STATISTICAL ANALYSIS PLAN

Sponsor: Sorrento Therapeutics, Inc.

Protocol Number: STI-5656-2001

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Study Title: A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED STUDY OF THE SAFETY AND EFFICACY OF STI-5656 (ABIVERTINIB MALEATE) IN SUBJECTS HOSPITALIZED DUE TO COVID-19

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Approval	Signature	Date
Eric Yan Sr. Statistical Consultant CPAN, Inc.		01/05/2021
Sponsor Representative Mike A. Royal MD JD MBA Chief Medical Officer Sorrento Therapeutics, Inc.		01/05/2021

ABBREVIATIONS

AE	adverse event
BMI	body mass index
cm	centimeter
COVID-19	Coronavirus 2019
CRP	C-reactive protein
DMC	data monitoring committee
e-CRF	electronic case report form
ECG	electrocardiogram
ECMO	extracorporeal membrane oxygenation
FiO2	fraction of inspired oxygen
ICU	intensive care unit
IP	investigational product
kg	kilogram
kg/m^2	kilogram per meter squared
L	liter
MAR	missing at random
max	maximum
MCAR	missing completely at random
MedDRA	Medical Dictionary for Regulatory Activities
mg	milligram
min	minimum
MMRM	Mixed-effects Model for Repeat Measures

MNAR	missing not at random
p.o.	By mouth
PaO2	partial pressure of arterial oxygen
PK	pharmacokinetics
PP	per protocol
QD	once daily
RRT	rapid response team
RT-PCR	reverse transcriptase polymerase chain reaction
SAE	Serious adverse event
SARS-CoV-2	severe acute respiratory syndrome coronavirus 2
SD	standard deviation
SOC	standard of care
SOC	System Organ Class
TEAE	treatment-emergent adverse event
VEGF-A	Vascular endothelial growth factor

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1.0 INTRODUCTION OF THE STATISTICAL ANALYSIS PLAN

The statistical analysis plan (SAP) is based on protocol STI-5656-2001 'A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of The Safety and Efficacy of Sti-5656 (Abivertinib Maleate) In Subjects Hospitalized Due to Covid-19', V5.0 dated 07Dec2020. It details the methodology to be used in analyzing the data and outlines the specifications in the Tables, Figures and Listings (TFLs) for data to be included for executing the final statistical analyses for this study.

PK analysis is not included in this plan.

The analyses specified in this document supersede any high-level analysis plan described in the protocol.

2.0 INTRODUCTION TO THE STUDY

2.1 Study Objectives

2.1.1 Primary Objective

- To assess the efficacy of STI-5656 in subjects with severe COVID-19

2.1.2 Secondary Objectives

The secondary objectives of this study are:

- To assess the safety and tolerability of STI-5656 in subjects with severe COVID-19
- To assess pharmacokinetics (PK) in the study population.

2.2 Study Endpoints

2.2.1 Primary Endpoint

The primary endpoint for the study is the:

- Proportion of subjects alive and free of respiratory failure at Day 28

2.2.2 Secondary Endpoints

- Types, frequencies, and severities of AEs and the relationships of AEs to IP; includes serious adverse events SAEs
- Proportion of subjects alive and free of respiratory failure at Day 60
- Change in clinical status (on a 0-8-point ordinal scale) of subject at Day 7, Day 14, and Day 28
- Proportion of subjects alive and discharged from ICU at Days 14 and 28
- Time from randomization to first occurrence of respiratory failure or death on study due to any cause up to Day 28
- Percent change from baseline in CRP at Days 3, 5, 7, 10, 14, 28
- Relative change from baseline in oxygenation index (PaO2/FiO2) up to Day 5

- All-cause mortality at Day 60 and Day 90
- Number of days alive and free of respiratory failure at Day 28
- Number of days with respiratory failure up to Day 28
- Number of days hospitalized up to Day 28
- Number of days in ICU (length of stay) up to Day 90
- Number of days alive outside of hospital up to Day 28
- Number of days alive outside of hospital up to Day 90
- To assess the pharmacokinetic profile in the study population

2.2.3 Exploratory Endpoints

- Change from baseline in absolute lymphocyte counts at Days 3, 5, 7, 10, 14, 28
- Change from baseline in ferritin at Days 3, 5, 7, 10, 14, 28
- Change from baseline in VEGF-A at Days 3, 5, 7, 10, 14, 28
- Change from baseline for inflammatory cytokines (IL-6, TNF-α, IFNγ, IL1β, IL-7, IL-8, IL-10, IL-12, IL-17, IL-18, IP-10) at Days 3, 5, 7, 10, and 28

