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Brief Title: Tofacitinib for Treatment of Moderate COVID-19 (I-TOMIC)

Date: 3/18/2024

Document: Amended SAP due to Study Termination

Protocol 2000027848 / WI256061

INVESTIGATION OF TOFACITINIB TO MITIGATE THE IMPACT OF COVID-19 (I-TOMIC) IN MODERATE SARS-COV-2 (MODERATE I-TOMIC)

Statistical Analysis Plan (SAP)

Version: **2.0**

Date: **18 Mar 2024**

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1. VERSION HISTORY

SUMMARY OF CHANGES

SAP Version	Change	Rationale
2.0	Hypothesis testing for treatment comparison will not be conducted. Only descriptive analyses will be generated.	The study concluded prematurely with a smaller-than-anticipated participant cohort, attributed to the return to pre-pandemic conditions as COVID-related restrictions eased during the recruitment phase. The abbreviated CSR is intended to be reported for this study (as per DMB10-GSOP), the changes in statistical reporting modification have been implemented.
1.0	Not Applicable	Not Applicable

2. INTRODUCTION

This SAP provides the detailed methodology for summary and statistical analyses of the data collected in Study 2000027848.

Statistical Analysis Plan (SAP) has been developed in response to the challenges posed by the COVID-19 pandemic, which led to a lower-than-anticipated recruitment of patients and the premature conclusion of the study. As a result, the estimands outlined in this version primarily focus on descriptive methods rather than comparative analysis between treatment groups. This document provides a comprehensive overview of the updated methodology for summarizing and analyzing the data collected in Study 2000027848, considering the modifications necessitated by the unique circumstances of the pandemic.

2.1. Modifications to the Analysis Plan Described in the Protocol

As rationalized above, no hypotheses testing for treatment comparison will be done, only descriptive analysis will be done by the treatment groups.

2.2. Study Objectives, Endpoints, and Estimands

Objectives/ Endpoints	Type of Endpoints [categorical (including binary), continuous, or time to endpoints]
Primary	
The primary objective of this study is to determine whether tofacitinib improves the clinical outcomes of patients with moderate SARS-CoV-2 infection as determined by the Primary outcome measure.	Binary endpoint

Endpoint: Proportion of subjects alive and not needing any form of mechanical ventilation, high flow oxygen, or ECMO by day 14 and day 30.	
Secondary	
Clinical improvement (defined as a 2-point increase) as measured by NIAID 8-point ordinal scale (i.e., 1 = death and 8 = Not hospitalized, no limitations on activities) at day 14.	Categorical endpoint
Clinical status using ordinal scale (days 3 through day 14): The ordinal scale is an assessment of the clinical status at the first assessment of a given study day. The scale is as follows: 1) Death; 2) Hospitalized, on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO); 3) Hospitalized, on non-invasive ventilation or high flow oxygen devices; 4) Hospitalized, requiring supplemental oxygen; 5) Hospitalized, not requiring supplemental oxygen - requiring ongoing medical care (COVID-19 related or otherwise); 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities.	Categorical endpoint
Time to recovery (Day of recovery is defined as the first day on which the subject satisfies one of the following three categories from the clinical status of ordinal scale: 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities) through day 14 and day 30 from day 1.	Time to endpoint.
Time to clinical improvement (defined as a 2-point increase on the ordinal scale).	Time to endpoint
Clinical status on ordinal scale at day 30, 60, and 90.	Categorical endpoint
Mortality rate at day 30, 60 and 90.	Binary endpoint
Proportion of patients requiring ICU admission and mechanical ventilatory support (defined as clinical status of 2 and hospitalization status = ICU) at 14 and 30 days.	Binary endpoint
Change from Baseline in inflammatory parameters (eg. hsCRP, procalcitonin, ferritin, D-dimers, LDH, fibrinogen, PT/PTT).	Continuous endpoint
Change from baseline in cytokines (e.g. IL-1, IL-2, IL-6, IL-8, TNF-α, IL-17A, IL-17F, IP-10, CCL5), as available	Continuous endpoint
Safety as assessed by reporting of adverse events, changes in clinical laboratory parameters (e.g., hemoglobin, hepatic transaminases, serum creatinine, bilirubin, and evidence of secondary infections) Safety Endpoints: Adverse events:	

