# CLINICAL STUDY REPORT SYNOPSIS

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| **Study Title** | A Phase 2/3 Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of ADG20 in the Treatment of Ambulatory Participants with Mild or Moderate COVID-19 (STAMP) |
| **Study Number** | ADG20-TRMT-001 |
| **Study Phase** | Phase 2/3 |
| **Compound** | Adintrevimab (ADG20) |
| **Indication** | COVID-19 |
| **Study Design** | Multicenter, efficacy, safety, pharmacokinetics, antiviral activity, randomized, double-blind, placebo-controlled, single-dose study to evaluate 300 mg adintrevimab by IM injection in ambulatory participants with mild or moderate COVID-19 |
| **Study Sponsor** | Invivyd, Inc. (formerly Adagio Therapeutics)<br>1601 Trapelo Road, Suite 178<br>Waltham, MA 02451 USA |
| **Study Initiation Date** | 26-Jul-2021 |
| **Study Completion Date** | 03-Nov-2022 |
| **Regulatory Agency Identifier Number** | US IND: 152327<br>EudraCT: 2020-006082-11<br>ClinicalTrials.gov: NCT04805671 |
| **Report Date** | 18-Apr-2023 |
| This study was conducted in accordance with local and/or national regulations (including all applicable data protection laws and regulations), ICH-GCP, and the ethical principles that have their origin in the Declaration of Helsinki regarding IEC review, informed consent, and the protection of human participants in biomedical research. | |

# STUDY CONDUCT

**STUDY CENTERS:** This study was conducted at 42 centers in 8 countries.

**STUDY STATUS**: Enrollment in STAMP was suspended on 11-Jan-2022 after the emergence and global spread of the Omicron variant in December 2021, against which adintrevimab has reduced in vitro neutralization potency, and it was thought that the 300 mg intramuscular (IM) dose was unlikely to provide benefit for disease due to this variant. The study was terminated early on 03-Nov-2022 due to the Sponsor's decision to discontinue further clinical development of adintrevimab. At the time of study termination, all participants had been followed for at least 6 months post dose.

| First Participant, First Visit | Last Participant, Last Visit | Database Lock Date |
|---|---|---|
| 26-Jul-2021 | 03-Nov-2022 | 21-Nov-2022 |

# METHODOLOGY

## Study Design

STAMP was a Phase 2/3, multicenter, double-blind, placebo-controlled, randomized study evaluating the safety, efficacy, pharmacokinetics, and antiviral activity of adintrevimab in ambulatory participants with mild or moderate COVID-19 who are at high risk of disease progression. Eligible participants were enrolled and randomized 1:1 to receive a single dose of 300 mg adintrevimab or placebo administered by IM injection. Randomization was stratified by age (12 to 17, 18 to 65, and >65 years) and country.

The study enrolled in two parts: Phase 2 to evaluate the initial safety, efficacy, pharmacokinetics (PK), and antiviral activity of adintrevimab versus placebo in adults, and Phase 3, enrolling additional adult and adolescent participants.

Participants received a single IM dose of study drug on Day 1 (Table 1). Participants recorded any injection site reactions (ISRs) using an e-diary (or paper back-up diary) daily on Day 1 post dose through Day 4. Nasopharyngeal (NP) swabs for SARS-CoV-2 RT-qPCR and sequencing were collected on Day 1 (pre dose) and Day 7. Participants were followed via telemedicine visits (via video or phone) and in-person clinic or at home visits through Day 29. Participants were to complete a COVID-19 Symptom Diary (including global impression questions) and collect their vital signs (temperature, oxygen saturation, and heart rate) daily from Day 1 to Day 29. Saliva samples for SARS-CoV-2 RT-qPCR (including viral load and sequencing as appropriate) were collected on Day 1 (pre dose) and Days 3, 5, 7, 11, 14, 21, and 29. Participants were to continue in long-term follow-up through Month 14, with additional visits for safety laboratory tests on Day 90 and Month 6.

**Table 1: Study Treatments Administered**

| Treatment | Dose | Administration Route (Volume) | Dose Regimen | Use |
|---|---|---|---|---|
| Adintrevimab | 300 mg | Intramuscular (3 mL) | Single dose on Day 1 | Experimental |
| Normal saline | Not applicable | Intramuscular (3 mL) | Single dose on Day 1 | Placebo |

## Eligibility Criteria

This study enrolled ambulatory adults aged ≥18 years or adolescents aged 12 to 17 years (inclusive) with mild or moderate COVID-19 who were considered at high risk of disease progression for their age group (as defined in the protocol). Participants had laboratory-confirmed mild or moderate COVID-19 with symptom duration of 5 days or less prior to randomization and a positive SARS-CoV-2 antigen or RT-PCR test taken within 5 days or less prior to randomization. Participants were not enrolled if they had received a prior SARS-CoV-2 vaccine or mAb, had a known active co-infection (eg, influenza, urinary tract infection, etc), or if they were currently or anticipated to be hospitalized or receiving supplemental oxygen.

## Objectives and Endpoints

The primary and secondary objectives and endpoints analyzed for this CSR are provided in Table 2.