3.0 STUDY DESIGN

This is a Phase 2, randomized, double-blind, placebo-controlled, 2-arm multicenter study to assess the safety and efficacy of oral STI-5656 (or placebo) in the setting of current SOC in subjects with RT-PCR confirmed SARS-CoV-2 infection and COVID-19 pneumonia (documented radiographically) requiring hospitalization. Subjects must have oxygen saturation levels <94% on room air or subject requires supplemental oxygen.

Eighty (80) subjects meeting eligibility criteria will be randomized at a 1:1 ratio to one of two treatment arms in addition to SOC treatments:

- Arm 1: STI-5656
- Arm 2: Placebo

The STI-5656 dose is 100 mg p.o. QD administered up to 14 days or until hospital discharge if sooner.

Details of the study conduct, visit schedule and assessments are described in the protocol. The Schedule of Assessments is referenced in Appendix 1.

An independent data monitoring committee (DMC) is established to evaluate the safety data from the study to ensure the ongoing safety of the study subjects and make recommendations to the Sponsor concerning safety and trial conduct (please refer to the DMC charter for details). An unblinded independent statistician will be used to facilitate DMC support.

4.0 RANDOMIZATION AND BLINDING

This is a randomized and double-blinded study.

Subjects will be randomized using the IRT on Day 1 to either Treatment Arm 1 (STI-5656 plus SOC) or Treatment Arm 2 (placebo plus SOC) (1:1 ratio) using central integrated response technology (IRT). Subject study discontinuation or study completion should also be registered in the IRT. Sponsor, investigator and the CRO will be blinded throughout the study. The independent statistician who supports the DMC is unblinded.

Emergency unblinding may be requested by the Investigator at any time if needed to properly assess the safety of a patient. The request should be submitted to the CRO and Sponsor's medical monitor.

5.0 SAMPLE SIZE CONSIDERATIONS

An evaluable sample size of 40 subjects per group will provide 80% power (alpha=0.05, 2-sided) to detect a difference between groups in the number of subjects alive and free of respiratory failure at Day 28. This assumes that 95.7% of subjects who received STI-5656 plus SOC and 70% of subjects who received placebo plus SOC only will be alive and free of respiratory failure at Day 28. This represents a treatment effect difference of approximately 26%.

6.0 ANALYSIS POPULATIONS

6.1 Full Analysis Set (FAS)

The full analysis set (FAS) includes all randomized patients. This is the intention to treat population. The FAS is based on the treatment allocated (as randomized). All efficacy endpoints will be analyzed using the FAS.

6.2 Safety Population

The safety population includes all randomized patients who received any study drug. This set is based on the treatment received (as treated). Treatment compliance/administration and all clinical safety variables will be analyzed using the safety population.

6.3 Per Protocol (PP) Population

The PP population is a subset of the FAS and excludes subjects with major protocol violations, entry criteria violations or missing visits. The PP population will be determined prior to the database lock and unblinding of the study. The PP population will be used for sensitivity analysis.

7.0 GENERAL STATISTICAL CONSIDERATION AND DEFINITIONS

7.1 Baseline and Visit Windows

Unless otherwise specified, baseline, which is defined as the last non missing assessment prior to the first dose of the study treatment, will be used in baseline and change from baseline analyses.

Analyses will be performed according to the scheduled visits.

7.2 Summary Statistics

Analysis will be summarized by treatment group of STI-5656 plus SOC or Placebo plus SOC, unless specified otherwise.

- Continuous endpoints will be summarized using descriptive statistics (number of participants, mean, standard deviation [SD], median, and maximum values) for each cohort. The summary statistic n will be the number of subjects with non-missing values. All means and medians will be reported to one more significant digit than the values being analyzed. Standard errors and standard deviations will be reported to two more significant digits than the values being analyzed. The minimum and maximum will be reported to the same number of significant digits as the values being analyzed.
- Categorical endpoints will be summarized as the number and percentage of participants per category for each cohort. Percentages will be out of the number of subjects in the population being reported, unless otherwise noted. All percentages will be rounded to one decimal point. The number and percentage of subjects will always be presented in the form XX (XX.X%) where the percentage is in parentheses. To ensure completeness, all summaries for categorical and discrete variables will include all categories, even if none of the subjects had a response in a particular category. Denominators for each analysis will be based on the population of interest (e.g., safety population; subjects with non-missing data).
- Subject listings of data will be presented for all enrolled subjects unless specified otherwise.