• Incidence of treatment emergent adverse events (TEAE), serious adverse events, AEs leading to discontinuation. Laboratory data • Change from baseline clinical laboratory parameters. • Incidence of clinically significant abnormalities in laboratory parameters. Vital signs • incidence of clinically significant abnormalities in vital signs Electrocardiogram • Changes from baseline for the ECG parameters • Incidence of clinically significant abnormalities in ECG results	Binary endpoint Continuous endpoint Binary endpoint Binary endpoint Continuous endpoint Binary endpoint
Intervention with additional immunomodulatory agent (i.e. IL-6 targeting therapy)	Binary endpoint
Change in SARS-CoV-2 viral titers during intervention	Continuous endpoint

2.2.1. Estimands

The estimand with treatment policy strategy will be utilized. All observed data (regardless of whether an intercurrent event occurs) will be included in the analysis. It includes the following 4 attributes:

- Population: Participants with COVID-19 pneumonia who meet all inclusion/exclusion criteria. The analysis will consider all observed data without employing any imputation for missing data;

- Variable: Yes or No for the occurrence of the event for categorical endpoints (including Binary endpoints), change from baseline for continuous endpoints and time to event for time to event endpoints.

- Intercurrent event(s): discontinuation of study intervention due to any reason or receiving rescue therapy.

- Population level summary: Proportion for categorical endpoints (including binary endpoints), mean for continuous endpoints and median time to event for time to event endpoints.

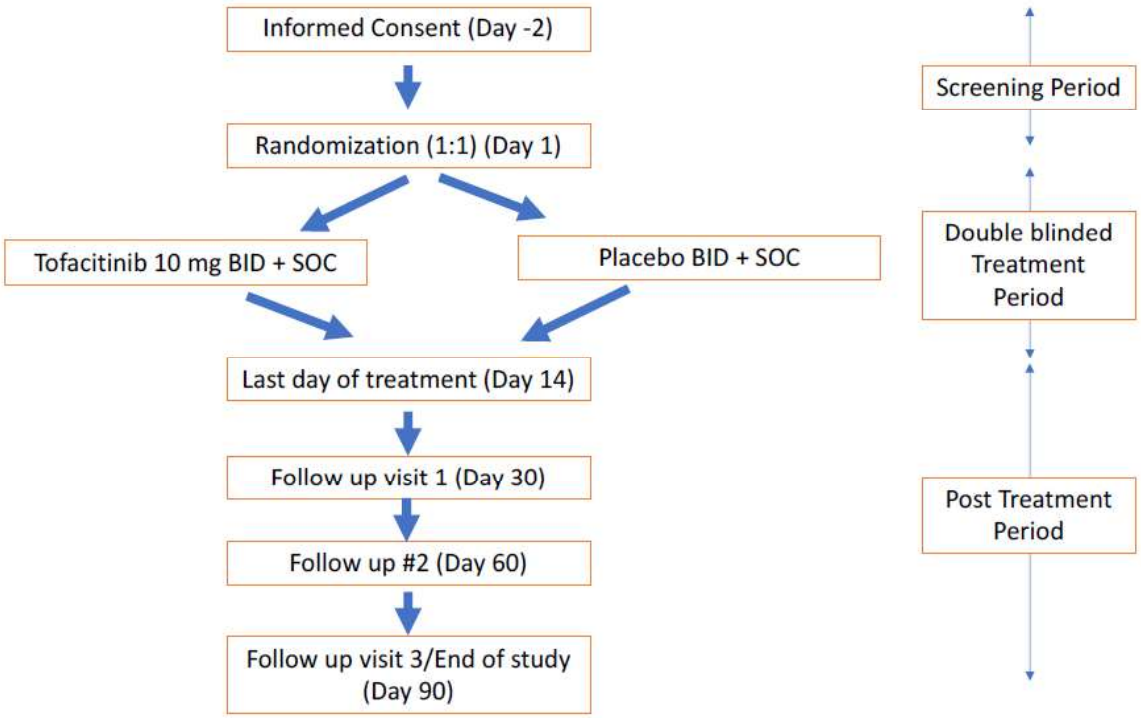
2.3. Study Design

The study concluded prematurely with a smaller-than-anticipated participant cohort, attributed to the return to pre-pandemic conditions as COVID-related restrictions eased during the recruitment phase. The situation warranted early termination of the study.

