# STATISTICAL ANALYSIS PLAN

WB007-001

A Phase I/2a Assessment of WB007 Ophthalmic Solution in Subjects with Primary Open-Angle Glaucoma or Ocular Hypertension

**Prepared for:**

Whitecap Biosciences

**Version and Author details:**

| | |
|---|---|
| Version Date: | 02 March 2021 |
| Version Number | 2.0 |
| Author: | [redacted] |

NCT# NCT04149899

**SIGNATURES**

The undersigned have approved this Statistical Analysis Plan for use in this study.

[redacted]

Date

[redacted]

Date

[redacted]
Statistical Consultant, Whitecap Biosciences

[redacted]

Date

[redacted]
Clinical Head, Whitecap Biosciences, LLC

# Table of Contents

# 1 INTRODUCTION

This statistical analysis plan (SAP) describes the statistical methods to be used during the reporting and analyses of data collected under Whitecap Biosciences Protocol WB007-001.

This SAP should be read in conjunction with the study protocol and case report form (CRF). This version of the plan has been developed using the protocol amendment No. 5, dated 30 Jan 2021. The final approval of the SAP will occur prior to database lock.

## 1.1 Changes from Protocol

The changes described in this section apply to Part 2 only.

The per protocol analysis to confirm the primary efficacy analysis in section 9.1 of protocol will be performed on a post hoc basis only as needed; however, the specific criteria of protocol deviations deemed to have potential impact on the primary endpoint will be determined and the exclusion of data points will be identified prior to the database lock.

The following secondary efficacy endpoint analysis will be performed on a post hoc basis as needed (protocol section 9.3.1.2):

- Mean IOP change from baseline at each time-matched hour at Day 14/Exit will be analyzed with a 2-way ANOVA method which will have treatment and the baseline IOP stratum (IOP ≤25 mm Hg and > 25 mm Hg) as the main effects in the model.

The following subgroup analysis will be performed on a post hoc basis as needed (protocol section 9.5):

- Descriptive statistics for the primary analysis will also be provided by each Baseline IOP stratum.

# 2 STUDY OBJECTIVES

The objective of this study is to assess the safety, ocular tolerability and IOP-lowering effects of WB007 (also known as AGN-227535) in adult subjects with primary open-angle glaucoma or ocular hypertension.

The clinical hypotheses for these studies are:

Parts 1/2: AGN-227535 has an acceptable safety and tolerability profile.

Part 1: The IOP-lowering effects of at least 1 concentration of AGN-227535 are sufficient for evaluation to proceed to Part 2.

Part 2: The primary hypothesis is that AGN-227535 ophthalmic solution effectively lowers IOP. Specifically, at least 1 concentration of AGN-227535 demonstrates an IOP lowering effect.

# 3 STUDY DESIGN

This is a 2-part study designed to evaluate the safety, tolerability and IOP-lowering effects of AGN-227535 in subjects with primary open-angle glaucoma (POAG) or ocular hypertension (OHT). Approximately 100 subjects are planned to be enrolled at up to approximately 5 study centers in the United States.

In Part 1, an open-label dose-escalation of AGN-227535 [redacted] is planned in order to assess initial safety, tolerability and IOP-lowering effects. Approximately 6 subjects will be exposed to a single dose (to one eye) at each concentration level. Between cohorts, all available data will be used to assess the appropriateness to pursue the next concentration. Approximately 25 subjects will be screened so that 18 subjects complete the study.

In Part 2, in addition to the primary analysis of the within-group mean IOP change from baseline, a parallel comparison of AGN-227535 with timolol 0.5% is planned. Study treatments will be administered twice-daily for 14 days. Up to 2 investigational doses will be chosen based on results from Part 1. Subjects will be randomized in a 2(:2):1 ratio to receive one of up to two concentrations of AGN-227535 (based on results from Part 1) or timolol ophthalmic solution 0.5% and will be stratified based on IOP at Baseline, Hour 0 (≤ 25 mm Hg versus > 25 mm Hg). Approximately 24 subjects per AGN-227535 group and 12 subjects for the timolol group will be given study treatment. If 2 investigational doses are selected: approximately 75 subjects will be screened so that 60 subjects complete the study.