7.3 Missing or Incomplete Data

Subjects who are randomized to the study and discontinue before the end of the study will not be replaced. Missing values will not be imputed unless otherwise specified.

For success/failure endpoints, subjects who discontinue prior to the specified time point will be included in the analysis as treatment failures and censored at the last day of follow-up for the time-to-event analysis.

For all other endpoints, the mixed effect model repeat measurement (MMRM) analysis will be employed. The MMRM analysis only includes the available data. It has been demonstrated that the MMRM approach leads to estimators with comparatively small bias, and controls Type I error rates at a nominal level in the presence of missing completely at random (MCAR) or missing at random (MAR) and some possibility of missing not at random (MNAR) data (see https://pubmed.ncbi.nlm.nih.gov/19212876/).

7.4 Interim Analysis

A non-binding interim futility analysis will be performed after 40 subjects have reached the study primary endpoint. The analysis will be performed by an independent biostatistician who will have no contact with the study team.

This interim analysis will use non-binding futility boundaries. At 50% planned subjects (40 subjects out of 80 subjects total), futility interim will be performed. O'Brien-Fleming beta spending function will be used. Futility bound on Z scale is 0.537. The futility bound is crossed if an observed Z statistic is less than 0.537. Nominal beta is 0.296 with cumulative beta being 0.065 at the interim and 0.192 at the final analysis. The above interim planning was performed under 1-sided test setting using nQuery Version 8.6.1.0. Using 1-sided alpha of 0.025, with

continuity correction, sample size of 40 per group (80 total) have 80.8% power (beta 0.192) to detect the difference of 95.7% in active arm vs 70% in control arm.

8.0 STATISTICAL ANALYSES

8.1 Subject Disposition

The number of percentage of subjects in screened, randomized, FAS population, Safety Population, PP Population, completed the study and discontinued from the study will be reported, along with the reason for discontinuation.

Percentages will be out of the number of safety population. Counts only will be reported for screened subjects.

8.2 Demographic and Baseline Characteristics

Demographic/baseline characteristics will be summarized descriptively by treatment group in Safety Population.

The following variables will be included:

- Age (years)
- Sex (male, female)
- Race (White, Black or African American, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, Other)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino)
- Height, Weight and Body Mass Index (BMI) (*Screening)*
- Height (cm)
- Weight (kg)
- BMI (kg/m^2)
- SARS-CoV-2 quantitative RT-PCR result *(Screening)*

8.3 Medical History

Medical history terms will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary. Medical history will be summarized by system organ class (SOC) term and preferred term for each cohort by treatment group. For subjects with the same SOC and preferred term occurring more than once, the first occurrence will be tabulated.

Conditions will be listed, including the verbatim investigator description of the relevant medical condition, the coded terms (SOC, preferred term), start date, end date, and whether or not the condition is ongoing.

8.4 Prior and Concomitant Medications

Prior medications are defined as all medications recorded in the CRF initiated prior to the start of the study treatment. Prior medications will be coded with the World Health Organization Drug

Dictionary (WHO-DD), and summarized by drug class (Anatomical Therapeutic Chemical [ATC] Level 3) and preferred term; a subject will be counted only once for each medication.

All medication will be listed with the prior medications flagged.

8.5 Protocol Deviations

Protocol deviations recorded will be reviewed and major deviations will be identified prior to database lock and unblinding of the study. The PP population will be determined and subjects with major protocol violations, entry criteria violations or missing visits will be excluded.

8.6 Study Drug Administration

Two STI-5656 or matching placebo capsules p.o. QD (two 50-mg capsules) are administered orally up to 14 days or until hospital discharge if sooner. If vomiting occurs within 30 minutes after a patient takes the dose and the patients can tolerate the medication, the vomited dose should be made up.

If the subject is unable to swallow, the capsule contents may be flushed down a nasogastric or feeding tube with water.

For study drug administration, descriptive statistics of the following parameters will be presented.

- Number of days on study treatment
- Total dose planned
- Total dose administered
- Total dose missed
- Compliance rate, defined as the total dose administered/total dose planned, expressed as a percentage.

