit.

KDQOL-SF 1.3

The KDQOL-SF 1.3 will be assessed at each visit. The KDQOL-SF 1.3 questionnaire is available from the RAND homepage including descriptions and sample programs for converting scores.

This questionnaire combines a kidney specific part and a part on general health aspects taken from the SF-36 questionnaire. The following steps are needed: a) non-valid responses should be set to missing, b) reversal and normalisation of all responses so scores go from 0 (negative) to 100 (positive), c) taking average of all non-missing values within each scale.

The data will be condensed in the scales below:

Kidney disease (n = number of items in each scale):

> Burden of kidney disease (n=4), Quality of social interaction (n=3), Cognitive function (n=3), Symptoms/problems (n=12), Effects of kidney disease (n=8), Sexual function (n=2), Sleep (n=4), Social support (n=2), Work status (n=2), Dialysis staff encouragement (n=2).

SF-36 (n = number of items in each scale):

> Physical functioning (n=10), Role limitations—physical (n=4), Pain (n=2), Emotional well-being (n=5), Role limitations—emotional (3), Social function (n=2), Energy/fatigue (n=5), General health (n=5).

Further, the SF-36 composite physical T-score and the SF-36 composite mental score will be derived. These scores are normalised compared to a US mean of 50 with a standard deviation of 10, the SAS code for this derivation is downloaded from the RAND homepage.

3 Analysis sets

3.1 Full analysis set

The Full Analysis Set will be defined as all patients enrolled. Because of the non-interventional nature of this study no other analysis set will be defined and all data presentations and analyses will be based on the FAS.

4 Statistical analyses and presentation of data

4.1 General considerations

The data from the clinical assessments will be summarised by feeder study, grand total and time point using descriptive techniques. Summary statistics (n, arithmetic mean, standard deviation, median, minimum and maximum values) will be presented for continuous variables (absolute values at each time point and, if relevant, changes from baseline) and counts and, if relevant, percentages will be presented for categorical variables. Where appropriate, the presentation of results will include confidence intervals of estimated effects and plots.

The following rules for displayed number of decimal places are considered for listings and tables:

- Actual values and change from baseline: Same number of decimal places as in data.
- Percentage change from baseline: One decimal place.
- Mean, median, SD, minimum and maximum: Same number of decimal places as in data.

Values below LLOQ are displayed in tables and listings and used in calculations as the LLOQ value.

All data will be listed. Patients will be identified by a two-level number: xx-yyy where xx = number of the feeder study and yyy = patient ID in the feeder study.

4.2 Subject disposition

The number of subjects in FAS will be summarized by feeder study. All 46 subjects from feeder studies that are eligible for the extension study will be accounted for. Furthermore, the number of subjects who withdraw from this study will be summarised overall, by withdrawal time, by reason for withdrawal and by feeder study.

4.3 Demographics and other baseline characteristics

The age, sex, race, country, site, height, weight and BMI will be summarised by feeder study.

Transplant characteristics will be tabulated.

Current immunosuppressive medication will be summarised by WHO drug version 153E, level 4 (chemical/therapeutic/pharmacological subgroup) called “medication class” in output, and by level 5 (chemical substance) called “medication name” in output.

Since this is a non-interventional follow-up study exposure and compliance are not applicable.

A summary of the protocol deviations will be presented.

4.4 Endpoints

4.4.1 Primary endpoint

The primary endpoint, overall graft survival, is defined as time from transplantation to graft loss evaluated at 1, 2, 3 and 5 years after first dose of imlifidase. Graft loss is defined as: Permanent return to dialysis for at least 6 weeks, re-transplantation or nephrectomy. If dialysis is used to

define graft loss, the date of graft loss will be the first day of the last ongoing dialysis period reported. The graft loss is evaluated at 1, 2, 3, and 5 years after dosing, but the time will be recorded as duration in days.

The primary endpoint will be analysed by the Kaplan-Meier survival method for the combined group with all feeder studies. The overall graft survival will be tabulated and presented graphically as a KM plot with 95% confidence limits, indicating the risk set per year and marking the censored observations. The following events will be censored at the time of occurrence: withdrawal from the study without graft loss, death not caused by graft loss, evaluation time point (the yearly evaluations - only for the annual reports not in the final reporting of the study) and end of study without graft loss. The survival percentage with 95% CI will be estimated at 1, 2, 3 and 5 years, or, for the yearly summary analyses as far as data allows.