For both Parts 1 and 2, potential subjects will be screened within the 50 days prior to initiation of treatment. Thus, the total duration of study participation for each subject is up to 2.5 months which includes 4 (Part 1) and 6 (Part 2) in-clinic visits. The visit schedule requires day-long visits at some time points to perform sufficient clinical assessments. The primary efficacy endpoint (Part 2) is IOP change from baseline at each time-matched hour at Day 14/Exit.

Part 2 of the study is designed as a parallel group comparison, randomized and double-masked to minimize investigator and subject bias, and eliminate possible confounding effects that are inherent in other study designs (e.g., crossover design). The selection of subjects, study endpoints, and therapy are in general similar to studies that established the safety and efficacy of other IOP-lowering treatments of subjects with glaucoma or ocular hypertension. Subjects who are chronically treated with ocular hypotensive medications will be required to undergo appropriate washout periods prior to study entry to eliminate residual effects of other active ocular hypotensive medications.

Subject safety will be monitored throughout the study.

## 3.1 Sample Size Considerations

For each cohort in Part 1 of the study a sample size of 6 patients will provide 83% power to detect a 3 mm Hg within group change from pre-dose assuming a standard deviation of 2 and two-sided alpha = 0.05, based on a one-sample t-test. With larger standard deviations (≥2.5) the power to detect this difference is <66%.

For Part 2, the sample size will provide >90% power to detect within-group mean change from baseline of at least a 3 mm Hg for the primary endpoint assuming a standard deviation of 2.5 with two-sided alpha = 0.05. In addition, power calculations were performed for the comparison of each dose of AGN–227535 versus Timolol. These calculations consider treatment differences (AGN–227535 minus Timolol) mean changes from baseline in study eye IOP in the mITT population at Day 14/Exit.

The power to detect treatment group differences from -1 to -4 mm Hg with common standard deviations (SDs) ranging from 2.5 to 3.5, based on a two-sample t-test are shown in the Table below.

**Power Calculations for Study Part 2 Tests of Treatment Difference**

*(AGN-227535 N = 24; Timolol N = 12; alpha = 0.05)*

| Treatment Group Difference | Common SD | Power (%) |
|---|---|---|
| -4 | 2.5 | 99 |
| | 3 | 96 |
| | 3.5 | 88 |
| -3 | 2.5 | 91 |
| | 3 | 78 |
| | 3.5 | 65 |
| -2 | 2.5 | 59 |
| | 3 | 45 |
| | 3.5 | 35 |
| -1 | ≥2.0 | <20 |

Additional sample size calculations were performed for tests of non-inferiority of either dose of AGN-227535 to Timolol. These calculations considered a non-inferiority margin of 1.5 mm Hg and one-sided α = 0.025. With a treatment group difference of -1 mm Hg, the power ranged from 50% for a common SD of 3.5 to 78% for a common SD of 2.5.

The calculation was based on the non-inferiority tests for the difference between two means using t-test as implemented in the commercial software PASS version 16.0.3 (2018).

### 3.2 Randomization and Study Eye Assignment

Part 1: No randomization is involved because all subjects in the same cohort receive the same treatment. If only one eye qualifies, the study medication will be administered to that eye. If both eyes qualify, the eye with the higher IOP at Baseline (Day -1) Hour 0 will be the study eye and will receive study medication. If both eyes have the same IOP value at this timepoint, the right eye will be the study eye.

Part 2: Subjects will be randomly assigned to 1 of up to 3 treatment arms (based on results from Part 1) in a 2(:2):1 allocation ratio to receive 1 of up to 2 AGN-227535 concentrations or timolol. To ensure balance of elements that could influence the IOP-lowering effects across treatment groups, the randomization will be stratified by baseline (Hour 0) IOP (≤25 mm Hg; >25 mm Hg). The randomization scheme will be prepared by Whitecap Biosciences or its designee. The IWRS, a module within eDC, will be used to confirm Baseline IOP eligibility and perform stratification and randomization of subjects. Subject treatment will be double-masked; neither the investigator nor the staff or subject will be aware of treatment assignment. All study treatments will be provided in similarly-appearing bottles with the same-colored bottle caps and identical cartons to maintain masking of the study. The study eye of each subject will be defined the same way as for the Part 1.

## 4 ANALYSIS POPULATIONS

Each population will be analysed based on the treatment received.

Part 1: The Safety population consisting of all treated subjects will be used for all analyses.