Subject listing of study drug administration will be presented.

9.0 EFFICACY EVALUATION

9.1 Primary Endpoint

The primary efficacy endpoint is the proportion of subjects alive and free of respiratory failure at Day 28, where respiratory failure, is defined based on resource utilization of any of the following modalities:

- Noninvasive positive pressure ventilation or continuous positive airway pressure
- Endotracheal intubation and mechanical ventilation
- Oxygen delivered by high-flow nasal cannula (heated, humidified, oxygen delivered via reinforced nasal cannula at flow rates >20 L/min with fraction of delivered oxygen ≥0.5)
- Extracorporeal membrane oxygenation

The number and percentage of subjects will be presented by treatment group using FAS population. Primary analysis to evaluate the differences between groups will utilize a

generalized linear mixed model, assuming a binomial distribution and a logit link. The model will include group as a fixed effect. Subjects who discontinue the study prior to Day 28 will be considered treatment failures.

Sensitivity analyses may be performed using PP population.

After 40 subjects have been enrolled and completed Day 28, an interim futility analysis will be performed to examine the proportion of subjects alive and free of respiratory failure at Day 28. The interim analysis is a non-binding analysis. See Section 7.4 for details.

9.2 Secondary Endpoints

9.2.1 Proportions

The same method used in the primary endpoint will be repeated for the following secondary efficacy endpoints:

- Proportion of subjects alive and free of respiratory failure at Day 60
- Proportion of subjects alive and discharged from ICU at Days 14 and 28
- All-cause mortality at Day 60 and Day 90

Subjects who discontinue the study prior to the study day end will be considered treatment failures.

9.2.2 Clinical Status

The 8-point ordinal scale will be summarized descriptively by treatment group and study day. The last known clinical status will be used for days with missing clinical status. All post-baseline days with missing ordinal scale score will use the previous last known clinical status. Additionally, stacked bar charts will be presented for the proportion of subjects in each category by group and study day.

9.2.3 Continuous Endpoints

For the following continuous endpoints, descriptive statistics will be presented by treatment group and study day. The changes or percent changes from baseline to each subsequent day will be calculated for each subject and descriptive statistics will be presented. Treatment differences between groups will be assessed using a mixed-effects model for repeat measures (MMRM). The model will include group, study day as fixed effects, baseline value as a covariate, interaction between study day and group, interaction between study day and baseline, and subject as a random effect.

- Percent change from baseline in C-reactive protein (CRP) at Days 3, 5, 7, 10, 14, 28
- Relative change from baseline in oxygenation index (PaO2/FiO2) up to Day 5

For each “number of days” endpoint listed below, descriptive statistics will be presented by treatment group. Treatment differences between groups will be assessed using analysis of variance (ANOVA) model with group as a fixed effect.

- Number of days alive and free of respiratory failure at Day 28

- Number of days with respiratory failure up to Day 28
- Number of days hospitalized up to Day 28
- Number of days in intensive care unit (ICU) (length of stay) up to Day 90
- Number of days alive outside of hospital up to Day 28
- Number of days alive outside of hospital up to Day 90

9.2.4 Time-to-Event Endpoint

For the time from randomization to first occurrence of respiratory failure or death on study due to any cause up to Day 28, the Kaplan-Meier method will be applied. Subjects will be censored at the time of last follow-up. For each group, the 25th percentile, median and 75th percentile will be presented, if possible. Treatment differences between groups will be assessed by the log-rank test.

9.3 Exploratory Endpoints

For the following exploratory endpoints, descriptive statistics will be presented by treatment group and study day. The changes from baseline to each subsequent day will be calculated for each subject and descriptive statistics will be presented. Treatment differences between groups will be assessed using a mixed-effects model for repeat measures (MMRM). The model will include group, study day as fixed effects, baseline value as a covariate, interaction between study day and group, interaction between study day and baseline, and subject as a random effect.

- Change from baseline in absolute lymphocyte counts at Days 3, 5, 7, 10, 14, 28
- Change from baseline in serum ferritin at Days 3, 5, 7, 10, 14, 28
- Change from baseline in vascular endothelial growth factor (VEGF-A) at Days 3, 5, 7, 10, 14, 28
- Change from baseline for inflammatory cytokines (IL-6, TNF-α, IFNγ, IL1β, IL-7, IL-8, IL-10, IL-12, IL-17, IL-18, IP-10) at Days 3, 5, 7, 10, and 28

10.0 SAFETY EVALUATION

10.1 Adverse Events

Treatment-emergent adverse events (TEAE) will be defined as any AE occurring post first administration of study drug. AEs will be coded using the MedDRA dictionary.

