Statistical Analysis Plan (SAP)

Study No. STP1-C004

A Phase 1b, Double-Blind, Placebo-Controlled, First-in-Human Study to Evaluate Safety, Tolerability and Pharmacokinetics of a Two-Week Oral Treatment with STP1 in a Subgroup of Adult Patients with Autism Spectrum Disorder

Version 1.1

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Approval Page

By entering into this Statistical Analysis Plan (SAP), the parties acknowledge and agree that this SAP shall be incorporated into and subject to the terms of the Master Services Agreement (MSA). Any changes requested by Client to this SAP shall be subject to Section I.C of the MSA requiring a mutually agreed upon "Change Order" prior to any modification of the procedures set forth herein.

I agree to the format and content of this document.

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Revision History

Version 1.0 to 1.1

- SAP updated based on the latest version of the protocol (v6.0)
- Added the cognition crystallized composite results to the in-text description of the NIH Toolbox analysis and to the corresponding table and listing shells in the appendix.
- Updated Section 6.2 to state that the eye tracking data will not be included in the final study database.

Table of Contents

1.0 Synopsis of Study Design Procedures

This study is a randomized, double-blind, placebo-controlled, parallel-group, 2-dose ascending study to assess the safety, tolerability, and pharmacokinetics (PK) of 2-week treatment with STP1 (combined doses of ibudilast and bumetanide) in adult patients with idiopathic Autism Spectrum Disorder Phenotype 1 (ASD-Phen1).

The primary objective of this Phase 1b study is to assess the safety and tolerability of 2-week oral treatment twice a day with STP1 in adult individuals with ASD-Phen1. The secondary objective is to determine the plasma pharmacokinetics of ibudilast and bumetanide when given orally in combination, as STP1, for 2 weeks. Additional exploratory objectives will be assessed as outlined in Section 6.0 of this SAP.

This SAP was written in accordance with the Clinical Study Protocol Version 6, Amendment 5. The SAP will be revised if there are future protocol amendments that impact the content included in this document.

1.1 Design and Treatment

The first dose cohort (8 eligible patients) will be randomized and allocated to one of two treatment groups using a 3:1 ratio:

- [redacted]mg oral twice a day (BID) ibudilast [redacted]mg oral BID bumetanide (N=6)
- Matching oral placebos BID (N=2)

For each dose cohort, the total duration of the study for each patient will be up to 6 weeks, divided as follows:

- A screening phase of up to 2 weeks (from Day -14 to Day -1)
- A double-blind treatment phase of 2 weeks (from Day 1 to Day 14)
- A follow-up phase of 2 weeks after treatment discontinuation (from Day 15 to Day 28)

Once the first cohort (8 patients) finishes 2 weeks of treatment and 2 weeks of follow-up, a Data Safety Monitoring Board (DSMB) will evaluate the safety data to decide whether the dose of ibudilast can be increased as planned to [redacted]mg, or the study shall be modified or be stopped.

If the DSMB decision supports the start of the next dose level, up to 8 additional eligible patients will be assigned to one of the following two treatment groups (a minimum of 3 patients should be exposed to the highest dose of STP1):

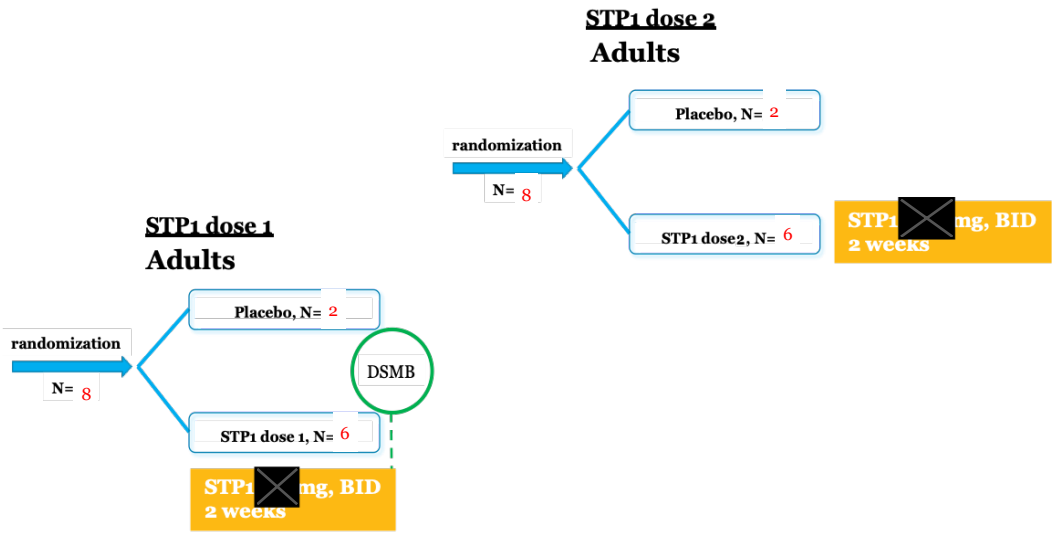
- [redacted]mg oral BID ibudilast/ 1 mg oral BID bumetanide (up to N=6)
- Matching oral placebos BID (up to N=2)

Patients that participated in the first dose cohort may be allowed to participate in

the second dose cohort if there is no safety concern and after drug washout. Any patient from Cohort 1 that is re-randomized into Cohort 2 will be counted as a new patient in the analysis. That is, re-enrolled patients will be assigned a new patient ID for Cohort 2, re-randomized, and have a new set of CRFs completed.

Figure 1 below summarizes an overview of the study design.

Figure 1. Overview of Study Design



For STP1 dose 2: N= up to 2 placebo and up to 6 STP1 dose 2, randomization is N= up to 8

1.2 Study Procedures

The study includes assessments at screening (Days -14 to -1), treatment period (Days 1 to 14), and the follow-up visits (Days 16-18 (optional) and Day 28).

Screening Period (Visit 1 - Day -14 to Day -1)

Patients will be screened for study eligibility within 14 days prior to treatment (Days -14 to -1). The following screening procedures will be performed:

- Sign an Informed Consent Form (ICF) before any of the study related procedures are performed
- Eligibility criteria including all inclusion and exclusion criteria
- Record demographics (including age, gender, height, weight, etc.)
- Record medical history including history of substance use
- Record previous and concomitant medications and therapies
- Measure vital signs (temperature, heart rate (HR), and respiratory rate)
- Orthostatic blood pressure (BP) and HR
- Perform physical examination

- Perform blood laboratory tests (serology, blood chemistry, hematology, and coagulation)
- Perform urinalysis laboratory test
- Perform 12-lead ECG
- Perform urine pregnancy test for women of childbearing potential
- Perform SARS-CoV-2 Test
- Perform alcohol urine test/substance abuse urine test
- Adverse event (AE) assessment and recording
- Perform study-specific assessments: (Suicidality (Columbia Suicide Severity Rating Scale [C-SSRS] or Columbia Classification Algorithm for Suicide Assessment [C-CASA]), Aberrant Behavior Checklist- Second Edition – Community (ABC-C), Social Responsiveness Scale, Second Edition (SRS-2), and Stanford Binet Intelligence Scales, Fifth Edition-Abbreviated Battery IQ (SB5 ABIQ), Ohio Autism Clinical Impression Scale -Severity (OACIS-Severity), [redacted] Test of Attentional Performance for Children (KiTAP), Children Sleep habit Questionnaire (CSHQ), Clinical Global Impressions – Severity (CGI-S) Scale
    - C-SSRS, OACIS- Severity, NIH-CTB, KiTAP, CSHQ and CGI-S are collected at Screening for only those patients enrolled under Version 4 or subsequent versions of the protocol

Treatment Period (Day 1 to Day 14)

The following procedures will be performed during the treatment period (visits at Day 1, Day 7 & Day 14):

Visit 2 - Day 1

- Randomization
- Physical examination
- Vital Signs (pre- and post-dose): including temperature, HR, respiratory rate, and BP
- Orthostatic BP assessment (pre- and post-dose)
- ECG-12 lead (pre- and post-dose)
- Substance abuse test (urine)
- Hearing assessment (collected for only those patients enrolled under Version 4 or subsequent versions of the protocol)
- Administration of the study medication
- Study medication supply
- Blood and urine sampling for PK
- Perform study-specific assessments: Suicidality assessment (C-SSRS or C-CASA), OACIS-Severity, NIH-CTB, KiTAP, CSHQ, and CGI-S

    - OACIS-Severity and CGI-S are collected for only those patients enrolled under Version 2 or 3 of the protocol. C-SSRS is collected for only those patients enrolled under Version 4 or subsequent versions of the protocol.
- Eye tracking assessment
- EEG (pre- and post-dose)
- Adverse Events
- Previous and Concomitant treatments

Visit 3 - Day 7

- Physical examination
- Vital Signs: including temperature, HR, and respiratory rate, and BP
- Orthostatic BP assessment
- ECG-12 lead
- Blood sampling for hematology, blood chemistry, and coagulation
- Urine sampling for urinalysis
- Administration of the study medication and drug accountability
- Blood sampling for PK
- Suicidality assessment (C-SSRS or C-CASA) (C-SSRS collected for only those patients enrolled under Version 4 or subsequent versions of the protocol)
- Hearing assessment (collected for only those patients enrolled under Version 4 or subsequent versions of the protocol)
- Adverse Event
- Previous and Concomitant treatments

Visit 4 - Day 14

- Physical examination
- Vital Signs: including temperature, HR, respiratory rate, and BP
- Orthostatic BP assessment
- ECG-12 lead
- Blood sampling for hematology, blood chemistry, and coagulation
- Urine sampling for urinalysis
- Administration of the study medication and drug accountability
- Blood and urine sampling for PK
- Hearing assessment (collected for only those patients enrolled under Version 4 or subsequent versions of the protocol)
- Perform study-specific assessments: Suicidality (C-SSRS and C-CASA), ABC-C, SRS-2, OACIS-S, Ohio Autism Clinical Impression Scale - Improvement (OACIS – C), [redacted] KiTAP, CSHQ, Clinical Global Impressions – Improvement (CGI-I) Scale, and CGI-S
    - C-SSRS is collected for only those patients enrolled under Version 4 or subsequent versions of the protocol.

- Eye tracking assessment
- EEG
- Adverse Events
- Previous and Concomitant treatments

Visit 5- Day 15 and Optional Visit 6/7/8 - Days 16/17/18

Patients enrolled under Version 2 or 3 of the protocol will have blood and urine PK sampling done 30 hours post Day 14 AM dose (i.e., Day 15). Patients enrolled under Version 4 or subsequent versions of the protocol will be given the option to have their follow-up blood PK sampling visit between Day 16 and Day 18.

- Blood and urine sampling for PK (urine sampling collected for only those patients enrolled under Version 2 or 3 of the protocol)
- Suicidality assessment (C-SSRS, C-CASA) (collected for only those patients enrolled under Version 4 or subsequent versions of the protocol)
- AEs
- Previous and concomitant treatments

Visit 9- Day 28 - End of Study Follow-Up Visit

Patients who complete the Day 15 study visit or discontinue from the study early will be asked to return to the clinic on Day 28 (± 2 days) for the Follow-up visit. After study completion, AEs should be followed according to the study protocol.

