STATISTICAL ANALYSIS PLAN

LPS17180 (FEXPRESAR)

A Phase IIIb, single-center, double-blind, two-arms, placebo-controlled, randomized, parallel-group clinical trial to evaluate the efficacy and safety of 2-day pre-treatment with fexofenadine in patients suffering from Seasonal Allergic Rhinitis

AUTHOR: [redacted]

VERSION NUMBER AND DATE: FINAL V1.0 17Feb2023

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

Statistical Analysis Plan Final V1.0 (Dated 17Feb2023) for Protocol LPS17180 dates 21st September 2022.

	Name	Signature	Date (DDMmmYYYY)
Author:	[redacted]		
Position:	[redacted]		
Company:	IQVIA		

Upon review of this document, the undersigned approves this version of the Statistical Analysis Plan, authorizing that the content is acceptable for the reporting of this study.

	Name	Signature	Date (DDMmmYYYY)
Approved By:	[redacted]		
Position:	[redacted]		
Company:	Opella Healthcare		
Approved By:	[redacted]		
Position:	[redacted]		
Company:	Opella Healthcare		

MODIFICATION HISTORY

Unique Identifier for this Version	Date of the Document Version	Author	Significant Changes from Previous Authorized Version
Draft 1.0	21Dec2022	[redacted]	Not Applicable – First Version
Final 1.0	17Feb2023	[redacted]	Updated as per sponsor comments on Draft Version 1.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ANCOVA	Analysis of Covariance
AR (1)	first order Autoregressive
AUC	Area under the curve
CI	Confidence Interval
CS	Compound Symmetric
CTCAE	Common Terminology Criteria for Adverse Events
EEU	Environmental Exposure Unit
H	Hour
ITT	Intent-to-Treat
LS	Least Squares
mITT	modified Intent-to-Treat
MMRM	Mixed Models for Repeated Measures
NIC	National Cancer Institute
PPAS	Per Protocol Analysis Set
PT	Preferred Term
Q1	First Quartile
Q3	Third Quartile
SAF	Safety Analysis Set
SAP	Statistical Analysis Plan
SAR	Seasonal allergic rhinitis
SE	Standard Error
SOC	System Organ Class
STL	Statistical Team Lead
TNSS-3	Total Nasal Symptoms Score of 3 symptoms
TOSS	Total Ocular Symptoms Score
TSS	Total Symptoms Score
V	Visit

1. INTRODUCTION

This statistical analysis plan (SAP) describes the rules and conventions to be used in the presentation and analysis of efficacy and safety data for Protocol LPS17180 (FEXPRESAR). It describes the data to be summarized and analysed, including specifics of the statistical analyses to be performed.

This SAP is based on protocol version 1.0 dated 21 September 2022.

2. STUDY OBJECTIVES AND ESTIMANDS

2.1. Primary Objective

To evaluate the efficacy of fexofenadine 180 mg when started 2 days before the exposure to the allergen in patients suffering from seasonal allergic rhinitis (SAR).

2.2. Secondary Objectives

- To evaluate the efficacy of fexofenadine when started 2 days before the exposure to the allergen in patients suffering from SAR in terms of preventing nasal and ocular symptoms of rhinorrhea, sneezing, and nasal itching, red/burning eyes, tearing, and itchy/watery eyes.
- To evaluate the safety of fexofenadine when started 2 days before the exposure to the allergen in patients suffering from SAR.

2.3. Exploratory Objectives

- To evaluate the efficacy for total score and all individual symptoms: nasal, ocular, throat (9 symptoms in total: nasal and ocular symptoms of rhinorrhea, sneezing, nasal itching, and nasal congestion; red/burning eyes, tearing, and itchy/watery eyes; and itching of ears/palate or throat).
- To assess the proportion of satisfaction in the 2 groups.
- To assess the use of rescue medication in the 2 groups.

2.4. Safety Objectives

- To evaluate the safety of fexofenadine when started 2 days before the exposure to the allergen in patients

suffering from SAR.

2.5. Estimands

Not applicable.