Part 2: The following populations will be used for analysis:

- The Safety population will consist of all treated subjects. All safety analyses will be performed using the safety population.
- The Modified Intent-to-treat (mITT) will consist of all randomized and treated subjects who provide IOP data at baseline and at least one post-baseline IOP assessment. This population will be used for analyses of efficacy data.
- The Per-Protocol (PP) population is a subset of the mITT population and consists of subjects and data points which did not have any protocol deviations deemed to have potential impact on the primary endpoint. The protocol instructs subjects to apply study treatment every morning and every evening approximately 12 hours apart each day. The 12-hour time window, if violated, may impact the Hour 0 IOP measurement on the following day. It is determined that the IOP measurement at Hour 0 on Day 4 or Day 14 visit will be excluded from the PP population if the duration between the time of evening dose on the day before and Hour 0 on the day of visit deviates from the 12-hour requirement by more than 1 hour (i.e., outside the [11 hours, 13 hours] window).

# 5 STUDY VARIABLES AND COVARIATES

## 5.1 Primary Efficacy Endpoints (Part 2)

The primary response measure is IOP. The mean hour-matching IOP change from baseline will be the primary efficacy endpoint.

## 5.2 Secondary and Other Efficacy Endpoints (Part 2)

IOP values at each scheduled hour of Day 14/Exit. The mean IOP value will be the secondary efficacy endpoint. Also see section 1.1.

## 5.3 Subgroup Analyses (Part 2)

Subgroup analysis for Part 2 of the study will be performed on post hoc basis as needed, including by baseline IOP stratum, by investigational site, and by prior medication category (e.g., Timolol users vs non-users). Also, see section 1.1.

## 5.4 Safety Endpoints

All safety analyses will be performed on the Safety Population.

Safety and tolerability will be assessed by reporting of AEs, ECG, vital sign measurements, clinical laboratory results, BCVA, slit lamp biomicroscopy, macroscopic hyperemia, pupil size, visual fields, dilated fundus examination, and subject comfort.

# 6 DATA CONVENTION

Statistical programming and analyses will be performed using SAS® Version 9.4 or higher. Output will be provided in RTF and/or PDF format for tables, listings, and figures using landscape orientation. All study data will be listed by study part subject, treatment, and visit (as applicable) based on all enrolled or safety subjects. Subject data listings will be organized by study part, cohort treatment groups.

One database lock will occur when all subjects (both Part 1 and Part 2) have either completed the study or discontinued from the study prematurely, and all data queries have been resolved. Randomization release will occur following the database lock.

Change from baseline for all variables will be hour-matched. When there is no hour matched value (for example, cup-to-disc ratio), change from baseline will be calculated from post baseline values minus the baseline.

### 6.1 Missing Data

Unless otherwise stated, missing data will be handled using the following approach:

- Analyses performed for the mITT population will use the method of last observation carried forward (LOCF) to impute missing values. No imputation for missing data will be performed for the safety population.
- For start date, partial dates will have first day of the month imputed if day is missing, and January of that year will be imputed if month is missing. If both day and month are missing, January 01 will be imputed.
- For end date, partial dates will have last day of the month imputed if day is missing, and December of that year will be imputed if month is missing. If both day and month are missing, December 31 will be imputed. An exception is that missing dates of prior and concomitant medications will not be imputed.
- Where severity or relationship is missing for adverse events, most conservative imputation will be made; in that a missing severity will be imputed as 'severe' and a missing relationship as 'related'.

### 6.2 Descriptive Statistics

Descriptive statistics will be provided in 3 areas: (1) demographics and baseline characteristics for Parts 1 and 2, (2) IOP analyses as noted in Sections 5.1 and 5.2 for Part 2, and (3) adverse events analysis for Part 2.

For continuous variables, descriptive statistics will include the number of subjects (n), mean, standard deviation (SD), median, minimum and maximum. Categorical variables will be summarized using absolute and relative frequencies (i.e., counts and percentages). All data to be summarized will be presented by cohort treatment groups using appropriate descriptive statistics.

Unscheduled data, such as information from unscheduled visits or investigator comments, will be included in the data listings. In general, these data will be excluded from the summary tables unless otherwise specified.

## 7 DISPOSITION AND EXIT STATUS

### 7.1 Subject Disposition

Subject disposition (completed, discontinued and reason for discontinuation) for Part 1 of the study will be listed for all treated subjects by cohort treatment groups. For Part 2 of the study, subject disposition will be listed for all randomized subjects by cohort treatment groups.