The following procedures will be performed:

- Physical examination
- Vital Signs: including temperature, HR, respiratory rate, and BP
- Orthostatic BP assessment
- ECG-12 lead
- Pregnancy Test (urine) in females
- Blood sampling for hematology, blood chemistry, and coagulation
- Urine sampling for urinalysis
- Drug accountability (if not done at Day 14 visit for only those patients enrolled under Version 4 or subsequent versions of the protocol)
- Blood sampling for PK (collected for only those patients enrolled under Version 2 or 3 of the protocol)
- Perform study-specific assessments: Suicidality (C-SSRS, C-CASA), ABC-C, SRS-2, [redacted], KiTAP, CSHQ, CGI-I, and CGI-S
    - C-SSRS is collected for only those patients enrolled under Version 4 or subsequent versions of the protocol. SRS-2 is collected for only those patients enrolled under Version 2, 3, or 4 of the protocol.
- Hearing assessment (collected for only those patients enrolled under Version 4 or subsequent versions of the protocol)

- Eye tracking assessment
- EEG
- Adverse Events
- Previous and Concomitant treatments

1.3 Sample Size

The target number of patients to be enrolled in this study is up to 16 individuals with ASD-Phen1. Assuming a dropout rate of roughly 20%, the maximum sample size of 20 patients will be enrolled in the study in order to ensure that up to 16 patients (up to 8 per dose level) will have evaluable data after 2 weeks of treatment and 2 weeks of follow-up. They will be randomized with a 3:1 ratio to one of the 2 groups (active/placebo) for each dose level.

Up to six patients per dose level on active and up to two on placebo per dose level is considered sufficient for the primary objective.

1.3.1 Replacement of Study Patients

If a patient withdraws from the study after randomization but before receiving any treatment, the next patient randomized will be assigned the same randomization number. This will ensure that the treatment allocation within each treatment group is preserved.

If a patient withdraws from the study after receiving any amount of treatment, the next patient randomized will be assigned to the next available randomization number.

2.0 Data Analysis Considerations

2.1 Types of Analyses

For this Phase 1b study, descriptive statistics will be provided for all variables by treatment group (placebo data will be pooled from the two dose cohorts). For continuous endpoints, summary statistics, i.e., n (number of non-missing observations), mean, standard deviation (SD), median, minimum, and maximum will be provided. For categorical variables, the frequency count and proportion in each category will be summarized.

As mentioned in Section 1.2 of the SAP, some assessment time points will vary according to which protocol amendment was in place at the time a patient was enrolled. Data from all time points will be summarized as appropriate in accordance with the details provided below in Section 3 – 7.

All data collected will be presented in the by-patient data listings, sorted by patient and by time point, where appropriate.

2.2 Analysis Populations

The following analysis populations will be defined for the study:

Safety Analysis Population: The safety population will consist of all patients who have received at least one administration of the study treatments, whether prematurely withdrawn from the study or not. For the safety analysis population, data will be analyzed according to the treatment actually taken.

Pharmacokinetic (PK) Analysis Population: The PK population will consist of all patients with at least one administration of the study treatments, and with at least one sample collected and analyzed for plasma drug concentration, whether prematurely withdrawn from the study or not.

Exploratory Analysis Population: The Exploratory population will consist of all randomized patients who meet the inclusion/exclusion criteria, received full-course of the study drug as per randomization, have completed the main relevant visits and without any major protocol violations which would render the data unreliable.

Analyses of safety will be performed on the Safety population, as will baseline patient characteristics and demographics. Analysis of PK variables will be performed on the PK population. Analyses of PD data will be performed on the Exploratory population. Prior to the final analysis, a blinded review of the protocol violations will be held in order to determine exclusions from the Exploratory population.

2.2.1 Subgroup Definitions

Analyses will be presented by treatment ([redacted]mg ibudilast/[redacted]mg bumetanide, [redacted]mg ibudilast [redacted]mg bumetanide, or placebo (placebo data will be pooled from the two dose cohorts)) as indicated below and shown in Appendix B.

2.3 Missing Data Conventions

No missing value imputation will be used. That is, all analyses will be based on the observed data (i.e., complete case analysis).

2.4 Interim Analyses

An evaluation of the data by an independent DSMB will take place after 8 patients finish 2 weeks of treatment and 2 weeks of follow-up. The primary responsibilities of the DSMB are to:

1. Review and evaluate the accumulated study data for patient safety, study conduct and progress, and

2. Make recommendation to STALICLA concerning the continuation, modification, or termination of the trial.

Refer to the separate Interim Analysis Plan (IAP) for further details on the interim analyses.

2.5 Study Center Considerations in the Data Analysis

A study center is defined as a treatment administration site or group of treatment administration sites under the Placebo and supervision of the same Principal Investigator (PI). This study will be conducted as a single study center, and therefore, study center considerations are not applicable. In case additional site(s) is (are) added with patients enrolled, the SAP will be revised if needed.

2.6 Documentation and Other Considerations

The data analyses will be conducted using SAS® Software, version 9.4 or later.

3.0 Analysis of Baseline Patient Characteristics

Baseline and demographic characteristics will be summarized by treatment for all patients in the Safety population. Placebo data will be pooled from the two dose groups. Continuous variables will be displayed via summary statistics (n, mean, median, SD, minimum, and maximum). Categorical variables will be summarized via frequency counts and proportions.

A detailed listing of demographics data for each patient will also be provided as shown in Appendix B.

4.0 Analysis of Safety

4.1 Description of Safety Variables

The safety variables for this study are:

- AEs
- Vital Signs and physical examinations
- ECG
- Clinical Laboratory Parameters
- Hearing Assessment

4.2 Analysis of Safety Variables

Adverse Events

Prior to analysis, all AEs will be recorded and classified on the basis of the Medical Dictionary for Regulatory Activities (MedDRA®) terminology. The number and proportion of patients with at least one AE will be summarized by system organ class (SOC) and by preferred term (PT) within SOC for each treatment group.

Similar tables will be provided to display the number and proportion of patients with at least one treatment- related AE, at least one treatment-related AE that led to study treatment discontinuation, at least one serious AE (SAE), at least one treatment-related SAE, at least one treatment-related SAE that led to study treatment discontinuation, at least one AE of special interest (AESI), and at least one AESI that led to study treatment discontinuation by SOC and by PT within SOC. For the purposes of this study, a treatment-related AE is any AE with a relationship to study drug of 'Related'.

In addition, tables will be constructed to summarize AEs by relationship to study drug and by severity.

A separate AE summary table will be constructed to display the number of patients with at least one AE, the number of patients with at least one treatment-related AE, the number of patients with at least one treatment-related AE that led to study treatment discontinuation, the maximum severity of AE by patient, the highest relationship of AE to treatment, the number of patients experiencing at least one SAE, the number of patients with at least one treatment-related SAE, the number of patients with at least one treatment-related SAE that led to study treatment discontinuation, the maximum severity of SAE by patient, the highest relationship of SAE to treatment, the number of patients with at least one AESI, the number of patients with at least one AESI that led to study treatment discontinuation, and the number of deaths.

All AEs will be provided in data listings as shown in Appendix B. AEs having an end date prior to signing the informed consent for this study will not be displayed in the AE data listings.

Vital Signs

The vital signs parameters of interest include temperature, respiratory rate, and orthostatic blood pressure and orthostatic heart rate.

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline values for standard vital sign measurements (temperature and respiratory rate) by visit and time for each treatment. The Day 1 prior to treatment time point will serve as baseline. If there are multiple vital signs taken at any time point, then the latest set of vital signs

will be used for the analysis.

Additionally, summary statistics will be computed on the raw and change from baseline values for the orthostatic vital sign measurements (BP and HR) by visit and time for each treatment. The Day 1 prior to treatment time point will serve as baseline. Spaghetti plots of the raw values for orthostatic diastolic BP, orthostatic systolic BP and orthostatic HR will be displayed by patient, time point and treatment.

All vital signs will be provided in data listings as shown in Appendix B. Vital signs taken while standing will be included in the data listings but will not be summarized in the tables.

Physical Examination
All physical examination results will be listed as shown in Appendix B.

ECG
The ECG parameters of interest include HR, PQ, QRS, QT, RR, and QTcF along with information on T and U waves.

As the ECGs are performed in triplicate at Day 1 prior to treatment, the average of the three values for each of the ECG parameters will be used as the baseline value. Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline values for each parameter by visit and time by treatment and overall. The Day 1 prior to treatment time point will serve as baseline. Spaghetti plots of the raw values for HR and QTcF will be displayed by patient, time point and treatment.

The ECG Interpretations for each of the three ECGs on Day 1 prior to treatment will be used to obtain a Combined Overall ECG Interpretation. The Combined Overall ECG Interpretation in relation to clinical significance at Day 1 prior to treatment (i.e., baseline) will be determined as follows:

- If at least one ECG Interpretation= ‘Abnormal – clinically significant’, then the Combined Overall ECG Interpretation = ‘Abnormal – clinically significant’.
- Else if there are no readings such that ECG Interpretation = ‘Abnormal – clinically significant’ and there is at least one ECG Interpretation = ‘Abnormal – not clinically significant’, then the Combined Overall ECG Interpretation = ‘Abnormal – not clinically significant’.
- Else if there are no readings such that ECG Interpretation = ‘Abnormal – clinically significant’ or ‘‘Abnormal – not clinically significant’ and there is at least one ECG Interpretation = ‘Normal’, then the Combined Overall ECG Interpretation = ‘Normal’.
- Else if all readings have a missing result for ECG Interpretation then the Combined Overall ECG Interpretation is missing.

Additionally, results from the ECG findings will be determined for T wave, U wave, and ECG Interpretation regardless of clinical significance. The Combined Overall T wave, U wave, and ECG Interpretation at Day 1 prior to treatment (i.e. baseline) will be determined by parameter as follows:

- If at least one ECG finding = 'Abnormal', then the Combined Overall finding = 'Abnormal'.
- Else if there are no readings such that ECG finding = 'Abnormal' and there is at least one ECG finding = 'Normal', then the Combined Overall finding = 'Normal'.
- Else if all readings have a missing result for ECG finding then the Combined Overall finding is missing.

Shift tables will be constructed to show the changes in ECG findings in relation to clinical significance (e.g., normal, abnormal clinically significant (CS), abnormal not clinically significant (NCS)) and findings (e.g., normal, abnormal) by parameter from baseline to each visit by treatment and overall.

All ECG data will be provided in data listings as shown in Appendix B.

Laboratory Results

The laboratory tests of interest include blood chemistry, serology, hematology, coagulation, and urinalysis results.

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline values for each quantitative laboratory parameter by visit for each treatment group and overall. The screening time point will serve as baseline.

Spaghetti plots of the raw values for sodium, chloride, calcium, magnesium, phosphate, potassium, and platelet count will be displayed by patient, time point and treatment.

For those urinalysis parameters that are qualitative in nature, the number and proportion of patients with each result for each parameter will be summarized by visit and treatment.

Shift tables will be constructed to show the changes in laboratory results in relation to clinical significance (e.g., normal, abnormal clinically significant (CS), abnormal not clinically significant (NCS)) from baseline to each visit. This analysis will be repeated for blood chemistry results for electrolytes (sodium, chloride, calcium, magnesium, phosphate, potassium).

A shift table for blood chemistry results for electrolytes will be constructed to show the changes in laboratory results in relation to range of normal results (e.g., normal, high, low) from baseline to each visit.

The count and proportion of patients with blood chemistry results for electrolytes outside of the normal range (low, high) for each visit will be summarized by treatment and overall.

All laboratory results data will be provided in data listings as shown in Appendix B.

Hearing Assessment
The patient responses to the hearing assessment for each visit will be listed as shown in Appendix B.

5.0 Analysis of Pharmacokinetics

5.1 Description of Pharmacokinetic Variables

PK sampling will be collected from all patients for measurement of plasma and urine concentrations of ibudilast and bumetanide.

Blood samples will be drawn on Days 1, 7, 14/15 and, optionally, between Days 16 to 18, and urine samples will be collected on Days 1 and 14 to determine concentrations of ibudilast and bumetanide. Non-compartmental analysis (NCA) will be utilized to analyze data from the sampling schema. See Table 1 for the PK sample schedule.