The study is a randomized, double blinded, placebo-controlled Phase 2b study of the efficacy and safety of tofacitinib in hospitalized adult (18-65 years old) male and female

patients with SARS-CoV-2 and pneumonia who require supplemental oxygen and have serologic markers of inflammation but do not need mechanical ventilation (see Inclusion criteria). Sixty patients will be recruited to receive tofacitinib or placebo in addition to standard of care (SOC) in a 2:1 ratio. Subjects will be screened during hospitalization. Patients with confirmed SARS-CoV-2 infection, and meeting all other Inclusion and Exclusion criteria, will be randomized to either treatment with tofacitinib or placebo in addition to SOC during hospitalization (dose adjusted, if required), with the exception of any immunomodulatory agents (as documented in the inclusion/exclusion criteria). Tofacitinib will be administered in a dose of 10 mg PO BID until return to their clinical baseline (as defined by need for supplementary oxygen) and will continue to be administered at 5 mg PO BID for a total duration of therapy of 14 days; follow-up off tofacitinib will continue up to Day 90. Because patients are likely to be discharged from the hospital soon after returning to clinical baseline, patients will continue to be administered tofacitinib 5 mg BID for a total duration of treatment of 14 days in order to prevent rebound of CRS that could theoretically occur with abrupt cessation of immunomodulatory therapy. In these cases, patients will be discharged home with a pill bottle labeled as investigational drug containing the appropriate number of pills (either tofacitinib or placebo). Rescue therapy is defined as IL-6 targeting agent or other non-FDA approved, compassionate use or expanded access when considered as medically necessary (AS REVIEWED BY THE PI) (Protocol section 6.1.2). Per protocol, subjects will discontinue from study treatment prior to taking rescue therapy.

Figure 1. Study Schema



3. ENDPOINTS AND BASELINE VARIABLES: DEFINITIONS AND CONVENTIONS

3.1. Primary Efficacy Endpoint(s)

The primary objective is to determine whether tofacitinib improves the clinical outcomes of patients with moderate SARS-CoV-2 infection as determined by the primary outcome measure. The primary endpoint is proportion of subjects alive and not needing any form of mechanical ventilation, high flow oxygen, or ECMO by day 14.

3.2. Secondary Efficacy Endpoint(s)

- Clinical improvement (defined as a 2-point increase) as measured by NIAID 8-point ordinal scale (i.e., 1 = death and 8 = Not hospitalized, no limitations on activities) at day 14.
- Clinical status using ordinal scale (days 3 through day 14): The ordinal scale is an assessment of the clinical status at the first assessment of a given study day.
- Time to recovery [Time Frame: Day 1 through Day 14] (Day of recovery is defined as the first day on which the subject satisfies one of the following three categories from the clinical status of ordinal scale: 6) Hospitalized, not requiring supplemental oxygen - no longer requires ongoing medical care; 7) Not hospitalized, limitation on activities and/or requiring home oxygen; 8) Not hospitalized, no limitations on activities.
- Time to clinical improvement (defined as a 2-point increase on the ordinal scale).
- Clinical status on ordinal scale at day 30, 60, and 90
- Mortality rate at day 30, 60, 90
- Proportion of patients requiring ICU admission and mechanical ventilatory support
- Change from baseline in inflammatory parameters hsCRP, procalcitonin, ferritin, D-dimers, LDH, fibrinogen, PT/PTT
- Change from baseline in cytokines IL-1, IL-2, IL-6, IL-8, TNF-α, IL-17A, IL-17F, IP-10, CCL5 as available.
- Intervention with additional immunomodulatory agent (i.e. IL-6 targeting therapy)
- Change in SARS-CoV-2 viral titers during intervention.