### 7.2 Extent of Study Drug Exposure

Exposure to treatment group for Part 1 of the study will be listed for all treated subjects, and for Part 2 study, exposure to treatment group will also be listed for all randomized subjects.

For Part 2 of the study, treatment compliance will be listed by cohort treatment groups. For this, duration of exposure will be calculated as date of last dose minus date of first dose plus 1.

### 7.3 Protocol Deviations

A subject listing will be provided that includes the date of the deviation and the deviation description.

### 7.4 Screen Failures

The reason for screen failure for both Part 1 and 2 of the study will be listed.

## 8 BASELINE CHARACTERISTICS

### 8.1 Demographics and Baseline/Screening Characteristics

All demographic and baseline data for Part 1 and 2 of the study will be summarized per treatment group and overall. These will be presented for the safety population, and will include age, race, sex, ethnicity, iris color, childbearing potential for female subjects, height, and weight. A listing for demographics and baseline characteristics for Part 1 and 2 of the study will be presented showing the above parameters.

### 8.2 Prior and Concomitant Medications

Prior and concomitant medications will be presented for each subject coded per the World Health Organization (WHO) Anatomical Therapeutics Chemical (ATC) Drug dictionary. Prior medication are those medications that stopped prior to dosing. Concomitant medications are those medications that either started anytime from dosing onwards or continued once subject had been dosed with study medication. Medications with partial dates that do not allow determination of whether prior or concomitant will be considered concomitant.

Prior and concomitant medications for Part 1 and 2 of the study will be listed separately. This listing will be presented for ocular and non-ocular prior and concomitant medications.

### 8.3 Medical History

Medical history will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 22 Subject listings of medical history will be generated separately for study part and for ocular and non-ocular data by System Organ Class (SOC) and Preferred Term (PT).

## 9 EFFICACY ANALYSIS

Part 1: Listings will be provided for all IOP measurements of the study eye and non-study eye by cohort, visit, and hour.

Part 2: Listings will be provided for all IOP measurements of the study eye and non-study eye by cohort, visit, and hour. Mean and/or median of the IOP measurements will also be presented along with hour-matched change from baseline IOP values.

Apart from listings, statistical analysis will be carried out for Part 2 of the study. Efficacy analyses are described in detail within this section. Analyses performed for the mITT population will use the method of last observation carried forward (LOCF) to impute missing values. Efficacy analyses will be presented for the study eye and non-study eye. The study eye would be considered the main analysis for each endpoint.

For Part 2, the primary efficacy analysis is the within-group mean change from baseline at hour 2, the time of peak efficacy of timolol, on Day 14. As this is an exploratory trial, all treatment comparisons will be made at the two-sided $\alpha = 0.05$ level without adjustment for multiple comparisons.

### 9.1 Primary Efficacy Endpoint Analysis

The primary response measure is IOP. Two consecutive measurements of IOP will be taken for each eye, with the right eye measured first. If the first two measurements of either eye differ by more than two mm Hg, a third measurement will be taken for the eye. Depending on the number of measurements required and obtained, the IOP for a given eye will be represented by either the average or the median of the readings.

Baseline is defined as the value of Day -1 prior to treatment. The change from baseline for each eye at each post-baseline assessment is calculated as the IOP at that assessment minus the IOP at the corresponding hour at baseline. The primary efficacy endpoint analysis will be evaluated in the study eye.

The null hypothesis that the mean IOP hour-matching change from baseline is equal to 0 mm Hg will be tested and a corresponding 95% confidence interval will be calculated, based on the 1-sample t-test procedure at each hour on Days 4 and 14. The primary hypothesis is that at least one dose of AGN-227535 ophthalmic solution has a statistically significant within-group mean IOP change from baseline at Hour 2 on Day 14/Exit in the mITT population.

In addition, for exploratory purposes, each dose of AGN-227535 is hypothesized to be non-inferior to Timolol ophthalmic solution 0.5% with respect to change from baseline (follow-up minus baseline) in study eye IOP at each time-matched hour evaluated (hours 0, 2 4, and 8) on Day 4 and Day 14/Exit in the mITT population. The non-inferiority analyses will be performed via analysis of covariance (ANCOVA) which will have treatment as the main effect and the baseline hour-matched IOP as the covariate in the model. When there is no hour-matched baseline value (for example, 30 min post-dose), change from baseline will be calculated from baseline hour 0.