3. STUDY DESIGN

3.1. General Description

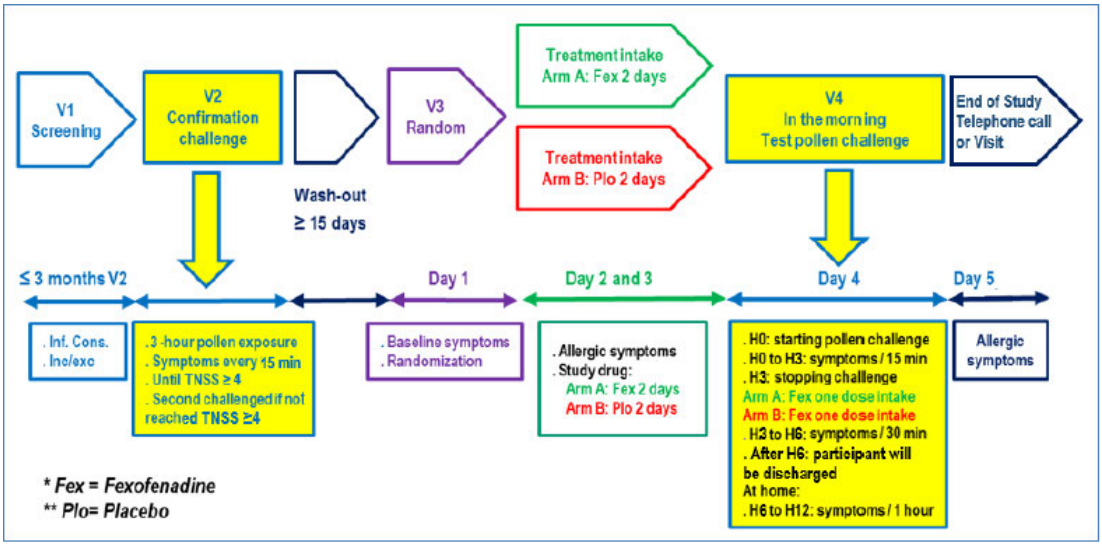
This is a Phase IIIb, randomized, double-blind, single-center, two-arm, parallel-group, placebo-controlled, proof-of-concept study, outside of Ragweed pollen season. Two Arms are planned:

• Arm A (active 2 days): two days of pre-treatment with fexofenadine, then fexofenadine 180 mg during the test pollen challenge

• Arm B (placebo 2 days): two days of pre-treatment with placebo, then fexofenadine 180 mg during the test pollen challenge

A total of 5 visits to the study site or the environmental exposure unit (EEU) are planned per participant. An adequate number of participants will be screened to achieve 96 participants randomized (86 evaluable participants).

Table A: Study Schema



Abbreviations: Fex = fexofenadine, FU = follow up, H = hour, Inc/exc = inclusion and exclusion criteria, Inf.Cons. = informed consent, Plo = placebo, TNSS = Total Nasal Symptoms Score, V = visit.

3.2. Schedule of Events

Schedule of events can be found in Section 1.3 of the protocol.

3.3. Changes to Analysis from Protocol

The SAP supersedes the statistical methods described in the clinical study protocol. Analysis methods that summarize and evaluate study efficacy endpoints for statistical significance will be implemented as described in the SAP.

An additional exploratory analysis as in primary analysis will be performed stratified by baseline TNSS-3 ≤7, TNSS-3 >7.

4. PLANNED ANALYSES

The following analyses will be performed for this study:

- Final Analysis

4.1. Data Monitoring Committee (DMC)

There will be no DMC for this study.

4.2. Interim Analysis

No interim analysis is planned.

4.3. Final Analysis

All final, planned analyses identified in this SAP will be performed by IQVIA Biostatistics following Sponsor Authorization of this Statistical Analysis Plan, Database Lock, Sponsor Authorization of Analysis Sets and Unblinding of Treatment.

5. ANALYSIS SETS

5.1. Process for Analysis Set Assignment

The subjects will be assigned to the analysis sets programmatically as per the definitions below.

5.2. All Subjects Enrolled Set [ENR]

The all subjects enrolled (ENR) set will contain all subjects who provide informed consent for this study.

5.3. Intent-To-Treat Analysis Set [ITT]

The intent-to-treat analysis set (ITT) will contain all eligible subjects (passed screening and confirmation challenge) who have been allocated to a randomized treatment regardless of whether study drug wallet was used or not.
Subjects will be classified according to randomized treatment.