Table 1. PK Sampling Schedule

PK Schedule[c]		
Time	Plasma[a]	Urine[b]
Day 1	0.25, 0.5, 1, 2, 4, and 6h post-AM dose	0 to 6h post-AM dose
Day 7	Pre-AM dose	
Day 14 (only AM dose) and 15	Pre-AM dose and 0.25, 0.5, 1, 2, 4, 6, 8, 10, 12 and 24h post-AM dose	0 to 4h, 4 to 8h, and 8-12h post-AM dose
Between Days 16 to 18[d]	48, 72, and 96 h post-AM dose of Day 14	

[a] Both ibudilast and bumetanide will be analyzed from the same blood draw for each specified sampling time point.
[b] Urine creatinine from the urine collection will be paired with a serum creatinine measurement to evaluate completeness of collection.
[c] All of these timepoints have a 5-minute window.
[d] Optional

The following PK plasma parameters will be estimated for each patient(as far as possible):

PK Parameter	Definition
$C_{max,\ Day\ 1}$	Maximum plasma concentration on Day 1
$C_{max,ss}$	Maximum plasma concentration at steady state
C_{Last}	Last measured plasma concentration following the last administration
C_{trough}	Minimum observed plasma concentration prior to drug administration
T_{max}	Time of maximum observed plasma concentration; if it occurs at more than one time point, T_{max} is defined as the first time point with this value
$t_{1/2}$	Terminal elimination half-life, calculated as $\ln(2)/\lambda z$
$AUC_{0\text{-last}}$	Cumulative area under the plasma concentration time curve calculated from 0 to the last measured plasma concentration following the last administration using the linear trapezoidal method
$AUC_{0\text{-tau (6h), Day 1}}$	Area under the plasma concentration time curve to the end of the dosing period following the first administration
$AUC_{0\text{-tau (6h), SS}}$	Area under the plasma concentration time curve to the end of the dosing period (6h) following the last administration
$AUC_{0\text{-12h, SS}}$	Area under the plasma concentration time curve to 12 hours post dose following the last administration
$AUC_{0\text{-}\infty}$	Area under the plasma concentration time curve extrapolated to infinity, calculated as $AUC_{0\text{-last}} + C_{Last}/\lambda z$
Vz/F	Apparent volume of distribution
Cl/F	Apparent total body clearance
Accumulation Ratio	Ratio of accumulation of a drug, calculated by the following equation: $AR_{AUC} = AUC_{0\text{-tau (6h), SS}} / AUC_{0\text{-tau (6h), Day 1}}$ and $AR_{Cmax} = C_{max,ss} / C_{max,\ Day\ 1}$

As the PK time schedules were different prior to the implementation of Version 4.0 (Amendment 3) of the clinical study protocol, the PK schedule of the first 4 patients is as follows:

Day 1

- Blood sampling at pre-AM dose and 0.25, 0.5, 1, 2, 4, 6 h post-AM dose
- Urine sampling at 0 to 6 h post-AM dose

Day 7

- Blood sampling at pre-AM dose

Day 14

- Blood sampling at pre-AM dose and 0.25, 0.5, 1, 2, 4, 6, 8, 10, 24 and 30 h post-AM dose
- Urine sampling 0 to 6 h and 24 to 30 h post-AM dose

5.2 Analysis of Pharmacokinetic Variables

Plasma and urine sample concentrations of ibudilast and bumetanide will be summarized by treatment, visit and time point using descriptive statistics.

Individual plasma concentrations of ibudilast and bumetanide will be depicted for each patient by treatment group using linear scale. Individual and mean plasma concentration- time profiles will be plotted in linear and semi-logarithmic scales.

PK parameter values will be summarized by treatment group using descriptive statistics (n, mean, SD, CV%, geometric mean, and 90% confidence interval). Plasma PK parameters such as $AUC_{0\text{-}tau}$, AUC_{last}, C_{max}, T_{max}, C_{trough}, apparent oral clearance, the elimination half-life, apparent volume of distribution and accumulation ratios will be calculated following single dose administration (as far as possible) and at steady state for both parent drugs.

Urine parameters include the following:

- Excretion rate by timepoint:
  - Day 1, 0-6h
  - Day 14, 0-4h
  - Day 14, 4-8h
  - Day 14, 8-12h
- Cumulative excretion, based on Day 14 sampling over 0-12h
- Renal clearance, based on Day 14 sampling over 0-12h

6.0 Exploratory Analyses

6.1 Description of Exploratory Variables

Exploratory variables for this study include:

- [redacted] and KiTAP subtask score
- OACIS-C
- ABC-C subscale scores
- SRS-2 subscale scores
- CSHQ total score
- Lactate and Pyruvate Blood Levels
- Change from baseline in CGI-S, as reflected by CGI-I
- Eye tracking
- EEG

6.2 Analysis of Exploratory Variables

[redacted] and KiTAP

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline values for each subtask variable by visit, treatment and overall. The Day 1 time point will serve as baseline.

[redacted]

OACIS-C

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw score for each question will be summarized by treatment and overall. Frequency counts and proportions will also be summarized for each response in the assessment by treatment and for each group of responses (very much improved or much improved; minimally improved, no change or minimally worse; and much worse or very much worse).

ABC-C

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline scores for each subscale by visit, treatment and overall. The Screening time point will serve as baseline.

SRS-2

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline scores for each subscale by visit, treatment and overall. The Screening time point will serve as baseline.

CSHQ

The number and proportions will be summarized for each value in the assessment by visit, question, treatment and overall. The Day 1 time point will serve as baseline.

Lactate and Pyruvate Blood Levels

Summary statistics (n, mean, median, SD, minimum, and maximum) will be computed on the raw and change from baseline values of lactate, pyruvate and lactate-pyruvate ratio (L:P ratio) by treatment and overall. The Screening time point will serve as baseline.

Spaghetti plots of the raw values for L:P ratio will be displayed by patient, time point and treatment.

CGI-S and CGI-I

Frequency counts and proportions for each response to the CGI-S and CGI-I assessments will be summarized by treatment and visit. Patients enrolled under

protocol Version 3 or earlier will be summarized at the following visits: Days 1, 14 and 28. Patients enrolled under Version 4 or later will be summarized at the following visits: Screening, Days 14 & 28. Data will be combined for overlapping visits.

Eye Tracking and EEG
Eye tracking will not be included in the final study database. However, EEG data will be included in the final study database.

Both the eye tracking and EEG data will not be incorporated into the analysis datasets nor the tables, listings, and figures covered in this SAP. Analysis plans for the eye tracking and EEG variables will be presented in a separate document. The variables to be analyzed to assess changes from Day 1 to Day 14 are as follows:

Eye Tracking variables:
1. Time spent mouth and eyes
    a. Region
    b. Total time

7.0 Other Relevant Data Analyses/Summaries

7.1 Patient Disposition

A table will be constructed with the number of screen failures and enrolled patients. For those patients who are screen failures, the number and proportion for each reason for screen failure will be summarized. Of those enrolled, frequency counts and proportion of the number of patients withdrawing from the study before study completion and the number completing the study will be displayed. For those patients that withdraw before completion of the study or discontinue treatment of STP1, the number and proportion for each reason for withdrawal will be tabulated. The table will include summary counts and proportions by treatment and overall. A data listing of all patient completion and withdrawal data will also be constructed.

7.2 Additional Assessments

Suicidality (C-SSRS, C-CASA) assessments will be performed at Screening, throughout the treatment period and at the follow-up visits, as specified in the protocol. The SB5 ABIQ assessment will be completed at Screening only. These assessments will be listed for all patients in the Safety population as shown in Appendix B.

7.3 Medical History

Prior to analysis, all medical history terms will be coded using the MedDRA coding dictionary. The number and proportion of patients with at least one medical history term will be summarized by system organ class (SOC) and by preferred term (PT) within SOC for each treatment group.

A complete medical history of past and present illnesses and surgeries will be listed as shown in Appendix B.

7.4 Concomitant Medication

All concomitant medications will be coded with the WHO Drug Dictionary. A table will be constructed with number and proportion of patients by ATC level 4 and preferred term.

All concomitant medications will be listed as shown in Appendix B.

8.0 List of Analysis Tables, Figures and Listings

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
1	Patient Disposition	X	X
2	Demographics and Baseline Data Summary Statistics–Continuous Variables (Safety Population)	X	X
3	Demographics and Baseline Data Summary Statistics–Categorical Variables (Safety Population)	X	X
4	Summary of Adverse Events (Safety Population)	X	X
5	Number and Proportion of Patients with Adverse Events (Safety Population)	X	X
6	Number and Proportion of Patients with Treatment-Related Adverse Events (Safety Population)	X	X
7	Number and Proportion of Patients with Treatment-Related Adverse Events that Led to Study Drug Discontinuation (Safety Population)	X	X
8	Number and Proportion of Patients with Serious Adverse Events (Safety Population)	X	X
9	Number and Proportion of Patients with Treatment-Related Serious Adverse Events (Safety Population)	X	X
10	Number and Proportion of Patients with Treatment-Related Serious Adverse Events that Led to Study Drug Discontinuation (Safety Population)	X	X
11	Number and Proportion of Patients with Adverse Events of Special Interest (Safety Population)	X	X
12	Number and Proportion of Patients with Adverse Events of Special Interest that Led to Study Drug Discontinuation (Safety Population)	X	X
13	Number and Proportion of Patients with Adverse Events by Relationship to Study Drug (Safety Population)	X	X
14	Number and Proportion of Patients with Adverse Events by Severity (Safety Population)	X	X
15	Vital Sign Parameter Summary Statistics (Safety Population)	X	X
16	Orthostatic Vital Sign Parameter Summary Statistics (Safety Population)	X	X
17	ECG Parameter Summary Statistics (Safety Population)	X	X
18	ECG Results Shift Table by Visit and Clinical Significance (Safety Population)	X	X
19	ECG Results Shift Table by Visit (Safety Population)	X	X
20	Blood Chemistry Parameter Summary Statistics (Safety Population)	X	X
21	Hematology Parameter Summary Statistics (Safety Population)	X	
22	Coagulation Parameter Summary Statistics (Safety Population)	X	
23	Quantitative Urinalysis Parameter Summary Statistics (Safety Population)	X	
24	Summary of Qualitative Urinalysis Results by Parameter (Safety Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
25	Blood Chemistry Results Shift Table by Visit and Clinical Significance (Safety Population)	X	X
26	Hematology Results Shift Table by Visit and Clinical Significance (Safety Population)	X	
27	Coagulation Results Shift Table by Visit and Clinical Significance (Safety Population)	X	
28	Quantitative Urinalysis Results Shift Table by Visit and Clinical Significance (Safety Population)	X	
29	Blood Chemistry Results for Electrolytes Shift Table by Visit and Clinical Significance (Safety Population)	X	
30	Blood Chemistry Results for Electrolytes Shift Table by Visit and Range of Normal Results (Safety Population)	X	X
31	Number and Proportion of Patients with Blood Chemistry Results for Electrolytes Outside of Normal Range (Safety Population)	X	X
32	Summary Statistics of Ibudilast and Bumetanide Plasma Concentration Levels by Treatment, Visit and Time (PK Population)	X	X
33	Summary Statistics of Ibudilast and Bumetanide Urine Concentration Levels by Treatment, Visit and Time (PK Population)	X	X
34	Summary Statistics of Estimated PK Plasma Parameters for Ibudilast by Treatment (PK Population)	X	X
35	Summary Statistics of Estimated PK Plasma Parameters for Bumetanide by Treatment (PK Population)	X	X
36	Summary Statistics of Estimated PK Urine Parameters for Ibudilast by Treatment (PK Population)	X	X
37	Summary Statistics of Estimated PK Urine Parameters for Bumetanide by Treatment (PK Population)	X	
38	[redacted]	X	X
39	KiTAP Summary Statistics (Exploratory Population)	X	
40	OACIS-C Summary Statistics (Exploratory Population)	X	X
41	Summary of Responses for OACIS-C Assessment by Question (Exploratory Population)	X	X
42	Summary of Responses for OACIS-S Assessment by Question (Exploratory Population)	X	X
43	ABC-C Summary Statistics (Exploratory Population)	X	X
44	SRS-2 Summary Statistics (Exploratory Population)		
45	Summary of Responses for CSHQ Assessment by Question (Exploratory Population)	X	X
46	Lactate and Pyruvate Blood Level Summary Statistics (Exploratory Population)	X	X
47	Summary of Responses for CGI-S Assessment by Visit (Exploratory Population)	X	X
48	Summary of Responses for CGI-I Assessment by Visit (Exploratory Population)	X	X
49	Number and Proportion of Patients with Medical History Events (Safety Population)	X	X