A summary of TEAEs will be presented as the number and percentage of subjects with at least one of the following:

- Any AE
- Any TEAE
- TEAE by Severity
- TEAE by Causality
- TEAEs leading to study discontinuation

- TEAEs leading to death (with outcome of Fatal)
- SAEs
- SAEs by Causality

AEs and TEAEs will be summarized by SOC and preferred term by treatment group. For subjects with the same SOC and preferred term occurring more than once, the first occurrence will be tabulated. AEs and TEAEs will also be presented for each preferred term by maximum severity, by nearest relationship to study drug, and for serious AEs.

10.2 Laboratory Results

For each continuous laboratory parameter (chemistry, coagulation, hematology), descriptive statistics will be presented for each study day collected and for the changes from baseline for by treatment group.

Categorical urinalysis parameters will be presented as the number and percentage of subjects per category for each study day collected by treatment group.

For laboratory parameters with normal ranges, the shift from Baseline (low, normal, high) to each subsequent study day (low, normal, high) will be presented by treatment group.

10.3 Respiratory Status

Respiratory status data collected will be provided in a subject listing.

10.4 Vital Signs Measurements

Vital signs measurement [body temperature (F), respiratory rate, radial pulse rate, systolic and diastolic blood pressure, and oxygen saturation (pulse oximetry will be summarized descriptively by treatment group for each study day collected. Additionally, the changes from baseline will be calculated and descriptive statistics presented.

10.5 Electrocardiogram (ECG) Results

For each ECG parameter, descriptive statistics will be presented for each cohort by treatment group for values collected.

10.6 Physical Examination

The results of the physical examination will be listed for each subject and study day collected.

10.7 Pregnancy Test for FCBP

The results of the pregnancy test will be listed for each assessment visit day collected.

11.0 CHANGES TO THE PLANNED ANALYSES

During the analysis and reporting process, any deviations from the statistical plan designed for this protocol will be described and justified in the clinical study report.

12.0 APPENDICES

12.1 Appendix 1: Schedule of Assessments

Assessments	Screening (Day -4 to -1)	Day 1 (Dose 1)[1]	Daily until hospital discharge	Hospital discharge or Early Term [2]	Outpatient visit: Day 28	Telephone Follow-up at Day 60 and 90
Informed Consent	X					
Assess eligibility	X	X				
Demographics[3]	X					
RT-PCR assay for SARS-CoV-2[4]	X					
Medical history (including COVID-19 history)	X					
Concomitant medications	X	X	X	X	X	
Physical exam, including weight; height[5]	X			X	X	
Vital signs[6]	X	X	X	X	X	
12-lead ECG (performed locally)[7]	X	X				
Pregnancy test for FCBP only[8]	X	X		X	X	
Urinalysis[9]	X	X	X		X	
Blood for hematology, coagulation and chemistry[10]	X	X	X	X	X	
Blood for CRP , serum ferritin, VEGF-A and cytokines[11] **Day 3, 5, 7, 10, 14 and 28 only**	X	X	X	X	X	
Respiratory Status[12]	X	X	X	X		
Adverse Events[13]	X	X	X	X	X	
Assess clinical status[14]	X	X	X	X		
IRT entry (at screening, randomization, then early termination or study completion	X	X		X		X
Study Drug administration (QD p.o.)		X	X[15]			

Assessments	Screening (Day -4 to -1)	Day 1 (Dose 1)[1]	Daily until hospital discharge	Hospital discharge or Early Term [2]	Outpatient visit: Day 28	Telephone Follow-up at Day 60 and 90
Sampling for pharmacokinetics[16]	X[16]	X[16]	X[16]			
Survival and additional experimental meds/ hospitalization/ICU status					X	X