5.4. Per Protocol Analysis Set [PPAS]

Not applicable.

5.5. Safety Analysis Set [SAF]

The safety analysis set (SAF) will contain all subjects in the ITT set who receive at least one dose of study medication and subjects will be classified according to treatment received.
If there is any doubt whether a subject was treated or not, they will be assumed treated for the purposes of analysis.

5.6. Modified Intent-To-Treat Analysis Set [mITT]

The modified intent-to-treat analysis set (mITT) will contain all eligible, ITT, and treated subjects with Total Nasal Symptoms Score of 3 symptoms (TNSS-3) evaluation at H0 at V4 and at least a further time point at Visit 4.
Subjects will be classified according to randomized treatment.

6. GENERAL CONSIDERATIONS

6.1. Reference Start Date and Study Day

Study Day will be calculated from the reference start date and will be used to show start/stop day of assessments and events. It will appear in every listing where an assessment date or event date appears.

Reference start date is defined as the day of randomization (Day 1 is the day of randomization).

- If the date of the event is on or after the reference date, then:
- Study Day = (date of event – reference date) + 1.
- If the date of the event is prior to the reference date, then:
- Study Day = (date of event – reference date).

In the situation where the event date is partial or missing, the date will appear partial or missing in the listings, and Study Day, and any corresponding durations will be presented based on the imputations specified in APPENDIX 2; Partial Date Conventions.

6.2. Baseline

Unless otherwise specified, baseline is defined as the last non-missing measurement taken prior to reference start date (including unscheduled assessments). Baseline of the symptoms scoring will be H0 at visit 4 value according to the analysis.

6.3. Derived Timepoints

Not applicable.

6.4. Unscheduled Visits and Early Termination Data

In general, for by-visit summaries, data recorded at the nominal visit will be presented. Unscheduled measurements will not be included in by-visit summaries.

Listings will include scheduled, unscheduled, and early discontinuation data.

6.5. Windowing Conventions

No visit windowing will be performed for this study.

6.6. Statistical Tests

The default significant level will be (5%); CIs (confidence intervals) will be 95% and all tests will be two-sided, unless otherwise specified in the description of the analyses.

6.7. Common Calculations

For quantitative measurements, change from baseline will be calculated as:

- Test Value at Visit X – Baseline Value

6.8. Software Version

All analyses will be conducted using SAS version 9.4 or higher.

7. STATISTICAL CONSIDERATIONS

Unless otherwise specified, all statistical tables will be provided by treatment group and will first present the results in the active group (FEXPRESAR) and then the results in the placebo group. The column 'overall' displaying all patients (all treatment groups combined) will be presented where appropriate.

The descriptive summary for continuous data will include the number of non-missing observations (n), mean, standard deviation, median, 25th percentile and 75th percentile, minimum, and maximum. The number of subjects with missing data will be displayed when relevant.
Categorical data will be summarized for each treatment group using counts (n) and percentages (%). The number of subjects with missing data will be displayed when relevant, but it will not be included in the denominator for the calculation of percentages unless otherwise specified.

If the original data has N decimal places, then the summary statistics will have the following decimal places:

- Minimum and maximum: N
- Mean, median, percentiles, confidence intervals, ratios: N + 1

- SD: N + 2

Percentages will be reported to one decimal place. P-values should be reported to three decimal places, except values <1.000 but >0.999 will be presented as '>0.999' (e.g., 0.9998 is presented as >0.999); and values <0.001 will be presented as '<0.001' (e.g., 0.0009 is presented as <0.001)

7.1. Adjustments for Covariates and Factors to be Included in Analyses

The following covariates and factors are used in the analyses. For details of their inclusion in the models, see the specific analysis section.

- TNSS-3 at Day 1/Visit 4 H0
- (Total Ocular Symptoms Score) TOSS at Day 1/Visit 4 H0
- (Total Symptoms Score) TSS at Day 1/Visit 4 H0
- Individual symptoms score at Day 1
- Treatment group (Fexofenadine 180 mg, Placebo)
- Time point (H0 to H12)
- Treatment group by time point
- Stratification factor – Visit 2 TNSS-3 (TNSS-3 ≤7, TNSS-3 >7)

7.2. Multicenter Studies

Not applicable.