Table No.	Table Title	Included in Final Tables	Shown in Appendix B
50	Number and Proportion of Patients Taking Concomitant Medications by ATC Level 4 and Preferred Term (Safety Population)	X	X

Listing No.	Listing Title	Included in Final Listings	Shown in Appendix B
DL1	Patient Disposition Data Listing	X	X
DL2	Demographics Data Listing	X	X
DL3	Adverse Events Data Listing	X	X
DL4	Vital Signs Data Listing	X	X
DL5	Baseline ECG Data Listing	X	X
DL6	ECG Data Listing	X	X
DL7	Blood Chemistry Laboratory Results Data Listing	X	X
DL8	Serology Laboratory Results Data Listing	X	X
DL9	Hematology Laboratory Results Data Listing	X	X
DL10	Coagulation Laboratory Results Data Listing	X	
DL11	Urinalysis Laboratory Results Data Listing	X	
DL12	Hearing Assessment Data Listing	X	X
DL13	Pharmacokinetic Blood Sample Data Listing	X	X
DL14	Pharmacokinetic Urine Sample Data Listing	X	X
DL15	Plasma Concentrations Data Listing	X	X
DL16	Urine Concentrations Data Listing	X	X
DL17	Plasma Pharmacokinetics Parameters Data Listing	X	X
DL18	Urine Pharmacokinetics Parameters Data Listing	X	X
DL19	C-SSRS Data Listing	X	X
DL20	C-CASA Data Listing	X	X
DL21	OACIS-S Data Listing	X	X
DL22	OACIS-C Data Listing	X	X
DL23	SRS-2 Data Listing	X	X
DL24	SB5 ABIQ Data Listing	X	X
DL25	[redacted]	X	X
DL26	KiTAP Data Listing	X	
DL27	ABC-C Data Listing	X	X
DL28	CSHQ Data Listing	X	X
DL29	Lactate-Pyruvate Data Listing	X	X
DL30	CGI-S/CGI-I Data Listing	X	X
DL31	Medical History Data Listing	X	X
DL32	Concomitant Medications Data Listing	X	X
DL33	Physical Exam Data Listing	X	X
DL34	Study Drug Administration Data Listing	X	X
DL35	Drug Accountability Data Listing	X	X
DL36	Urine Pregnancy Test Data Listing	X	X
DL37	Protocol Deviations Data Listing	X	X
DL38	Patients Excluded from Safety Population Data Listing	X	X
DL39	Patients Excluded from PK Population Data Listing	X	

Listing No.	Listing Title	Included in Final Listings	Shown in Appendix B
DL40	Patients Excluded from Exploratory Population Data Listing	X	

Figure No.	Figure Title	Included in Final Listings	Shown in Appendix B
FIG1	Orthostatic Vital Signs - Spaghetti Plot of Systolic Blood Pressure by Patient, Time and Treatment (Safety Population)	X	X
FIG2	Orthostatic Vital Signs - Spaghetti Plot of Diastolic Blood Pressure by Patient, Time and Treatment (Safety Population)	X	
FIG3	Orthostatic Vital Signs - Spaghetti Plot of Heart Rate by Patient, Time and Treatment (Safety Population)	X	
FIG4	ECG Parameters - Spaghetti Plot of Heart Rate by Patient, Time and Treatment (Safety Population)	X	
FIG5	ECG Parameters - Spaghetti Plot of QTcF by Patient, Time and Treatment (Safety Population)	X	
FIG6	Blood Chemistry - Spaghetti Plot of Sodium by Patient, Time and Treatment (Safety Population)	X	X
FIG7	Blood Chemistry - Spaghetti Plot of Chloride by Patient, Time and Treatment (Safety Population)	X	
FIG8	Blood Chemistry - Spaghetti Plot of Calcium by Patient, Time and Treatment (Safety Population)	X	
FIG9	Blood Chemistry - Spaghetti Plot of Magnesium by Patient, Time and Treatment (Safety Population)	X	
FIG10	Blood Chemistry - Spaghetti Plot of Phosphate by Patient, Time and Treatment (Safety Population)	X	
FIG11	Blood Chemistry - Spaghetti Plot of Potassium by Patient, Time and Treatment (Safety Population)	X	
FIG12	Hematology - Spaghetti Plot of Platelet Count by Patient, Time and Treatment (Safety Population)	X	
FIG13	Biomarker - Spaghetti Plot of L:P Ratio by Patient, Time and Treatment (Safety Population)	X	
FIG14	Patient Plasma Concentration Levels of Ibudilast for Treatment Group = [redacted]mg Ibudilast– Linear Scale – Days 1-28 (PK Population)	X	X
FIG15	Patient Plasma Concentration Levels of Ibudilast for Treatment Group = [redacted]mg Ibudilast– Linear Scale – Days 1-28 (PK Population)	X	
FIG16	Patient Plasma Concentration Levels of Ibudilast for Treatment Group = [redacted]mg Ibudilast– Semi-Logarithmic Scale – Days 1-28 (PK Population) Patient Plasma	X	
FIG17	Concentration Levels of Ibudilast for Treatment Group = [redacted]mg Ibudilast– Semi-Logarithmic Scale – Days 1-28 (PK Population)	X	

Figure No.	Figure Title	Included in Final Listings	Shown in Appendix B
FIG18	Patient Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast– Linear Scale – Days 1-28 (PK Population)	X	
FIG19	Patient Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast– Linear Scale – Days 1-28 (PK Population)	X	
FIG20	Patient Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast– Semi-Logarithmic Scale – Days 1-28 (PK Population)	X	
FIG21	Patient Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast– Semi-Logarithmic Scale – Days 1-28(PK Population)	X	
FIG22	Mean Plasma Concentration Levels of Ibudilast for Treatment Group =[redacted]mg Ibudilast – Linear Scale – Days 1-28 (PK Population)	X	X
FIG23	Mean Plasma Concentration Levels of Ibudilast for Treatment Group =[redacted]mg Ibudilast – Linear Scale – Days 1-28 (PK Population)	X	
FIG24	Mean Plasma Concentration Levels of Ibudilast for Treatment Group =[redacted]mg Ibudilast – Semi-Logarithmic Scale – Days 1-28 (PK Population)	X	
FIG25	Mean Plasma Concentration Levels of Ibudilast for Treatment Group =[redacted]mg Ibudilast – Semi-Logarithmic Scale – Days 1-28 (PK Population)	X	
FIG26	Mean Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast – Linear Scale – Days 1-28 (PK Population)	X	
FIG27	Mean Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast – Linear Scale – Days 1-28 (PK Population)	X	
FIG28	Mean Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast – Semi-Logarithmic Scale – Days 1-28 (PK Population)	X	
FIG29	Mean Plasma Concentration Levels of Bumetanide for Treatment Group =[redacted]mg Ibudilast – Semi-Logarithmic Scale – Days 1-28 (PK Population)	X	

9.0 References

Not applicable.

Appendix A – Tables, Figures and Listing Specifications

Orientation

Tables, figures, and listings will be displayed in landscape.

Margins

Margins will be 1 inch on all sides. Table, figure, and listing boundaries will not extend into the margins.

Font

Courier New, 8 point.

Headers

The table number will be on the second line of the title area. The title area will contain the Sponsor name, the study number, and the name of the table. The title area will contain the page number (Page x of y) on the far right, one line above the name of the table.

Footers

- The first line will be a solid line.
- Next will be any footnotes regarding information displayed in the table.
- Below these footnotes will be displayed “STATKING Clinical Services (month day, year)” on the far left.
- The last line will display the name of the SAS program that generated the table and (if applicable) the source data reference.

Table Disclaimer

The format of the mock tables shown in the appendix of this Statistical Analysis Plan (SAP) will be the format of the deliverable tables to the extent that Word document constructed tables can match production tables produced by SAS. This formatting includes the content and format of the header and footer areas of the tables. The Sponsor agrees to the format of the tables as shown in the appendix.

Further programming charges will be applicable for changes in the format of tables (including title statements, notes, data dependent footnotes, etc.) made after the approval of the SAP.

Missing Values

All missing values will be displayed on the output tables/listings as blanks.

Computation Values for Study Dates

The date format to be used is dd-mmm-yyyy. Missing parts of dates are not shown (e.g., for a missing day value, the value displayed is in mmm-yyyy format).

Appendix B – Table Shells

Table 1. Patient Disposition
STALICLA SA - Study No. STP1-C004

	STP1-[redacted] ibudilast (N=xxx)[a]	STP1-[redacted] ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)
Screen Failures				xx
Reason for Screen Failure				
xxxxxxxxxxxxxxxxxx				xx
xxxxxxxxxxxxxxxxxx				xx
xxxxxxxxxxxxxxxxxx				xx
Enrolled	xx	xx	xx	xx
Completed	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
Discontinued	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Reason for Patient Discontinuation				
Adverse Event	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Investigator Decision	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Consent Withdrawn	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patient Non-compliance	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Death	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Other	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Reason for Discontinuation from STP1				
Pregnancy	xxx (xxx)	xxx (xxx)		xxx (xxx)
Patient Non-compliance	xxx (xxx)	xxx (xxx)		xxx (xxx)
Patient Unblinding	xxx (xxx)	xxx (xxx)		xxx (xxx)
xxxxxxxxxxxxxxxxx	xxx (xxx)	xxx (xxx)		xxx (xxx)
xxxxxxxxxxxxxxxxx	xxx (xxx)	xxx (xxx)		xxx (xxx)

[a] The denominator for all proportions is the number of enrolled patients in the corresponding treatment group and overall.

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 2. Demographics and Baseline Data Summary Statistics – Continuous Variables
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Variable	Treatment Group	n	Mean	Std Dev	Median	Min	Max
Age (years)	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	Placebo	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Height (cm)	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	Placebo	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
Weight (kg)	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	Placebo	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
BMI	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	Placebo	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
[redacted]	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	Placebo	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx
SB5-ABIQ	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx
	Placebo	xxx	xxx	xxx	xxx	xxx	xxx
	Overall	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 3. Demographics and Baseline Data Summary Statistics – Categorical Variables
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Demographics Variable	Category	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
Sex	Male	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Female	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Race	American Indian	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Asian	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Black	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Hawaiian	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	White	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Other	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Ethnicity	Hispanic	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	Not Hispanic	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 4. Summary of Adverse Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxxx)

	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
Patients with at Least One Adverse Event (AE)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One Treatment-Related AE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One Treatment-Related AE that Led to Study Treatment Discontinuation	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Maximum AE Severity Grade				
Mild	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Moderate	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Severe	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Highest Relationship of AE to Study Drug				
Not Related	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Related	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One Serious AE (SAE)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One Treatment-Related SAE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One Treatment-Related SAE that Led to Study Treatment Discontinuation	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[Table continues on next page.]