3.3. Other Efficacy Endpoint(s)

N/A

3.4. Baseline Variables

Unless specifically stated otherwise, the Baseline value is defined as the last non-missing measurement prior to the first administration of study drug at Day 1. As per protocol, it is intended all Day 1 assessments will be performed prior to dosing.

3.5. Safety Endpoints

3.5.1. Adverse Events

An adverse event is considered a TEAE to a given treatment (for a participant who received at least of one dose of study intervention) if the event start date is on or after the treatment period start date and within 28 days of the treatment end date. The safety endpoints will be as follows.

- Incidence of TEAEs.
- Incidence of SAEs, and AEs leading to discontinuation.

3.5.2. Laboratory data

The following laboratory tests will be performed at time points identified in the Schedule of Activities. Unscheduled clinical labs may be obtained at any time during the study to assess any perceived safety concerns at the investigator's discretion or Sponsor's request.

- Blood and urine laboratory tests including lactate dehydrogenase (LDH), complete blood count with differential (CBC), comprehensive metabolic panel (CMP), cytokine panel, cardiac panel, coagulation, inflammation panel, and urinalysis.

The following endpoints for laboratory data will be analyzed.

- Incidence of clinically significant abnormalities in laboratory parameters
- Changes in Clinical laboratory parameters from the baseline (hemoglobin, hepatic transaminases, serum creatinine, bilirubin, and evidence of secondary infections).

3.5.3. Vital signs

Vital signs (pulse, blood pressure, respiratory rate, temperature) will be measured as indicated in the Schedule of Activities of the protocol. The following endpoint will be analyzed: incidence of clinically significant abnormalities in vital signs.

3.5.4. Electrocardiogram (ECG)

ECGs should be collected at times specified in the Schedule of Activities of the protocol. The following endpoints will be analyzed:

- Changes from baseline for the ECG parameters

4. ANALYSIS SETS (POPULATIONS FOR ANALYSIS)

Population	Description	Applicable Analysis
Full analysis set (FAS)	All participants randomly assigned to study intervention. Participants will be analyzed according to the	All efficacy endpoints

	intervention to which they were randomized.	
Safety analysis set (SAS)	All participants randomly assigned to study intervention and who take at least 1 dose of study intervention. Participants will be analyzed according to the intervention to which they received.	All safety endpoints

If a participant is randomized but receives the incorrect treatment, then the participant will be reported under the randomized treatment group for all efficacy analyses. If a participant is randomized but receives partially incorrect treatment, then the participant will be summarized under the treatment received for most of the time during the study, for all safety analyses.

5. GENERAL METHODOLOGY AND CONVENTIONS

Final analyses will occur after database lock after LSLV.

5.1. Hypotheses and Decision Rules

No Hypotheses testing.

5.2. General Methods

5.2.1. Analyses for Categorical (including Binary) Endpoints

Categorical (including binary) data will be analyzed using the Estimand with treatment policy strategy specified in Section 2.2.1. All summary statistics are based on each treatment group.

- The number of participants, number, and percent of participant with event along with the 95% confidence interval by Clopper-Pearson exact method (see reference in Section 8) will be presented for observed data.

- For Binary data over time, line plot for the event rate and 95% CI will be presented.

5.2.2. Analyses for Continuous Endpoints

Continuous endpoints will be analyzed using the Estimand with treatment policy strategy specified in Section 2.2.1.

The data for each continuous endpoint will be summarized by treatment group and by time point in tables containing descriptive statistics (N [which is the number of participants evaluable for the endpoint at the time point], mean, standard deviation, standard error of the mean, minimum, 1st, 2nd (i.e., median) and 3rd quartiles and maximum) for actual and change from baseline values for those endpoints measured at baseline. In case when N=1 (i.e., only one participant is available/evaluable for summary), standard deviation and standard error will be reported as “NA” (not applicable) while the remaining statistical parameters will

have the same value as the mean. For selected endpoints, mean (+/-SD) over time by treatment group will be plotted.