7.3. Missing Data

Missing safety data will not be imputed.

A missing symptom score will be imputed using linear interpolation between the last available preceding value and the first following non missing value; if no following non-missing value is available, the last available value will be carried forward up to H+12. Baseline value will not be extended in case of all post baseline values are missing.

7.4. Intercurrent Events

Not applicable.

7.5. Multiple Comparisons/ Multiplicity

The following multiplicity testing procedures will be used to control the type I error:

- The secondary efficacy endpoints will be tested only if the primary endpoint is significant.
- The multiplicity of secondary efficacy endpoints will be handled using Hochberg's step-up test.
- For the other secondary efficacy endpoints and the exploratory efficacy endpoints, p-values will be provided for descriptive purpose only.
- The number of Adverse Events defined as other secondary endpoint will be analysed only with descriptive statistics (no p-value will be provided).

7.6. Active-Control Studies Intended to Show Non-inferiority or Equivalence

Not applicable.

7.7. Examination of Subgroups

No subgroup analyses will be performed for this study.

8. OUTPUT PRESENTATIONS

APPENDIX 1 shows conventions for presentation of data in outputs.
The templates provided with this SAP describe the presentations for this study and therefore the format and content of the summary tables, figures, and listings to be provided by IQVIA Biostatistics.

9. DISPOSITION AND WITHDRAWALS

All subjects who provide informed consent will be accounted for in this study.

9.1. Disposition

Subject disposition and withdrawals, and reasons for exclusion from each analysis set, including inclusion and exclusion criteria will be summarized for the ENR set. The primary reason for discontinuation of study, including any of the following, will be summarized by treatment group:

- Screen Failure
- Adverse Event
- EEU challenge intolerance
- Poor Compliance to Protocol
- Study Terminated by Sponsor
- Patient Withdrew Consent
- Investigator Decision
- Death
- Other

A listing of all subjects who discontinued from the trial and their reason for discontinuation will be provided.

9.2. Protocol Deviations

Protocol deviation data will be obtained via Clinical Trial Management System Protocol Deviations (CTMS PD) log. Deviation data will be categorized as Critical, Major and Minor based on Severity. The number and percentage of subjects with any important protocol deviations will be presented for the SAF Analysis Set by treatment group.

10. DEMOGRAPHIC AND OTHER BASELINE CHARACTERISTICS

Demographic data and other baseline characteristics will be presented for the ITT and mITT.
No statistical testing will be carried out for demographic or other baseline characteristics.
The following demographic and other baseline characteristics will be reported for this study:

- Age (years)
- Sex
- Race
- Ethnicity
- Weight (kg)

- Height (cm)
- BMI (kg/m^2)
- Allergic symptoms scoring (TNSS-3, TOSS, TSS)
- Skin prick test (Allergen and Reaction diameter(mm))
- Patients with only ragweed positive (monosensitized) and patients with at least one allergen test positive with another allergen than ragweed (polysensitized).
- Duration of Allergic Rhinitis (years)
- Severity symptom scoring (4-7 and 8-9), which is TNSS-3 ≤7, TNSS-3 >7 at visit 2

Age, Weight, Height, BMI, Skin prick test – Reaction diameter, and Duration to Allergic Rhinitis will be summarized using descriptive statistics by treatment group. Sex, Race, Ethnicity, Allergic symptoms score, and Skin prick test – Allergen will be summarized with the number and percentages by treatment group.

10.1. Derivations

- BMI (kg/ m^2) = weight (kg)/ height (m)^2
- Duration of Allergic Rhinitis (years) = {(Date of Visit 1 – Start date of Allergic Rhinitis) +1}/365.25

Note: The Start date of Allergic Rhinitis will be taken from the Allergic Medical History eCRF page.

11. MEDICAL HISTORY

Medical History including Allergic Medical History information will be presented for the SAF by treatment group.

- Medical History will be coded using Medical Dictionary for Regulatory Activities (MedDRA) version 25.1
    - Medical History conditions are defined as those conditions which stop prior to or at Screening.
    - Presented by SOC and PT.