Abbreviations: AEs: adverse events; ALC: Absolute lymphocyte count; ALT: alanine aminotransferase; AST: aspartate aminotransferase; CRP: C-reactive protein; BUN: blood urea nitrogen; CMP: complete metabolic panel; COVID-19: Coronavirus Disease 2019; D: day; ECG: electrocardiogram; ECMO: extracorporeal membrane oxygenation; ET: Early Termination; F: Fahrenheit; FCBP: female of childbearing potential; FiO_2: Fraction of inspired oxygen; IRT: Interactive Response Technology; IL: Interleukin; IFNγ: interferon gamma; QD: once daily; PaO_2: partial pressure of oxygen in arterial blood; p.o.: by mouth; RBC: red blood cells; rbc/hpf: red blood cells per high power field; RRT: rapid response team; RT- PCR: Reverse transcription polymerase chain reaction; TNFα: tumor necrosis factor alpha; WBC: white blood cells

[1] All assessments on Day 1 are to be performed prior to first dose of STI-5656. Day 1 laboratory results do not need to be available prior to randomization (and first dose of STI-5656 if assigned to that arm) if lab results are available from the previous 24 hours

[2] If the subject wishes to discontinue from the study prior to Day 28 or hospital discharge, every effort should be made to perform an Early Termination (ET) Visit within 7 days after the decision to discontinue the study.

[3] Demographics includes age, sex, race, ethnicity, date of birth.

[4] SARS-CoV-24 positive RT-PCR test results received more than 7 days prior to planned randomization may be used to confirm eligibility if the site is unable to obtain a repeat sample and confirm results prior to planned randomization day and if the subject has progressive disease consistent with COVID-19.

[5] Height at screening only

[6] Vital signs include body temperature (F), respiratory rate, radial pulse rate, systolic and diastolic blood pressure, and oxygen saturation (pulse oximetry). Pulse and blood pressure should be taken with subject in at least in a semi-recumbent position. It is preferred to collect vital signs approximately mid-afternoon each day. Vital signs may be obtained at additional times as deemed necessary by the Investigator.

[7] ECG to be performed at Screening, between 2 and 4 hours after study drug dosing, and as clinically indicated.

[8] Females of childbearing potential must have a negative pregnancy test at screening and within 24 hours before randomization (Day 1) unless the previous negative pregnancy test was within 72 hours of Day 1. Urine pregnancy test is acceptable. The test should be repeated at the time of the Day 28 visit.

[9] Urinalysis performed locally. Urinalysis includes protein, glucose, and blood (microscopic) – red blood cells per high power field (rbc/hpf).

[10] Laboratory tests performed locally.
Hematology: Hemoglobin, hematocrit, red blood cell (RBC) count, RBC indices, mean corpuscular hemoglobin, mean corpuscular hemoglobin concentration, platelet count (or estimate), and white blood cell count including differential.
Coagulation: INR, PTT.
Chemistry: performed locally. 14-analyte complete metabolic panel (CMP) : Albumin, alkaline phosphatase (ALP), alanine aminotransferase (ALT), aspartate aminotransferase (AST), bicarbonate, total bilirubin (TBIL), blood urea nitrogen (BUN), calcium, chloride, creatinine, glucose, potassium, sodium, total protein, D-dimer, fibrinogen.

[11] Cytokines include TNFα, IFNγ, IL-6, IL-1β, IL-7, IL-8, IL-10, IL-12, IL-17, IL-18, IP 10, VEGF-A

[12] Record FiO_2 (and PaO_2) at the time of arterial blood gas sampling. If PaO2 is not available, use SPO_2. Other respiratory status data to collect includes oxygen supplementation status: mechanical ventilation, face mask, nasal cannula or room air. Radiographic findings will also be collected.

[13] AEs will be collected from the time of informed consent to Day 60. Any ongoing AEs at Day 28 will be followed until resolution or stabilization.

[14] An 8-category ordinal scale of patient health status ranges: 0=no clinical or virological evidence of infection; 1=no limitation of activities; 2=limitation of activities; 3=hospitalized, no oxygen therapy; 4=oxygen by mask or nasal prongs; 5=non-invasive ventilation or high-flow oxygen; 6=intubation and mechanical ventilation; 7=ventilation + additional organ support – pressors, rapid response team (RRT), extracorporeal membrane oxygenation (ECMO); 8=death. See Section 18.2 for form.

[15] STI-5656 or placebo administration up to Day 14 or hospital discharge, whichever is sooner for subjects in Treatment Arm 1. Study drug capsules should be taken orally with 200-250 mL of water following at least 2 hours of fasting.

[16] Samples will be collected from the first 20 subjects enrolled. Sampling timepoints are as follows: Day 1 (predose) and at 0.5, 1, 2, 4, 8, 12, postdose on dosing days 1 and 8.