5.2.3. Analyses for Time-to-Event Endpoints

For time to recovery and time to clinical improvement

- If subject died prior to or on the specified time point (Day 14 or Day 30), the result for time to event will be censored on the date of death regardless of if subjects have experienced recovery or clinical improvement prior to Death.

- If no death is recorded through the specified time point (Day 14 or Day 30): For a participant who experiences the event of recovery/clinical improvement through Day 14 or Day 30, the time to event will be the study day corresponding to the earliest visit date at which the participant has already experienced the event.

- For all participants who have not experienced the event, their time to event will be right censored at the last available measurement time of the clinical status through Day 14 or Day 30.

Time to event endpoints will be analyzed using the Estimand with treatment policy strategy specified in Section 2.2.1.

The number of participants, number and percent of participants censored, and participants with recovery or clinical response will be provided for each treatment group. The median and quartiles time to event will be estimated by the Kaplan-Meier method.

5.3. Methods to Manage Missing Data

All data will be evaluated as observed, and no imputation method for missing values will be used.

6. ANALYSES AND SUMMARIES

6.1. Primary Endpoint(s)

The primary endpoint of proportion of subjects alive and not needing any form of mechanical ventilation, high flow oxygen, or ECMO by day 14, will be analyzed as described in Section 5.2.1 by treatment group based on FAS defined in Section 4.

6.2. Secondary Efficacy Endpoint(s)

The secondary efficacy endpoints are listed in Section 3.2.

For the categorical (including binary) endpoints, results will be analyzed as described in Section 5.2.1 by treatment group based on FAS defined in Section 4.

For continuous endpoints, results will be analyzed as described in Section 5.2.2 by treatment group based on FAS defined in Section 4.

For time to endpoints, results will be analyzed as described in Section 5.2.3 by treatment group based on FAS defined in Section 4.

6.3. Subset Analyses

N/A

6.4. Baseline and Other Summaries and Analyses

6.4.1. Baseline Summaries

The following demographics and Baseline characteristics will be summarized by treatment group and for total.

- Gender (female, male)
- Race (American Indian or Alaska Native, Asian, Native Hawaiian or other Pacific Islander, Black or African American, White, more than one race and not reported)
- Ethnicity (Hispanic or Latino, Not Hispanic or Latino and unknown or not reported)
- NIAID ordinal scale of disease severity scores (i.e., 1 = death and 8 = Not hospitalized, no limitations on activities)
- Prothrombin time/partial prothrombin time (PT/PTT)
- Days since onset of symptoms
- Days since diagnosis
- Fibrinogen
- D-dimer
- Hs-CRP
- Ferritin
- Procalcitonin
- LDH
- Tobacco history (type of substance, Usage (Never, current and former)
- Height
- Weight

6.4.2. Study Conduct and Participant Disposition

Participants evaluation for FAS and SAS, disposition, and discontinuation will be summarized by treatment group and for total.

6.4.3. Study Intervention Compliance

- Actual Dosing Days (ADY) is defined as the total number of dosing days on which study drug was administered.

- Exposure Time is defined as the total number of days from first to and including last day of study dosing (Last Oral Dosing Date - First Oral Dosing Date + 1);

- Dose Compliance is defined as the number of doses of study drug the subject took out of the expected total number of doses of study drug

    - ADY1 = Date of returning to clinical baseline – Date of first dosing (Day 1) + 1

    - Expected Doses (by mg):

        (a) ADY1 ≥ 14, Expected Doses = 14 * 20 mg = 280 mg;

(b) ADY1 < 14, Expected Doses = ADY1 * 20 mg + (14 – ADY1) * 10 mg = (140 + 10 * ADY1) mg;

- Dose Compliance = (Total Actual Doses/ Expected Doses) * 100%

The continuous endpoints of actual Dosing Days, exposure Time, total actual doses and dose Compliance will be summarized as described in Section 5.2.2 by treatment group based on SAS as defined in Section 4.

Number and percent will be reported for subjects in Actual Dosing Days categories (≤7 days, 8 ~ 13 days, 14 days), and Dose Compliance categories (< 70%, 70% ~ 130%, > 130%).