12. CONCOMITANT ILLNESSES

Not applicable.

13. CONCOMITANT MEDICATIONS

Medications or vaccines will be presented for the SAF and coded using **WORLD HEALTH ORGANIZATION-DRUG DICTIONARY (WHO-DD)** version currently in effect.
See APPENDIX 2 for handling of partial dates for medications, in the case where it is not possible to define a medication as prior, concomitant, or post treatment, the medication will be classified by the worst case, i.e., concomitant.

- 'Prior' medications are medications which started and stopped prior to the first dose of study medication.
- 'Concomitant' medications are any treatments received by the subject concomitantly to the IMP or study procedure, from day 1 until day 5.

14. STUDY MEDICATION EXPOSURE

The extent of exposure will be assessed and summarized by actual treatment received within the safety population.
The duration of exposure to pollen at visit 2 and visit 4 will also be presented.

14.1. Derivations

- Duration of exposure (days) = date of last study medication administration – date of first study medication administration + 1.

- Duration of exposure to Pollen (hours) = (End time of the challenge -Start time of the challenge)/60*60

15. STUDY MEDICATION COMPLIANCE

Compliance to study medication will be presented for the SAF.
A participant will be considered noncompliant if they did not take the planned doses of study drug as required by the protocol. Treatment compliance will be summarized by randomized, double-blind, placebo-control study part and by post pollen challenge, open-label study part by number and percentage of participants compliant per arm.
For Randomized, double-blind, placebo-control study part:
0% (missed both the doses), 50% (missed one dose), 100% (took both the dose), >100% (took additional dose)
For Open label study part:
0% (missed dose), 100% (took dose), >100% (took additional dose)

The descriptive statistics of compliance percentage will be presented by treatment group.

15.1. Derivations

Randomized, double-blind, placebo-control study part:
Compliance percentage = (Number of tablets taken/2) *100

Open label study part:
Compliance percentage = (Number of tablets taken) *100

16. EFFICACY OUTCOMES

16.1. Primary Efficacy

16.1.1. Primary Efficacy Variable & Derivation

The primary efficacy endpoint is AUC (Area under the curve) of TNSS-3 from H0 to H6 at Visit 4.

The TNSS-3 is a composite score calculated as the sum of rhinorrhea, sneezing, and nasal itching scores (maximum 9). The individual scores are collected in e-diary.
The AUC will be computed using the linear trapezoidal method provided in reference section 22 (Ref 3) (22).

16.1.2. Intercurrent Event Handling and Data Imputation for Primary Efficacy Variable(s)

Not applicable.

16.1.3. Primary Analysis of Primary Efficacy Variable(s)

The primary efficacy analysis will be performed for the mITT.
The primary analysis will be the comparison of the primary efficacy endpoint (ie, AUC of the TNSS-3 from H0 to H6 at V4) between fexofenadine and placebo, using an analysis of covariance (ANCOVA) with treatment group as fixed effect and the baseline value of TNSS-3 (i.e., at H0 at V4) as covariate. The mean TNSS-3 and its 95% CI will be plotted across time from H0 to H6 at Visit 4. This plot will also include the LS mean and 95% CI of the AUC.

16.1.4. Supplementary Analysis of Primary Efficacy Variable(s)

Not applicable.

16.1.5. Sensitivity Analysis of Primary Efficacy Variable(s)

The primary analysis will be performed for observed cases.

16.2. Secondary Efficacy

The secondary efficacy analyses will be performed for the mITT.

16.2.1. Secondary Efficacy Variables & Derivations

The TOSS is a composite score calculated as the sum of red/burning eyes, tearing, itchy/watery eyes scores (maximum 9). The individual scores are collected in e-diary. The AUC will be computed using the linear trapezoidal method (22) for all the variables below. The mean score and its 95% CI will be plotted across respective timepoints. This plot will also include the LS mean and 95% CI of the AUC.

- AUC of TOSS from H0 to H6 at V4
- AUC of TNSS-3 from H0 to H12 at V4
- AUC of TOSS from H0 to H12 at V4
- AUC of TNSS-3 from randomization (D1) to V4 (D4)
- AUC of TOSS from randomization (D1) to V4 (D4)

16.2.2. Intercurrent Event Handling and Data Imputation for Secondary Efficacy Variable(s)

Not Applicable.