[a] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 4. Summary of Adverse Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxxx)

	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
Maximum SAE Severity Grade				
Mild	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Moderate	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Severe	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Highest Relationship of SAE to Study Drug				
Not Related	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Related	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One AE of Special Interest (AESI)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Patients with at Least One AESI that Led to Study Treatment Discontinuation	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Deaths	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 5. Number and Proportion of Patients with Adverse Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a]:	STP1-[redacted]mg ibudilast (N=xxx)[b]	STP1-[redacted]mg ibudilast (N=xxx)[b]	Placebo (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Adverse Events (AEs)	xxx	xxx	xxx	xxx
Patients with at Least One AE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 6. Number and Proportion of Patients with Treatment-Related Adverse Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a,b]:	STP1-[redacted]mg ibudilast (N=xxx)[c]	STP1-[redacted]mg ibudilast (N=xxx)[c]	Placebo (N=xxx)[c]	Overall (N=xxx)[c]
Total Number of Treatment-Related Adverse Events (AEs)	xxx	xxx	xxx	xxx
Patients with at Least One Treatment-Related AE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] A treatment-related AE is any AE with a relationship to study drug of Related.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 7. Number and Proportion of Patients with Treatment-Related Adverse Events that Led to Study Drug Discontinuation
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a,b]:	STP1-[redacted]mg ibudilast (N=xxx)[c]	STP1-[redacted]mg ibudilast (N=xxx)[c]	Placebo (N=xxx)[c]	Overall (N=xxx)[c]
Total Number of Treatment-Related Adverse Events (AEs) that Led to Study Drug Discontinuation	xxx	xxx	xxx	xxx
Patients with at Least One Treatment-Related AE that Led to Study Drug Discontinuation	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a]
Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] A treatment-related AE is any AE with a relationship to study drug of Related.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 8. Number and Proportion of Patients with Serious Adverse Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a]:	STP1-[redacted]mg ibudilast (N=xxx)[b]	STP1-[redacted]mg ibudilast (N=xxx)[b]	Placebo (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Serious Adverse Events (SAEs)	xxx	xxx	xxx	xxx
Patients with at Least One SAE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 9. Number and Proportion of Patients with Treatment-Related Serious Adverse Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a,b]:	STP1-[redacted]mg ibudilast (N=xxx)[c]	STP1-[redacted]mg ibudilast (N=xxx)[c]	Placebo (N=xxx)[c]	Overall (N=xxx)[c]
Total Number of Treatment-Related Serious Adverse Events (SAEs)	xxx	xxx	xxx	xxx
Patients with at Least One Treatment-Related SAE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] A treatment-related AE is any AE with a relationship to study drug of Related.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 10. Number and Proportion of Patients with Treatment-Related Serious Adverse Events that Led to Study Drug Discontinuation
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a,b]:	STP1-[redacted]mg ibudilast (N=xxx)[c]	STP1-[redacted]mg ibudilast (N=xxx)[c]	Placebo (N=xxx)[c]	Overall (N=xxx)[c]
Total Number of Treatment-Related Serious Adverse Events (SAEs) that Led to Study Drug Discontinuation	xxx	xxx	xxx	xxx
Patients with at Least One Treatment-Related SAE that Led to Study Drug Discontinuation	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a]
Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] A treatment-related AE is any AE with a relationship to study drug of Related.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 11. Number and Proportion of Patients with Adverse Events of Special Interest
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a]:	STP1-[redacted]mg ibudilast (N=xxx)[b]	STP1-[redacted]mg ibudilast (N=xxx)[b]	Placebo (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Adverse Events of Special Interest (AESIs)	xxx	xxx	xxx	xxx
Patients with at Least One AESI	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 12. Number and Proportion of Patients with Adverse Events of Special Interest that Led to Study Drug Discontinuation
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Adverse Event Category[a]:	STP1-[redacted]mg ibudilast (N=xxx)[b]	STP1-[redacted]mg ibudilast (N=xxx)[b]	Placebo (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Adverse Events of Special Interest (AESIs) that Led to Study Drug Discontinuation	xxx	xxx	xxx	xxx
Patients with at Least One AESI that Led to Study Drug Discontinuation	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 13. Number and Proportion of Patients with Adverse Events by Relationship to Study Drug
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

	STP1-[redacted]mg ibudilast (N=xxx)[b]		STP1-[redacted]mg ibudilast (N=xxx)[b]		Placebo (N=xxx)[b]	
Adverse Event Category[a]:	Not Related	Related	Not Related	Related	Not Related	Related
Total Number of Adverse Events (AEs)	xxx	xxx	xxx	xxx	xxx	xxx
Patients with at Least One AE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a]
Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 14. Number and Proportion of Patients with Adverse Events by Severity
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

	STP1-[redacted]mg ibudilast (N=xxx)[b]			STP1-[redacted]mg ibudilast (N=xxx)[b]			Placebo (N=xxx)[b]		
Adverse Event Category[a]:	Mild	Moderate	Severe	Mild	Moderate	Severe	Mild	Moderate	Severe
Total Number of Adverse Events (AEs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Patients with at Least One AE	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Adverse events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 15. Vital Sign Parameter Summary Statistics
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Treatment	Parameter (units)[a]	Visit	Time	Data Type[b]	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] Vital sign parameters in this table include temperature and respiratory rate.
[b] RAW = observed data recorded in database; CFB = change from baseline = (results at current visit) - (Baseline results).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 16. Orthostatic Vital Sign Parameter Summary Statistics
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Treatment	Parameter (units)[a]	Visit	Time	Data Type[b]	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] Vital sign parameters in this table include orthostatic heart rate, orthostatic diastolic blood pressure, and orthostatic systolic blood pressure taken in the supine position.
[b] RAW = observed data recorded in database; CFB = change from baseline = (results at current visit) - (Baseline results).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 17. ECG Parameter Summary Statistics
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Treatment	Parameter (units)	Visit[a]	Time	Data Type[b]	n	Mean	Std Dev	Median	Min	Max
STP1–[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1–[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxx (xxx)	Baseline	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	xxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			xxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] The baseline raw value for each parameter is calculated using the average of the triplicate values from the ECG performed on Day 1 pre-dose.
[b] Raw = observed data; CFB = change from baseline = (results at current visit) - (Baseline results).
STATKING Clinical Services (DDMMMYYYY)
Source Program: xxxxxxx.sas

Table 18. ECG Results Shift Table by Visit and Clinical Significance
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

		Baseline[a]/Visit[b,c]								
Treatment	Visit	Normal/ Normal	Normal/ Abnormal CS	Normal/ Abnormal NCS	Abnormal CS/ Normal	Abnormal CS/ Abnormal CS	Abnormal CS/ Abnormal NCS	Abnormal NCS/ Normal	Abnormal NCS/ Abnormal CS	Abnormal NCS/ Abnormal NCS
STP1-[redacted]mg ibudilast	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
STP1-[redacted]mg ibudilast	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Placebo	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
Overall	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)

[a] The baseline ECG result performed in triplicate is determined as outlined in section 4.2 of the SAP.
[b] A normal result are those results that the Principal Investigator determined to be within normal range. CS = Clinically Significant. NCS= Not Clinically Significant.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 19. ECG Results Shift Table by Visit
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

			Baseline[a]/Visit[b,c]			
Treatment	Parameter	Visit	Normal/Normal	Normal/Abnormal	Abnormal/Normal	Abnormal/Abnormal
STP1-[redacted]mg ibudilast	xxxxx	xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
		xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
STP1-[redacted]mg ibudilast	xxxxx	xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
		xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
Placebo	xxxxx	xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
		xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
Overall	xxxxx	xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)
		xxxxxx	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)	xxx (xxxx)

[a] The baseline ECG result performed in triplicate is determined as outlined in section 4.2 of the SAP.
[b] A normal result are those results that the Principal Investigator determined to be within normal range.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (DDMMMYYYY)
Source Program: xxxxxxx.sas

Parameters in this table are T wave, U wave and ECG Interpretation.

Table 20. Blood Chemistry Parameter Summary Statistics
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Treatment	Parameter (units)	Visit	Data Type[a]	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = observed data recorded in database; CFB = change from baseline = (results at current visit) - (Baseline results).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for Hematology, Coagulation and Urinalysis.

Table 24. Summary of Qualitative Urinalysis Results by Parameter
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Parameter	Visit	Result	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
xxxxx	xxxxx	xxxxxx	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	xxxxx	xxxxxx	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		xxxxxx	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (DDMMMYYYY)
Source Program: xxxxxxx.sas

Table 25. Blood Chemistry Results Shift Table by Visit and Clinical Significance
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Parameter (units)	Treatment	Visit	Baseline/Visit[a,b] Normal/ Normal	Normal/ Abnormal CS	Normal/ Abnormal NCS	Abnormal CS/ Normal	Abnormal CS/ Abnormal CS	Abnormal CS/ Abnormal NCS	Abnormal NCS/ Normal	Abnormal NCS/ Abnormal CS	Abnormal NCS/ Abnormal NCS
xxxxxxxxxx (xxx)	STP1-[redacted]mg ibudilast	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	STP1-[redacted]mg ibudilast	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	Placebo	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	Overall	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
xxxxxxxxxx (xxx)	xxxxxxxx	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)

[a] A normal result are those results that the Principal Investigator determined to be within normal range. CS = Clinically Significant. NCS= Not Clinically Significant.

[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table format will be repeated for Hematology, Coagulation, Urinalysis, and Blood Chemistry Results for Electrolytes.
Laboratory parameters in Table 25 will exclude sodium, chloride, calcium, magnesium, phosphate, and potassium.
Laboratory parameters in Table 29 will include sodium, chloride, calcium, magnesium, phosphate, and potassium.

Table 30. Blood Chemistry Results for Electrolytes Shift Table by Visit and Range of Normal Results
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Laboratory Parameter (units)	Treatment	Visit	Baseline/Visit[a,b]								
			High/ High	High/ Normal	High/ Low	Normal/ High	Normal/ Normal	Normal/ Low	Low/ High	Low/ Normal	Low/ Low
xxxxxxxxxx (xxx)	STP1-[redacted]mg ibudilast	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	STP1-[redacted]mg ibudilast	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	Placebo	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
	Overall	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
xxxxxxxxxx (xxx)	xxxxxxxx	xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)
		xxxxxx	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)	xxx (xx)

[a]
A normal result are those results that the Principal Investigator determined to be within normal range.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Laboratory parameters include: sodium, chloride, calcium, magnesium, phosphate, and potassium.

Table 31. Number and Proportion of Patients with Blood Chemistry Results for Electrolytes Outside of Normal Range
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Parameter (units)	Visit	Result	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
xxxxxxxxxx (xxx)	xxxxxx	Low	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		High	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	xxxxxx	Low	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		High	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
xxxxxxxxxx (xxx)	xxxxxx	Low	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		High	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
	xxxxxx	Low	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
		High	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.

STATKING Clinical Services (DDMMMYYYY)
Source Program: xxxxxxx.sas

Laboratory parameters include: sodium, chloride, calcium, magnesium, phosphate, and potassium.