6.4.4. Concomitant Medications and Nondrug Treatments

Prior treatment are the ones stopped prior to Day 1 of study treatment. Concomitant treatments are the ones taken on Day 1 or after. Prior drug and non-drug treatment, concomitant drug (including SoC) and non-drug treatment will be summarized by treatment group. Number and percent of subjects used additional immunomodulatory agent (i.e., IL-6 targeting therapy), or other non-FDA approved, compassionate use or expanded access treatment will be reported by treatment group.

6.5. Safety Summaries and Analyses

The safety endpoints are listed in Section 3.5. All safety analyses will be performed on the SAS (Section 4).

For the categorical (including binary) endpoints, results will be analyzed as described in Section 5.2.1 by treatment group.

For continuous endpoints, results will be analyzed as described in Section 5.2.2 by treatment group.

7. INTERIM ANALYSIS

No interim analysis will be performed. Safety data will be reviewed by a Yale DSMB.

The first safety review was conducted after randomization of 24 subjects and there was no further review as additional patients were not enrolled.

8. REFERENCE

C. J. Clopper; E. S. Pearson. The Use of Confidence or Fiducial Limits Illustrated in the case of the Binomial. Biometrika, Vol. 26, No. 4. (Dec. 1934), pp. 404-413.

APPENDICES

Appendix 1. Definition and Use of Visit Windows in Reporting

The data will be analyzed at each scheduled visit per defined in section 6.3.1 of the study protocol.

Appendix 2. List of Abbreviations

Abbreviation	Term
AE	adverse event
BID	twice daily
CCL5	C-C motif chemokine ligand 5
CI	confidence interval
COVID-19	Corona Virus Infectious Disease-19
CRF	Case Report Form
ECG	electrocardiogram
ECMO	extra-corporeal membrane oxygenation
FAS	full analysis set
FDA	Food and Drug Administration (United States)
hs-CRP	high-sensitivity-C-reactive protein
ICU	Intensive Care Unit
IL	interleukin
IP-10	interferon gamma-induced protein-10
LDH	lactate dehydrogenase
MAX	Maximum
MIN	Minimum
N/A	Not Applicable
NIAID	National Institute of Allergy and Infectious Diseases
PT/PTT	prothrombin time/partial prothrombin time
SAE	serious adverse event
SAP	statistical analysis plan
SARS-CoV-2	Severe Acute Respiratory Syndrome-Coronavirus-2
SAS	safety analysis set
SD	standard deviation
SoC	standard-of-care
TEAE	treatment-emergent adverse event
TNF	tumor necrosis factor

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Validation Report

1

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Subject DN	EMAILADDRESS=operations@msbdocs.com,CN=TAIGLE LLC,OU=MSB,O=TAIGLE LLC,L=Irvine,ST=California,C=US
Email	operations@msbdocs.com
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Issuer DN	CN=Entrust Class 3 Client CA - SHA256,OU=(c) 2015 Entrust, Inc. - for authorized use only,OU=See www.entrust.net/legal-terms,O=Entrust, Inc.,C=US
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21 Mar 2024 12:49:011-0400	Balasubramaniam R UUID : eb677452-ade4-4d31-a3c4-e18c41205995 Email : Balasubramaniam.R@pfizer.com IP Address : 204.114.196.5 OS: Windows, Browser: Edge, Device: Desktop	Name : Protocol-2000027848_WI256061_ITOMIC_Statistical Analysis Plan_v2.0.pdf UUID : 5226e6af-d046-4f04-aaa8-d3eb18f275c7 Document Source : MSB	Signed	The recipient signed the document with no comments. Comments: None Signing Reason: None Consent: I understand that my Electronic Signature is Equivalent to my Handwritten Signature and is therefore legally binding. My Electronic Signature will remain unique to me, and under no circumstance I am allowed to disclose my password to any individual which may allow unauthorized access to system. I understand that I am accountable and responsible for all actions associated with my Electronic Signature.
21 Mar 2024 12:49:011-0400	Balasubramaniam R UUID : eb677452-ade4-4d31-a3c4-e18c41205995 Email : Balasubramaniam.R@pfizer.com		Completed	The ePak is completed successfully.