16.2.3. Analysis of Secondary Efficacy Variables

16.2.3.1. Analysis of Secondary Variables based on AUC

All secondary endpoints based on the AUC (i.e., TNSS-3 and TOSS) will be analysed using an ANCOVA model,

with treatment group as fixed effect and the baseline values as covariate. For the AUC assessment starting from Randomization (D1) to D4, symptom scoring at D1 will be used as baseline.

16.2.3.2. ANALYSIS OF TNSS-3, TOSS, AND TSS

The TNSS-3, TOSS, TSS, and individual symptom score by time point will be analysed given the mean and 95% confidence interval (CI).
The TNSS-3, TOSS, and TSS will be analysed using MMRM (Mixed Models for Repeated Measures), with treatment, time point and treatment group by time point interaction as fixed effect with their respective H0 scores as baseline covariate. The MMRM model will be run using PROC MIXED procedure with an unstructured correlation matrix to model the within-subject errors. If unstructured fails to converge, the following covariance structures will be tested: CS (compound symmetric) first, and then AR (1) (first-order autoregressive). Denominator degrees of freedom will be estimated using the Satterthwaite's approximation.
The descriptive statistics (number, mean, SD, median, Q1 and Q3, minimum, and maximum) of AUC and the statistics from the MMRM, least square (LS) means, standard errors (SEs) and 95% confidence intervals (CIs)) will be provided.

16.3. Exploratory Efficacy

[redacted]

[redacted]

16.3.2. Intercurrent Event Handling and Data Imputation for Exploratory Efficacy Variable(s)

Not applicable.

16.3.3. Analysis of Exploratory Efficacy Variables

[redacted]

17. QUALITY OF LIFE ANALYSIS

Not applicable.

18. SAFETY OUTCOMES

All outputs for safety outcomes will be based on the SAF.

There will be no statistical comparisons between the treatment groups for safety data, unless otherwise specified with the relevant section.

18.1. Adverse Events

Adverse Events (AEs) will be coded using Medical Dictionary for Regulatory Activities (MedDRA) Version 25.1.

The pre-treatment period starts the day of the signed informed consent and ends before administration of study drug. The treatment-emergent AE period starts at time of administration of study drug ends 3 days after administration of study drug.

See Appendix 2 for handling of partial dates for AEs. In the case where it is not possible to define an AE as treatment emergent or not, the AE will be classified by the worst case, i.e., treatment emergent.
An overall summary of number of subjects within each of the categories described in the sub-section below, will be provided as specified in the templates.
Listings will include pre-treatment AEs and TEAEs.

18.1.1. All TEAEs

Incidence of TEAEs will be presented by System Organ Class (SOC) and Preferred Term (PT) and broken down further by maximum severity and relationship to study medication.

18.1.1.1. SEVERITY

Severity is classed as mild/ moderate/ severe (increasing severity). TEAEs starting after the first dose of study medication with a missing severity will be classified as severe. If a subject reports a TEAE more than once within that SOC/ PT, the AE with the worst-case severity will be used in the corresponding severity summaries.

18.1.1.2. RELATIONSHIP TO STUDY MEDICATION

Relationship, as indicated by the Investigator, is classed as "Related" "Not Related". TEAEs with a missing relationship to study medication will be regarded as *"Related"* to study medication. If a subject reports the same AE more than once within that SOC/ PT, the AE with the worst-case relationship to study medication will be used in the corresponding relationship summaries.

18.1.2. TEAEs Leading to Discontinuation of Study Medication

TEAEs leading to permanent discontinuation of study medication will be identified by using the "Action taken" filed from the adverse events page of the eCRF.
For TEAEs leading to discontinuation of study medication, summaries of incidence rates (frequencies and percentages) by SOC and PT will be prepared.

18.1.3. Serious Adverse Events

Serious adverse events (SAEs) are those events recorded as "Yes" on "Serious" field on the Adverse Events page of the eCRF. A summary of serious TEAEs by SOC and PT will be prepared.