Table 32. Summary Statistics of Ibudilast and Bumetanide Plasma Concentration Levels by Treatment, Visit and Time
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Drug[a]	Treatment	Visit	Time (hrs)	n	Mean	Std Dev	Median	Min	Max
Ibudilast	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
	STP1-[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
Bumetanide	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a] Concentration levels measured in units of xxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 33. Summary Statistics of Ibudilast and Bumetanide Urine Concentration Levels by Treatment, Visit and Time
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Drug[a]	Treatment	Visit	Time (hrs)	n	Mean	Std Dev	Median	Min	Max
Ibudilast	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
Bumetanide	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
	STP1[redacted]mg ibudilast	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx
		xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
			xxx	xxx	xxx	xxx	xxx	xxx	xxx

[a] Concentration levels measured in units of xxx.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 34. Summary Statistics of Estimated PK Plasma Parameters for Ibudilast by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 1 of 2: STP1- [redacted] ibudilast

Visit	Parameter (units)	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	$C_{max,Day\ 1}$ (xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-tau(6h),Day\ 1}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AUC_{0-last} (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	$C_{max,ss}$ (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-tau(6h),SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-12h,SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AUC_{0-last} (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Overall	$AUC_{0-\infty}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{AUC}	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{Cmax}	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Table 34. Summary Statistics of Estimated PK Plasma Parameters for Ibudilast by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 2 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter (units)	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	$C_{max,Day\ 1}$ (xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0\text{-}tau(6h),Day\ 1}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0\text{-}last}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	$C_{max,ss}$ (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0\text{-}tau(6h),SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0\text{-}12h,SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0\text{-}last}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Overall	$AUC_{0\text{-}\infty}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{AUC}	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{Cmax}	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 35. Summary Statistics of Estimated PK Plasma Parameters for Bumetanide by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 1 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter (units)	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	$C_{max,Day\ 1}$ (xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-tau(6h),Day\ 1}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AUC_{0-last} (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	$C_{max,ss}$ (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-tau(6h),SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-12h,SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AUC_{0-last} (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Overall	$AUC_{0-\infty}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{AUC}	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{Cmax}	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 35. Summary Statistics of Estimated PK Plasma Parameters for Bumetanide by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 2 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter (units)	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	$C_{max,Day\ 1}$ (xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-tau(6h),Day\ 1}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AUC_{0-last} (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	$C_{max,ss}$ (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	T_{max} (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	C_{trough} (xxx /mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$t_{1/2}$ (hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-tau(6h),SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	$AUC_{0-12h,SS}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AUC_{0-last} (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Vz/F (mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cl/F (mL/hrs)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Overall	$AUC_{0-\infty}$ (hrs* xxx/mL)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{AUC}	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	AR_{Cmax}	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 36. Summary Statistics of Estimated PK Urine Parameters for Ibudilast by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 1 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	Excretion Rate(xxx/hr), 0-6h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	Excretion Rate(xxx/hr), 0-4h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 4-8h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 8-12h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cumulative Excretion (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Renal Clearance (mL/hr)	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 36. Summary Statistics of Estimated PK Urine Parameters for Ibudilast by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 2 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	Excretion Rate(xxx/hr), 0-6h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	Excretion Rate(xxx/hr), 0-4h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 4-8h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 8-12h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cumulative Excretion (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 37. Summary Statistics of Estimated PK Urine Parameters for Bumetanide by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 1 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	Excretion Rate(xxx/hr), 0-6h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	Excretion Rate(xxx/hr), 0-4h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 4-8h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 8-12h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cumulative Excretion (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Renal Clearance (mL/hr)	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 37. Summary Statistics of Estimated PK Urine Parameters for Bumetanide by Treatment
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Part 2 of 2: STP1-[redacted]mg ibudilast

Visit	Parameter	n	Mean	Std Dev	CV%	Geometric Mean	Lower 90% CI	Upper 90% CI
Day 1	Excretion Rate(xxx/hr), 0-6h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Day 14	Excretion Rate(xxx/hr), 0-4h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 4-8h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Excretion Rate(xxx/hr), 8-12h	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Cumulative Excretion (xxx)	xxx	xxx	xxx	xxx	xxx	xxx	xxx
	Renal Clearance (mL/hr)	xxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 38. NIH-CTB Summary Statistics
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Treatment	Neurological Function Domain	Visit	Data Type[a]	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = observed data recorded in database; CFB = change from baseline = (score at current visit) - (Baseline score).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Neurological Function Domain will include the following: Picture Vocabulary Test Raw Score, Pattern Comparison Processing Speed Test Raw Score, Flanker Inhibitory Control and Attention Test Raw Score, Dimensional Change Card Sort Test Raw Score, Oral Reading Recognition Test Raw Score, Cognition Crystallized Composite Uncorrected Standard Score, Cognition Crystallized Composite Age-Corrected Standard Score, Cognition Crystallized National Percentile (Age Adjusted), and Cognition Crystallized Composite Fully-Corrected T-score.

Table format will be repeated for KiTAP.

Table 40. OACIS-C Summary Statistics
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Treatment	Question	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx
	xxxxxxxxxxxxx	xxx	xxx	xxx	xxx	xxx	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 41. Summary of Responses for OACIS-C Assessment by Question
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Question	Response	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
General Level of Autism	Very Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	No Change	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Improved or Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Improved, No Change or Minimally Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Worse or Very Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
Social Interaction Skills	Very Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	No Change	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Improved or Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Improved, No Change or Minimally Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Worse or Very Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
xxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxx	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	xxxxxxxxxxxxx	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)

[a] The denominator for all proportions is the number of Exploratory population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 42. Summary of Responses for OACIS-S Assessment by Question
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Question	Response	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
xxxxxxxxxxxxxxxxxxxx	Normal	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Some symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Mild symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Moderate symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Marked symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Severe symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Among the Most Severe	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
xxxxxxxxxxxxxxxxxxxx	Normal	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Some symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Mild symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Moderate symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Marked symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Severe symptom/ behavior	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Among the Most Severe	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	xxxxxxxxxxxxxx	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)

[a] The denominator for all proportions is the number of Exploratory population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 43. ABC-C Summary Statistics
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Treatment	Subscale	Visit	Data Type[a]	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a]
RAW = observed data recorded in database; CFB = change from baseline = (score at current visit) - (Baseline score).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 44. SRS-2 Summary Statistics
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Treatment	Subscale	Visit	Data Type[a]	n	Mean	Std Dev	Median	Min	Max
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxxxxxx	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] RAW = observed data recorded in database; CFB = change from baseline = (score at current visit) - (Baseline score).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 45. Summary of Responses for CSHQ Assessment by Question
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Visit	Question	Response	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
xxx	xxxxxxxxxxxxxxxx	Never	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Rarely	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Sometimes	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Usually	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Always	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	xxxxxxxxxxxxxxxxx	Never	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Rarely	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Sometimes	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Usually	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		Always	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
xxx	xxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
		xxxxxxxxxxxxxx	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)

[a] The denominator for all proportions is the number of Exploratory population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 46. Lactate and Pyruvate Blood Level Summary Statistics
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Treatment	Parameter (units)	Visit	Data Type[a]	n	Mean	Std Dev	Min	Max	Median
STP1-[redacted]mg ibudilast	Lactate (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
	Pyruvate (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
	L:P Ratio (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
STP1-[redacted]mg ibudilast	xxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Placebo	xxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx
Overall	xxxxxxxxxx (xxx)	Baseline	RAW	xxx	xxx	xxx	xxx	xxx	xxx
		xxxxxx	RAW	xxx	xxx	xxx	xxx	xxx	xxx
			CFB	xxx	xxx	xxx	xxx	xxx	xxx

[a] Raw = observed data; CFB = change from baseline = (results at current visit) - (Baseline results).
STATKING Clinical Services (DDMMMYYYY)
Source Program: xxxxxxx.sas

Table 47. Summary of Responses for CGI-S Assessment by Visit
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Visit	Response	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
xxx	Not Assessed	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Normal, not at all ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Borderline mentally ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Mildly ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Moderately ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Markedly ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Severely ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Among the most extremely ill patients	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
xxx	Not Assessed	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Normal, not at all ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Borderline mentally ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Mildly ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Moderately ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Markedly ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Severely ill	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Among the most extremely ill patients	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)

[a] The denominator for all proportions is the number of Exploratory population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 48. Summary of Responses for CGI-I Assessment by Visit
STALICLA SA - Study No. STP1-C004
Exploratory Population (N=xxx)

Visit	Response	STP1-[redacted]mg ibudilast (N=xxx)[a]	STP1-[redacted]mg ibudilast (N=xxx)[a]	Placebo (N=xxx)[a]	Overall (N=xxx)[a]
xxx	Not assessed	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	No change from Baseline	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
xxx	Not assessed	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Improved	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	No change from Baseline	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Minimally Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)
	Very Much Worse	xx (xxx)	xx (xxx)	xx (xxx)	xx (xxx)

[a] The denominator for all proportions is the number of Exploratory population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 49. Number and Proportion of Patients with Medical History Events
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Medical History Category[a]:	STP1-[redacted]mg ibudilast (N=xxx)[b]	STP1-[redacted]mg ibudilast (N=xxx)[b]	Placebo (N=xxx)[b]	Overall (N=xxx)[b]
Total Number of Medical History Events	xxx	xxx	xxx	xxx
Patients with at Least One Medical History Event	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
System Organ Class 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a]
Medical history events coded with MedDRA Coding Dictionary Version XXX.
[b] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Table 50. Number and Proportion of Patients Taking Concomitant Medications by ATC Level 4 and Preferred Term
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Concomitant Medication Category[a,b]	STP1-[redacted]mg ibudilast (N=xxx)[c]	STP1-[redacted]mg ibudilast (N=xxx)[c]	Placebo (N=xxx)[c]	Overall (N=xxx)[c]
Total Number of Concomitant Medications	xxx	xxx	xxx	xxx
Patients Taking at Least One Concomitant Medication	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
ATC Level 4 Term	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
WHO Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
WHO Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
ATC Level 4 Term	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
WHO Preferred Term 1	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)
WHO Preferred Term 2	xxx (xxx)	xxx (xxx)	xxx (xxx)	xxx (xxx)

[a] Concomitant medications coded with WHO Coding Dictionary xxxxxxxxxxxx.
[b] Concomitant medication category will include anatomical therapeutic chemical (ATC) level 4 term followed by preferred term.
[c] The denominator for all proportions is the number of Safety population patients in the corresponding treatment group and overall.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Data Listing 1. Patient Disposition Data Listing
STALICLA SA - Study No. STP1-C004

Patient No.	Treatment	Date of Informed Consent	Date of Randomization	Disposition Status	Disposition Date	Date of Last Visit/ Withdrawal Date	If Withdrawn, Reason for Discontinuation	If Discontinued from STP1, Reason for Discontinuation
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Data Listing 2. Demographics Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Informed Consent Date	Date of Birth	Age (years)	Height (cm)	Weight (kg)	[redacted] Two Years of [redacted]	BMI	Gender	Ethnicity	Race	SB5-ABIQ FSIQ Score
xxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxx	xxx	xxx	xxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 3. Adverse Events Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Part 1 of 2

Patient No.	Treatment	Treatment Start Date	AE Start Date/ AE End Date	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Severity	AE of Special Interest?	Relationship to Study Drug	Serious? (Y/N)/ Reason Serious?
xxxxxxxxx	xxxxxx	xxxxxxx	xxxxxxxx/ xxxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xx/ xxxxxxxx
xxxxxxxxx	xxxxxx	xxxxxxx	xxxxxxxx/ xxxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xx/ xxxxxxxx

[a] Adverse events coded with MedDRA Coding Dictionary Version xxx.

Data Listing 3. Adverse Events Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Part 2 of 2

Patient No.	Treatment	Treatment Start Date	AE Start Date/ AE End Date	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Action Taken	Outcome	Led to Study Treatment Discontinuation (Y/N)?
xxxxxxxxx	xxxxxx	xxxxxxx	xxxxxxxx/ xxxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxx	xxxxxxxx	xxx
xxxxxxxxx	xxxxxx	xxxxxxx	xxxxxxxx/ xxxxxxxx	xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxx	xxxxx	xxxxxxxx	xxx

[a] Adverse events coded with MedDRA Coding Dictionary Version xxx.