The reason for graft loss will be displayed in a listing.

The protocol stipulates that explorative modelling of the influence of covariates on the graft loss may be defined in the SAP. With a maximum sample size of 46 patients and an expected small proportion of patients with graft loss, estimation of covariate parameters may be highly variable in which case the explorative modelling will not be performed.

4.4.2 Secondary endpoints

Graft loss not censored for death

This endpoint is defined as the primary endpoint except that death for any cause also counts as a graft loss and therefore this event will not be censored in this case. The endpoint will be analysed and presented as the primary endpoint.

Overall patient survival

The overall patient survival is defined as time from transplantation to death for any cause. This endpoint will be analysed and presented as for the primary endpoint. The following events will be censored at the time of occurrence: withdrawal from the study while alive, evaluation time point (the yearly evaluations) and end of study while alive.

Kidney function

The kidney function is evaluated by the three parameters eGFR, P-creatinine and proteinuria. The parameters are all presented together with the safety laboratory tests. Each variable will be tabulated by feeder study and total and by visit.

The eGFR will be calculated as described in the MDRD equation (1):

$$\text{eGFR (mL/min/1.73 m2)} = 175 \times (\text{Cr})^{-1.154} \times (\text{Age})^{-0.203} \times (0.742 \text{ if female}) \times (1.212 \text{ if African American}),$$

where Cr stands for creatinine value. This formula assumes that Cr is given in the mg/dL unit.

Number of graft rejection episodes

The number of graft rejection episodes following the Banff classification will be tabulated by 1, 2, 3 and 5 years, feeder study and grand total.

The Banff score from biopsies will be listed.

Treatment of graft rejection episodes

The treatment of graft rejection episodes will be summary tabulated by 1, 2, 3 and 5 years and by treatment type. Examples of treatment types are dialysis episodes, plasmapheresis and medication.

Comorbidity

Medically relevant comorbidities are e.g. infections, malignancy, diabetes mellitus, and cardiovascular events. These events will be tabulated at 1, 2, 3 and 5 years by comorbidity type.

DSA levels

DSA levels will be evaluated by SAB-HLA at 1, 2, 3 and 5 years. The DSA levels will be, listed, summarized in a table and presented graphically.

BK virus

The presence of BK virus along with clinically significance (yes/no) will be tabulated at 1, 2, 3 and 5 years.

ADA

The anti-imlifidase IgG will be tabulated by 1, 2, 3 and 5 years.

4.5 Safety

4.5.1 Adverse events

Adverse events (AEs) will be classified according to the Medical Dictionary for Regulatory Activities (MedDRA) version 20.0.

As there is no treatment in this study and as all patients have previously been treated with imlifidase, there will be made no distinction between treatment emergent and non-treatment emergent adverse events. All recorded AEs will be included in the presentation.

An AE overview summary table will be prepared including the number of subjects reporting an AE, the percentage of subjects (%) with an AE, and the number of events (E) reported for the following categories:

- All AEs
- Deaths
- Serious adverse events (SAEs)
- AEs leading to withdrawal
- Severe and life-threatening AEs

AEs will be summarised in a table by MedDRA system organ class (SOC) and preferred term (PT). The table will display the total number of subjects reporting an AE, the percentage of subjects (%) with an AE and the number of events (E) reported. AEs will be presented by SOC sorted alphabetically and PT sorted in decreasing frequency of occurrence.

Additional tables may be prepared if more than 20 events are recorded.

Data listings will be provided for:

- All AEs sorted by subject number
- All AEs sorted by MedDRA Preferred Term
- SAEs
- AEs leading to death
- AEs leading to withdrawal

4.5.2 Other safety endpoints

The safety laboratory parameters will be presented in summary tables by feeder study and visits. In addition, the parameters will be listed and presented by box plots.

4.6 Other endpoints

Two quality of life questionnaires will be used. The EQ-5D-5L is a general health questionnaire. The KDQOL-SF version 1.3 is a kidney specific questionnaire including a general health part as well.

The EQ-5D-5L will be presented by summarising the 5 individual items (mobility, self-care, usual activities, pain/discomfort, anxiety/depression), the VAS score and the overall derived index value by feeder study and visit.