Pairwise treatment group comparisons will be performed for each individual dose of AGN- 227535 versus timolol ophthalmic solution 0.5%. A 2-sided 95% confidence interval (CI) for the treatment difference (AGN-227535 Ophthalmic Solution minus Timolol ophthalmic solution 0.5%) will be constructed based on this ANCOVA model for each AGN-227535 dose. [redacted] If AGN-227535 ophthalmic solution is determined to be non-inferior to Timolol ophthalmic solution 0.5%, further, an attempt to show superiority of AGN-227535 over Timolol will be made. [redacted]

## 9.2 Secondary, Other and Subgroup Efficacy Endpoint Analyses

### 9.2.1 Secondary Efficacy Endpoint Analyses

The mean IOP values will be analyzed similarly as the mean IOP change from baseline as described in section 9.1. That is, summary statistics (N, mean, SD, min and max) of IOP values at each scheduled hour of each visit. Also, analyses of IOP values will be performed using an ANCOVA model with treatment as main effect and hour-matched baseline IOP as covariate

### 9.2.2 Other Efficacy Analyses

For each visit at Baseline, Day 4 and Day 14, a mean diurnal IOP value will be calculated for each subject by taking the average of the IOP value at all hours (0, 2, 4, and 8). The change from baseline mean diurnal IOP value will be analyzed by the ANCOVA model similarly as the primary efficacy endpoint analysis (section 9.1). In addition, the mean diurnal IOP value will be analyzed by the ANCOVA model similarly as the secondary efficacy endpoint analysis (section 9.2.1).

[redacted]

## 9.3 IOP Analysis of Non-Study Eye

Summary statistics of IOP values of non-study eyes will be provided by Day and Hour for each treatment group. Efficacy analysis (sections 9.1, 9.2.1 and 9.2.2) will also be carried out for non-study eye.

### 9.4 Interim Analysis

No interim statistical analysis is planned.

## 10 SAFETY ANALYSIS

Listings will be presented for all of the safety parameters (section 5.4) for Part 1 and 2 of the study, with the exception of adverse events, which will be summarized as described below. For slit-lamp biomicroscope and visual acuity parameters, potentially clinically significant findings will be flagged according to pre-defined criteria in the listings.

### 10.1 Safety Endpoint Analysis

#### 10.1.1 Adverse Events

All adverse events (AEs) reported during the study will be recorded and coded using MedDRA version 20.1 terminology. An AE will be considered as treatment-emergent if it has an onset during the treatment period or is pre-existing and worsens after the first dose of study medication is administered. Subjects may have more than one AE per System Organ Class (SOC) and Preferred Term (PT). At each level of subject summarization, a subject will be counted once if they reported one or more events and will be reported with the highest severity. In cases where severity or relationship is missing, the most conservative approach will be taken (i.e., highest severity and assumed to be related).

For Part 2 of the study, the number, and percent of subjects with adverse events will be tabulated by PT using counts and percentages by treatment groups. This summary will include all treatment emergent adverse events (TEAEs) regardless of causality, treatment-related TEAEs, all serious AEs, treatment-related serious AEs, and all adverse events leading to premature discontinuation of study treatment. A separate summary will also be produced for TEAEs by SOC and PT. For Part 1 of the study, no summary presentation of adverse events will be carried out.

Both parts of the study will present a listing of TEAEs by SOC and PT showing adverse events location (OD, OS or non-ocular), severity, relationship, discontinuation details, and action taken. Also, listing for serious adverse events, and adverse events leading to discontinuation will be generated for both parts of the study.

#### 10.1.2 Electrocardiogram (ECG)

For Part 1 of the study, baseline ECG parameters (Heart rate, PR Interval, QRS Duration, QT Interval, and QTc Interval) along with interpretation whether the subject's ECG is normal or abnormal will be listed by cohort treatment groups.

For Part 2 of the study, ECG parameters from baseline and post-baseline visits will be listed by cohort treatment groups. Change from baseline will also be presented in the listing.