18.1.4. Adverse Events Leading to Death

TEAEs leading to Death are those events which are recorded as "Yes" on "Death" filed on the Adverse Events page of the CRF. A summary of TEAEs leading to death by SOC and PT will be prepared.

18.1.5. Adverse Events Of Special Interest

Adverse events of special interest may be added, modified, or removed during a study by protocol amendment. Specific AESI(s) for this study include systemic hypersensitivity reactions with manifestations such as angioedema, chest tightness, dyspnea, flushing, and systemic anaphylaxis. A summary by SOC and PT will be prepared.

18.1.6. CTC Grading for Adverse Events

AEs will be graded using the NCI CTCAE v5.0 (https://ctep.cancer.gov/protocolDevelopment/electronic_applications/docs/CTCAE_v5_Quick_Reference_5x7.pdf).

For AEs that are not adequately addressed in the NCI CTCAE, the Investigator should classify the intensity of the AE using the following guidelines:

- Grade 1: Mild: Aware of sign or symptom, but easily tolerated; no intervention needed.
- Grade 2: Moderate: Discomfort enough to cause interference with usual activity, minimal non-invasive intervention indicated (e.g., short course of antibiotics).
- Grade 3: Severe: Medically significant but not immediately life-threatening; incapacitation with inability to work or do usual activity.
- Grade 4: Life-threatening: Refers to an event in which the participant was at risk of death at the time of the

event, as judged by the Investigator; urgent/emergent intervention indicated. This category should not be used for an event that hypothetically might have caused death if it were more severe.

- Grade 5: Fatal outcome.

Incidence of TEAEs will be presented by System Organ Class (SOC) and Preferred Term (PT) ,broken down by maximal grading.

18.2. Deaths

If any subjects die during the study as recorded in the Adverse Events page in eCRF, the information will be presented in a summary table and a data listing.

18.3. Laboratory Evaluations

A rapid antigen test will be performed before EEU entry, for SARS-CoV-2 infection.
Women of childbearing potential should only be included after a confirmed menstrual period and a negative highly sensitive urine pregnancy test.

The following listings will be provided for laboratory data:

- COVID-19 tests
- Urine Pregnancy test

18.3.1. Laboratory Specific Derivations

Not applicable.

18.3.2. Laboratory Reference Ranges and Markedly Abnormal Criteria

Not applicable.

18.3.3. CTC Grading for Laboratory Data

Not applicable.

18.4. ECG Evaluations

Not Applicable.

18.5. Vital Signs

The following Vital Signs measurements will be reported for this study:

- Systolic Blood Pressure (mmHg)
- Diastolic Blood Pressure (mmHg)
- Heart Rate (BEATS/MIN)
- Respiratory Rate (BREATHS/MIN)
- Oral Body Temperature (ºC)
- Weight (kg)
- Height (cm)

Summary table and listing will be presented for vital signs data.

18.6. Physical Examination

The following summaries will be provided for physical examination data:

- Incidence of abnormalities at screening and Visit 4 H6.
- Listing will be provided for physical examination.

18.7. Other Safety Assessments

The following will be presented:

- Nasal Examination: Incidence of abnormalities at screening and Visit 4 H6 and Listing
- Skin Prick Test: Summary of allergen and reaction diameter with data listing.

19. PHARMACOKINETIC ANALYSIS

Not applicable.

20. GENETIC ANALYSIS

Not applicable.

21. DATA NOT SUMMARIZED OR PRESENTED

Not applicable.

22. REFERENCES

1.A Phase IIIb, single-center, double-blind, two-arms, placebo-controlled, randomized, parallel-group clinical trial to evaluate the efficacy and safety of 2-day pre-treatment with fexofenadine in patients suffering from Seasonal Allergic Rhinitis; Protocol Number: LPS17180 (FEXPRESAR)2. LPS17180_eCRF Version 2.0_20Oct2022 - Unique Forms

3. Yeh, Shi-Tao & Collegeville, GlaxoSmithKline. (1991). Using trapezoidal rule for the area under a curve calculation.

APPENDIX 1. PROGRAMMING CONVENTIONS FOR OUTPUTS

[redacted]

[redacted]

APPENDIX 2. PARTIAL DATE CONVENTIONS

[redacted]

[redacted]