The KDQOL-SF 1.3 will be presented by summarising the scales in the kidney disease (burden of kidney disease, quality of social interaction, cognitive function, symptoms/problems, effects of kidney disease, sexual function, sleep, social support, work status, dialysis staff encouragement) and SF-36 (Physical functioning, Role limitations—physical, Pain, Emotional well-being, Role limitations—emotional, Social function, Energy/fatigue, General health) parts of the questionnaire including the composite scores. Tabulation will be by feeder study and visit.

5 Interim analyses

This is a prospective long-term follow-up study. The accumulating data collected is planned to be presented yearly. As there is no formal decision associated with these reports, there are no multiplicity issues and the yearly reports will be presented as is. Interim analyses will focus on the primary endpoint and selected secondary endpoints evaluating efficacy parameters.

6 Deviations from protocol analysis

The secondary endpoint graft loss not censored for death meaning ‘survival free of graft loss as well as death’ is not listed as an endpoint in the protocol (version 4.0 incl. Amend 03), but is only mentioned in section 11.6.1 Graft loss not censored for death.

7 Quality control

The quality control of the data will be performed as follows:

- By [redacted] Data Management for all CRF data following the data validation plan
- By [redacted] Statistics and Programming for all data received as either Trial Master export or as import from central lab data

The QC depends on the process below, but it will follow [redacted] Single Use Programs:

SDTM data sets will be generated by programs in the Statistical analysis system (SAS) by reading in lab data and export data from Trial Master and converting to SDTM formats following the SDTM specifications. The QC will include:

- Independent Code review
- CRF annotation review vs SDTM content
- Run of Pinnacle verification
- QC of CRF input vs output in SDTM on a sample of data
- Format and fonts in annotated CRF

ADaM data sets will be based on the SDTM data sets. The programming of the ADaM datasets will be performed in SAS and QC of the programs will include

- Independent code review
- Run of Pinnacle verification
- QC of SDTM input data vs output in ADaM or listings

Tables, listings and figures (TLF) will be created by SAS programs and based on the ADaM data sets. The programming of TLFs will be reviewed by an independent person.

Since there are no formal statistical analyses double programming will not be applied in this study.

The programming and execution of programs for producing data sets and tables, figures and listings follow the [redacted] on standard programs, programming environment and single use programs respectively.

SAS version 9.4 or later and SAS Viya version 3.5 will be used for data handling and presentation.

8 Layout of output

TLF shells are presented in a separate document. The planned table of content will also be presented separately. The final output may deviate slightly as decisions on numbering and layout of TLF and similar may be updated after signature of this SAP.

The output will follow [redacted] standard output templates. Tables and listings will first be prepared as individual RTF (Rich text format, which is a standard text format) files. This file type may be opened and saved in the currently available Microsoft Word versions. Graphical output will be prepared in PNG (Portable network graphics) format, which is the standard graphical format in current Microsoft software packages and therefore easily importable into Microsoft Word documents.

Tables and figures will per default be created in portrait format while listings will be in landscape format. Margins and font will be chosen to respect the requirements for filing with EMA (European medicines agency) and FDA (the US Food and drug administration).

The output items (tables, listings, figures) will be collected in Word documents as described in the TOC below. Separate Word documents will be created for tables (called 14.1), figures (called 14.2), and listings (called 16) respectively.

9 Tables, listings and figures

Tables and figure templates are prepared as separate documents. And overall table of content for the output is also maintained as a separate document. Templates and the table of content are working documents and may be updated also after the signature of the SAP.

The following sections contains lists of the tables, figures and listings (TLF) which will be produced.

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Figure 14.3.1. Anti-imlifidase ADA (IgG) - Box plot.

10 References

1. Levey AS, Stevens LA, Schmid CH, Zhang YL, Castro AF, Feldman HI, et al. A new equation to estimate glomerular filtration rate. Ann Intern Med. 2009; 150(9): 604-12.

11 Change log

Version	Effective date	Reason for revision
1.0	25 APR 2019	New document
2.0	04 APR 2023	Clarification of number of decimal places to use for various reporting added to section 4.1. Deviation from protocol added to section 6. List of tables listings and figure added to section 9