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 4. Vital Signs Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Treatment Start Date	Visit	Visit Date	Time	Patient Position[a]	Parameter (Units)	Result
xxxxxx	xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx(xxx)	xxxxxx
	xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx(xxx)	xxxxxx

[a] Patient position will distinguish between supine blood pressure and heart rate and standing blood pressure and heart rate.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 5. Baseline ECG Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Part 1 of 2

Patient No.	Treatment	Date of ECG	Time	ECG Parameters					
				HR	PQ	QRS Duration	QT Interval	RR	QTcF
xxxx	xxxxxx	xxxxxx	xxxx	xxx	xxx	xxxx	xxxx	xx	xxxx
			xxxx	xxx	xxx	xxxx	xxxx	xx	xxxx
			xxxx	xxx	xxx	xxxx	xxxx	xx	xxxx

The Day 1 prior to treatment (i.e., pre-dose) time point serves as baseline.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 5. Baseline ECG Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Part 2 of 2

				ECG Results				
Patient No.	Treatment	Date of ECG	Time	T Wave	U Wave	ECG Interpretation	If Abnormal, Clinically Significant (Y/N)?	Description
xxxx	xxxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxxxxx	xxxxxxx	xxxxxxxxxxx
				xxxx	xxxx	xxxxxxx	xxxxxxx	xxxxxxxxxxx
				xxxx	xxxx	xxxxxxx	xxxxxxx	xxxxxxxxxxx

The Day 1 prior to treatment (i.e., pre-dose) time point serves as baseline.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 6. ECG Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Part 1 of 2

Patient No.	Treatment	Visit	Date of ECG	Pre-Dose/ Post-Dose	Time	ECG Parameters[a]					
						HR	PQ	QRS Duration	QT Interval	RR	QTcF
xxxx	xxxxxx	xxxxx	xxxxxxx	xxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xx	xxxx
				xxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xx	xxxx
xxxx	xxxxxx	xxxxx	xxxxxxx	xxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xx	xxxx
				xxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xx	xxxx

[a] ECG parameters and results for T Wave, U Wave and ECG Interpretation displayed at Baseline (i.e., Day 1 pre-dose time point) are the average and combined overall results.

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 6. ECG Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Part 2 of 2

						ECG Results[a]				
Patient No.	Treatment	Visit	Date of ECG	Pre-Dose/ Post-Dose	Time	T Wave	U Wave	ECG Interpretation	If Abnormal, Clinically Significant (Y/N)?	Description
xxxx	xxxxxx	xxxxx	xxxxxxx	xxxxx	xxxx	xxxx	xxxx	xxx	xxxxxxx	xxxxxxxxxxx
				xxxxx	xxxx	xxxx	xxxx	xxx	xxxxxxx	xxxxxxxxxxx
xxxx	xxxxxx	xxxxx	xxxxxxx	xxxxx	xxxx	xxxx	xxxx	xxx	xxxxxxx	xxxxxxxxxxx
				xxxxx	xxxx	xxxx	xxxx	xxx	xxxxxxx	xxxxxxxxxxx

[a] ECG parameters and results for T Wave, U Wave, and ECG Interpretation displayed at Baseline (i.e., Day 1 pre-dose time point) are the average and combined overall results.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 7. Blood Chemistry Laboratory Results Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date of Visit	Parameter (units)	Result	Normal Range		Normal/High/Low[a]	Normal/Abnormal CS/ Abnormal NCS[b]
						Low	High		
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxx	xxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxx	xxxxxxxxxx

[a] Indicates whether the results of the parameter indicated were within the normal range, lower than the normal range, or higher than the normal range.
[b] Indicates whether the results of the parameter indicated were Normal, Abnormal Clinically Significant (CS), and Abnormal Not Clinically Significant (NCS).
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 8. Serology Laboratory Results Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date of Visit	Parameter (units)	Result
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 9. Hematology Laboratory Results Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

						Normal Range		
Patient No.	Treatment	Visit	Date of Visit	Parameter (units)	Result	Low	High	Normal/High/Low[a]
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx (xxx)	xxx	xxx	xxx	xxxxx

[a] Indicates whether the results of the parameter indicated were within the normal range, lower than the normal range, or higher than the normal range.
STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Listing format repeats for Coagulation and Urinalysis.

Data Listing 12. Hearing Assessment Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date of Visit	Any changes in hearing since last visit?	If yes, explain
xxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxx	xxxxxxxxxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 13. Pharmacokinetic Blood Sample Data Listing
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Patient No.	Treatment	Visit	Dose Date/ Time	Blood Draw Completed (Y/N)	Reason Not Completed	Time Point	Time of Blood Sample	Time of Plasma Extraction	Time of Aliquot Freezing
xxxx	xxxxxx	xxxx	xxxxx/ xxxxx	xxx	xxxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx
						xxxxxxxx	xxxx	xxxx	xxxx
xxxx	xxxxxx	xxxx	xxxxx/ xxxxx	xxx	xxxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx
						xxxxxxxx	xxxx	xxxx	xxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 14. Pharmacokinetic Urine Sample Data Listing
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Patient No.	Treatment	Visit	Dose Date/ Time	Urine Collection Completed (Y/N)	Reason Not completed	Time Point	Time of Urine Sample	Urine Volume (mL)	Time of Aliquot Freezing
xxxx	xxxxxx	xxxx	xxxxx/ xxxxx	xxx	xxxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx
						xxxxxxxx	xxxx	xxxx	xxxx
xxxx	xxxxxx	xxxx	xxxxx/ xxxxx	xxx	xxxxxxxxx	xxxxxxxx	xxxx	xxxx	xxxx
						xxxxxxxx	xxxx	xxxx	xxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 15. Plasma Concentrations Data Listing
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Patient No.	Treatment	Visit	Time Point	Sample Collected(Y/N)?	Sample Date/ Time	Ibudilast Plasma Concentration (units)	Bumetanide Plasma Concentration (units)
xxxx	xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)
			xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)
xxxx	xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)
			xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 16. Urine Concentrations Data Listing
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Patient No.	Treatment	Visit	Time Interval	Sample Collected(Y/N)?	Sample Date/Time	Ibudilast Urine Concentration (units)	Bumetanide Urine Concentration (units)
xxxx	xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)
			xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)
xxxx	xxxxxx	xxxx	xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)
			xxxxxxxx	xxxx	xxxx/xxxx	xxxxxxx (xxx)	xxxxxxx (xxx)

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

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Data Listing 17. Plasma Pharmacokinetics Parameters Data Listing
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Patient No.	Treatment	Visit	Drug	Parameter (units)	Value
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxx.sas

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Data Listing 18. Urine Pharmacokinetics Parameters Data Listing
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

Patient No.	Treatment	Visit	Drug	Parameter (units)	Value
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
xxxxx	xxxx	xxxxx	xxxxx	xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx
				xxxxxxxxxxxx(xxx)	xxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxx.sas

Data Listing 19. C-SSRS Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Question	Response
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 20. C-CASA Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Question	Response
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxxxxxxxxxx	xxxx

STATKING Clinical Services (month day, year)
Source Program: xxxxxxx.sas

Data Listing 21. OACIS-S Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Question	Response
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx

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Data Listing 22. OACIS-C Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Question	Response
xxxx	xxxxxx	xxxx	xxxx	General Level of Autism	xxxx
				Social Interaction Skills	xxxx
				Aberrant/Abnormal Behavior	xxxx
				Repetitive and Ritual Behaviors	xxxx
				Verbal Communication Skills	xxxx
				Nonverbal Communication Skills	xxxx
				Hyperactivity and Inattention	xxxx
				Anxiety and Fears	xxxx
				Sensory Sensitivities	xxxx
				Restricted and Narrow Interests	xxxx
xxxx	xxxxxx	xxxx	xxxx	General Level of Autism	xxxx
				Social Interaction Skills	xxxx
				Aberrant/Abnormal Behavior	xxxx
				Repetitive and Ritual Behaviors	xxxx
				Verbal Communication Skills	xxxx
				Nonverbal Communication Skills	xxxx
				Hyperactivity and Inattention	xxxx
				Anxiety and Fears	xxxx
				Sensory Sensitivities	xxxx
				Restricted and Narrow Interests	xxxx

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Data Listing 23. SRS-2 Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Time	Global Score	Social Awareness	Social Cognition	Social Communication	Social Motivation	Mannerisms
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
		xxxxxx	xxxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
		xxxxxx	xxxxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx

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Data Listing 24. SB5 ABIQ Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Date	Abbreviated IQ Test	IQ Test Performed with Last 2 years? (Y/N)	FSIQ Score
xxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx

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Data Listing 25. NIH-CTB Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Neurological Function Domain	Score
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxx	xxxx
				xxxxxxxxxxxxx	xxxx

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Neurological Function Domain will include the following: Picture Vocabulary Test Raw Score, Pattern Comparison Processing Speed Test Raw Score, Flanker Inhibitory Control and Attention Test Raw Score, Dimensional Change Card Sort Test Raw Score, Oral Reading Recognition Test Raw Score, Cognition Crystallized Composite Uncorrected Standard Score, Cognition Crystallized Composite Age-Corrected Standard Score, Cognition Crystallized National Percentile (Age Adjusted), and Cognition Crystallized Composite Fully-Corrected T-score.

Listing format repeats for KiTAP.

Data Listing 27. ABC-C Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

					Subscales				
Patient No.	Treatment	Visit	Date	Time	Irritability	Social Withdrawal	Stereotypic Behavior	Hyperactive/ Noncompliance	Inappropriate Speech
xxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
		xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
		xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx

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Data Listing 28. CSHQ Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date	Category	Question	Response
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
		xxxx	xxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
xxxx	xxxxxx	xxxx	xxxx	xxxxxxxxxxxxx	xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx
					xxxxxxxxxxxxxxxxx	xxxx

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Data Listing 29. Lactate-Pyruvate Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date of Visit	Lactate (units)	Pyruvate (units)	L:P Ratio
xxxx	xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxx	xxxxxxx
xxxx	xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxx	xxxxxxx

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Data Listing 30. CGI-S/CGI-I Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date of Visit	Severity of Illness	Global Improvement
xxxx	xxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx	
		xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxx

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Data Listing 31. Medical History Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	MedDRA System Organ Class[a]/ MedDRA Preferred Term/ CRF Verbatim Term	Start Date	End Date	Ongoing? (Y/N)
xxxxxx	xxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	xxx
xxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxx	xxxxxxx	xxx

[a] Medical history terms coded with MedDRA Coding Dictionary Version xxx.
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Data Listing 32. Concomitant Medications Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	WHO Preferred Term[a]/ Verbatim Drug Name/ Indication/ ATC Level 4 Term	Dose (units)	Frequency	Start Date	Stop Date	Route	Indication	Ongoing? (Y/N)
xxxxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx (xxx)	xxxxxxxx	xxxxxxx	xxxxxxx	xxxxx	xxxxxxx	xxxxx
xxxxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx/ xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxx (xxx)	xxxxxxxx	xxxxxxx	xxxxxxx	xxxxx	xxxxxxx	xxxxx

[a] Concomitant medication coded with WHO Coding Dictionary xxxxxxxxx.
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Data Listing 33. Physical Exam Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Date Conducted	Body System	Result	If Abnormal, Clinically Significant (Y/N)?	Abnormality
xxxx	xxxxxx	xxxxxxx	xxxxxxx	xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
		xxxxxxx	xxxxxxx	xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx

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Data Listing 34. Study Drug Administration Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Morning Dose Administered (Y/N)?	Reason Morning Dose Not Administered	Date Morning Dose Administered	Time Morning Dose Administered
xxxx	xxxxxx	xxxx	xxx	xxxxxxxxxxxx	xxxxxxx	xxxxxxx
		xxxx	xxx	xxxxxxxxxxxx	xxxxxxx	xxxxxxx
xxxx	xxxxxx	xxxx	xxx	xxxxxxxxxxxx	xxxxxxx	xxxxxxx
		xxxx	xxx	xxxxxxxxxxxx	xxxxxxx	xxxxxxx

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Data Listing 35. Drug Accountability Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Study Drug Dispensed Kit Number	Date Study Drug Dispensed	Number of Pills Dispensed	Study Drug Returned Kit Number	Date Study Drug Returned	Number of Pills Returned	Did Patient Take Study Medication as Directed (Y/N)?	If No, Please Specify
xxxx	xxxxxx	xxxx	xxxxxxx	xxxxxxx	xxxxxxx					
		xxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxx	xxxxxxx
		xxxx				xxxxxxx	xxxxxxx	xxxxxxx	xxx	xxxxxxx
xxxx	xxxxxx	xxxx	xxxxxxx	xxxxxxx	xxxxxxx					
		xxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxxxxxx	xxx	xxxxxxx
		xxxx				xxxxxxx	xxxxxxx	xxxxxxx	xxx	xxxxxxx

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Data Listing 36. Urine Pregnancy Test Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Visit	Pregnancy Test Required? (Y/N)	Pregnancy Test Performed? (Y/N)	Reason Pregnancy Test Not Performed	Date and Time of Pregnancy Test	Result of Pregnancy Test
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxx
		xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxx
		xxxxxx	xxxxxx	xxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxx

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Data Listing 37. Protocol Deviations Data Listing
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

Patient No.	Treatment	Date of Deviation	Deviation Description	Deviation Major or Minor
xxxx	xxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx
xxxx	xxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx

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Data Listing 38. Patients Excluded from Safety Population Data Listing
STALICLA SA - Study No. STP1-C004
All Patients (N=xxx)

Patient No.	Treatment	Reason for Exclusion
xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx
xxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxx

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Data listing will be repeated for the PK and Exploratory populations.

Page x of y

Figure 1. Orthostatic Vital Signs - Spaghetti Plot of Systolic Blood Pressure by Patient, Time and Treatment
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

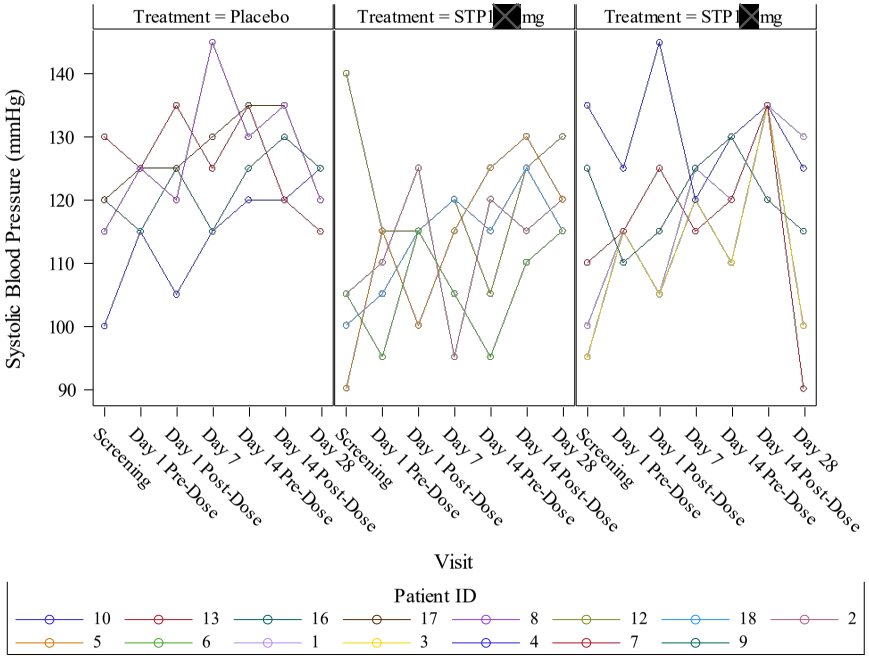

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Figure format will be repeated for Orthostatic Vital Signs – Diastolic Blood Pressure (Figure 2), Orthostatic Vital Signs – Heart Rate (Figure 3), ECG Parameters – Heart Rate (Figure 4), and ECG Parameters – QTcF (Figure 5).
Note: the axis values and labels will vary depending on the figure generated and the data in the database. Patient ID's will be displayed as in the study database.

Page x of y

Figure 6. Blood Chemistry - Spaghetti Plot of Sodium by Patient, Time and Treatment
STALICLA SA - Study No. STP1-C004
Safety Population (N=xxx)

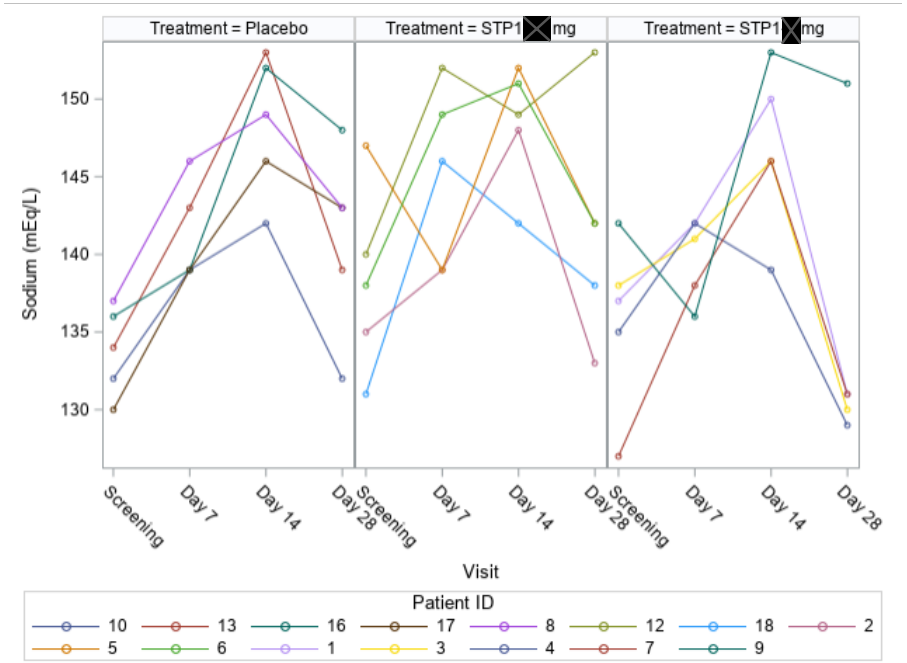

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Figure format will be repeated for Figure format will be repeated for Blood Chemistry – Chloride (Figure 7), Blood Chemistry – Calcium (Figure 8), Blood Chemistry – Magnesium (Figure 9), Blood Chemistry – Phosphate (Figure 10), Blood Chemistry – Potassium (Figure 11), Hematology – Platelet Count (Figure 12), and Biomarker – L:P Ratio (Figure 13). Note: the axis values and labels will vary depending on the figure generated and the data in the database. Patient ID's will be displayed as in the study database.

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Figure 14. Patient Plasma Concentration Levels of Ibudilast for Treatment Group = [redacted]mg Ibudilast- Linear Scale – Days 1-28
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

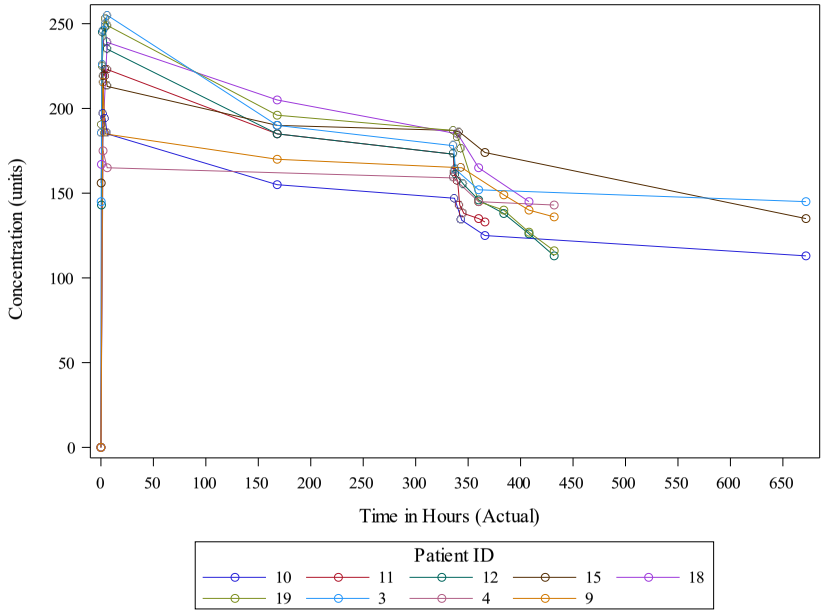

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Figure format will be repeated for the 10mg ibudilast treatment group for ibudilast concentration levels, for the [redacted]mg and [redacted]mg ibudilast treatment groups for bumetanide concentration levels. These figures will be repeated in the semi-logarithmic scale for each combination of treatment group and study drug concentration level.
Note: the axis values and labels in the figure may vary. Patient ID's will be displayed as in the study database.

Page x of y

Figure 22. Mean Plasma Concentration Levels of Ibudilast for Treatment Group = [redacted]mg Ibudilast – Linear Scale – Days 1-28
STALICLA SA - Study No. STP1-C004
PK Population (N=xxx)

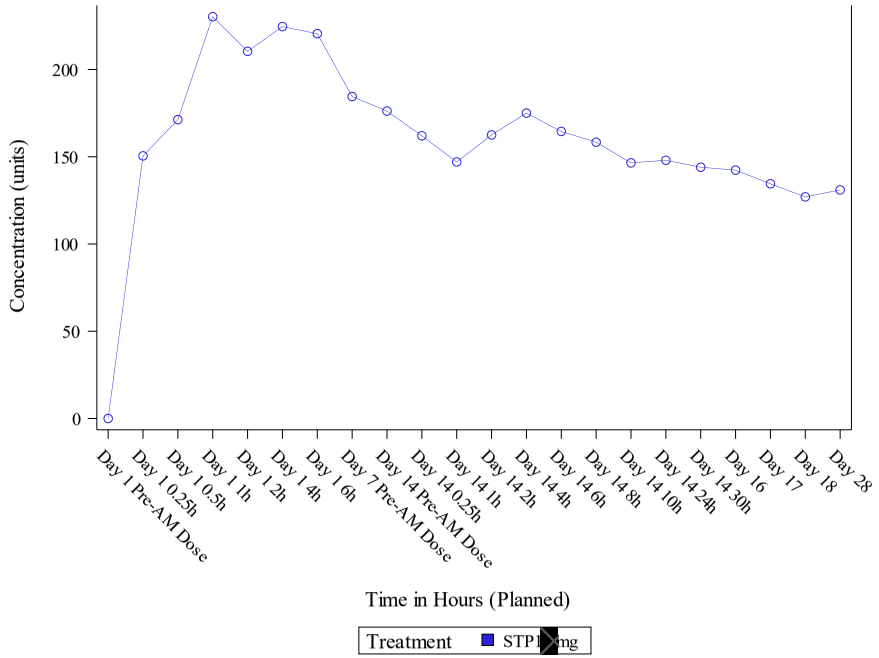

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Figure format will be repeated for the 10mg ibudilast treatment group for ibudilast concentration levels, for the 5mg and 10mg ibudilast treatment groups for bumetanide concentration levels. These figures will be repeated in the semi-logarithmic scale for each combination of treatment group and study drug concentration level. Note: the axis values and labels in the figure may vary.

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