#### 10.1.3 Biomicroscopy

Slit-lamp biomicroscopy will be listed for Part 1 and 2 of the study by cohort treatment groups. Parameters with positive (no zeros or missing) findings will be presented. At any timepoint, a parameter will be omitted if there is no positive finding on either eye. Potentially clinically significant findings will also be flagged on the following category:

- Hour-matched change from baseline is of ≥2 grade worsening

The biomicroscopy Case Report Form (CRF) includes multiple categories, each of which includes multiple parameters to be evaluated. If the CRF's leading question "Were there any biomicroscopic findings?

(Yes/No)" is answered "No", then all parameters in all categories are to be treated as zero score or negative grade, even though they will show as "missing" in the database. If the CRF's leading question is answered "Yes", then the leading question of each category "Were there any /category/ findings (Yes/No)?" must be answered. If the category's leading question is answered "No", then all parameters in the category are to be treated as zero score or negative grade, even though they will show as "missing" in the database. Thus, a parameter with a "missing" value in the database will be treated as either zero score or negative grade under either of the two conditions below:

1. When the CRF's leading question about any biomicroscopic findings is answered "No".
2. When the CRF's leading question about any biomicroscopic findings is answered "Yes" and the category's leading question about any findings is answered "No".

### 10.1.4 Vital Signs

For Part 1 and 2 of the study, vital signs will be listed by cohort treatment groups, visit, hour and measurement position (supine or standing). Change from baseline and change from supine to standing will be presented in the listing.

### 10.1.5 Best Corrected Visual Acuity (BCVA)

BCVA will be listed by cohort treatment groups and visit for both Snellen Equivalent and logMar measurements under standard lighting condition (both Part 1 and 2) and low luminance condition (Part 2 only). Potentially clinically significant findings under the standard lighting condition will be flagged according to the following category:

- Change from baseline is ≥ 15 letters improvement or worsening (logMar)

### 10.1.6 Other Safety Analysis

A number of safety measures, for example: Clinical Laboratory Test, Urine Pregnancy Test, Physical Examination, Visual Fields, Macroscopic Hyperemia, Dilated Fundus Examination, Pupil Size, and Subject Comfort will only be presented in the listing.

## 10.2 Data Monitoring

No formal Data Monitoring Committee is planned. Between dose-escalation groups in Part 1, all available data collected to date will be used to assist in decision making to continue to the next dose or to stop the study. All data collected in Part 1 will be used to select 1 or 2 concentrations of AGN-227535 to evaluate in Part 2. The decision to proceed or to stop the study will be made by the Medical Monitor, the Head of Clinical and the Chief Executive Officer. All decisions will be documented. If needed, IOP summary data as described in Section 9 and data listings or tabulations of non-IOP data for Part 1 will be provided for the decision-making purpose.

# 11 VALIDATION

Derived datasets will be independently reprogrammed by a second programmer. The separate datasets produced by the two programmers must match 100%. Tables and listings will be independently reprogrammed by a second programmer for numeric results. Statisticians will be involved in the process of programming and validating tables that include inferential statistical results.

## 12 GLOSSARY OF ABBREVIATIONS

| | |
|---|---|
| ANOVA | Analysis of Variance |
| ATC | Anatomical Therapeutics Chemical |
| BCVA | Best Corrected Visual Acuity |
| bpm | Beats Per Minute |
| CRF | Case Report Form |
| ECG | Electrocardiogram |
| IOP | Intra-ocular Pressure |
| IWRS | Interactive web-response system |
| LOCF | Last Observation Carried Forward |
| MedDRA | Medical Dictionary for Regulatory Activities |
| Mm Hg | Millimeters of mercury |
| mITT | Modified Intent-to-Treat |
| OD | Right Eye |
| OHT | Ocular Hypertension |
| OS | Left Eye |
| POAG | Primary Open Angle Glaucoma |
| PP | Per Protocol |
| PR | Pulse Rate |
| PT | Preferred Term |
| SAP | Statistical Analysis Plan |
| SAE | Serious Adverse Event |
| SD | Standard Deviation |
| SOC | System Organ Class |
| SOP | Standard Operating Procedure |
| TEAE | Treatment-Emergent Adverse Event |
| WHO | World Health Organization |

## 13 VERSION HISTORY

| Version | Date | Details |
|---|---|---|
| 1.0 | 18 Feb 2021 | SAP Approval |
| 2.0 | 02 Mar 2021 | • Section 13 added<br>• Table of Contents Refreshed |