**Table 2: Objectives and Endpoints**

| Objectives | Endpoints |
|---|---|
| **Primary** | |
| To evaluate the efficacy of adintrevimab compared to placebo in the treatment of mild or moderate COVID-19 in participants at high risk of disease progression | COVID-19-related hospitalization or all-cause death through Day 29 |
| To evaluate the safety and tolerability of adintrevimab compared to placebo through Day 29 in participants with mild or moderate COVID-19 and high risk of disease progression | Assessment of safety through Day 29 based on:<br>• The incidence of TEAEs<br>• Incidence of solicited injection site reactions through Day 4<br>• Changes from baseline in clinical laboratory tests (ie, CBC with differential, serum chemistry, coagulation)<br>• Changes from baseline in vital signs (body temperature, heart rate, respiration rate, and systolic and diastolic blood pressure) |
| **Secondary** | |
| To evaluate the effect of adintrevimab on the following clinical parameters in participants with mild or moderate COVID-19 and high risk of disease progression:<br>• Severity of COVID-19<br>• COVID-19-related emergency room visits, COVID-19-related hospitalizations, or all-cause death<br>• Time to sustained resolution of COVID-19 symptoms<br>• COVID-19-related medically attended visits<br>• Time to sustained recovery of COVID-19 symptoms<br>• All-cause mortality | • Severe/critical COVID-19 or all-cause death through Day 29<br>• COVID-19-related emergency room visits, COVID-19-related hospitalization, or all-cause death through Day 29<br>• Time to sustained resolution of COVID-19 symptoms through Day 29<br>• COVID-19-related medically attended visit (telemedicine, physician office, urgent care center, emergency room, hospitalization) or all-cause death through Day 29<br>• Time to sustained recovery defined as sustained improvement or resolution of COVID-19 symptoms through Day 29<br>• All-cause death through Day 29, Day 60, and Day 90 |

| Objectives | Endpoints |
|---|---|
| To evaluate the effect of adintrevimab on SARS-CoV-2 viral load and clearance in participants with mild or moderate COVID-19 and high risk of disease progression | • Change from baseline in SARS-CoV-2 viral load ($log_{10}$ copies/mL) to Day 7 (±1) assessed by RT-qPCR from NP samples<br>• Viral load >5 $log_{10}$ copies/mL on Day 7 (±1) based on NP samples<br>• Duration of SARS-CoV-2 viral shedding from Day 1 through Day 29 assessed by RT-qPCR from saliva samples<br>• Change from baseline in SARS-CoV-2 viral load ($log_{10}$ copies/mL) to Days 3, 5, 7, 11, and 14 assessed by RT-qPCR from saliva samples<br>• SARS-CoV-2 viral clearance (Days 5, 7, 11, 14, 21, and 29) assessed by RT-qPCR from saliva samples (and NP samples for Day 7)<br>• SARS-CoV-2 viral load AUC assessed by RT-qPCR from saliva samples from baseline to Day 29 |
| To evaluate the long-term safety and tolerability of adintrevimab compared to placebo in participants with mild or moderate COVID-19 and high risk of disease progression | Assessment of safety based on:<br>• The incidence of TEAEs<br>• Changes from baseline in clinical laboratory tests (ie, CBC with differential, serum chemistry, coagulation)<br>• Changes from baseline in vital signs (body temperature, heart rate, respiration rate, and systolic and diastolic blood pressure) |
| To evaluate the PK of adintrevimab following IM administration | PK parameters of adintrevimab: As data permit, $C_{max}$, $T_{max}$, $AUC_{0\text{-last}}$, $AUC_{0\text{-inf}}$, CL, $V_d$, and $t_{1/2}$. Additional PK parameters may be calculated as data permit. |
| To evaluate the immunogenicity (ADAs) to adintrevimab | Incidence of ADAs against adintrevimab |
| To evaluate the emergence of resistance to adintrevimab | Genotypic characterization of viral isolates for reduced susceptibility to adintrevimab, with phenotypic evaluation as appropriate |

ADA=antidrug antibody; AUC=area under the concentration-time curve; CBC=complete blood count; CL=clearance; $C_{max}$=maximum serum concentration; COVID-19=coronavirus disease 2019; IM=intramuscular(ly); NP=nasopharyngeal; PK=pharmacokinetic(s); RT-PCR=reverse transcription polymerase chain reaction; RT-qPCR=quantitative reverse transcription polymerase chain reaction; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; $t_{1/2}$=half-life; TEAE=treatment-emergent adverse events; $V_d$=volume of distribution.

## Number of Participants (Planned and Analyzed)

The planned enrollment total was approximately 1084 participants; however, enrollment was suspended in January 2022 and the study was terminated on 03-Nov-2022. At the time of enrollment pause, 399 participants were randomized in the study: 198 in the adintrevimab arm and 201 in the placebo arm.

## Statistical and Analytical Methods

A summary of the statistical analysis methods is provided in Version 6 of the study protocol, with details provided in Version 1.0 of the SAP. The data in this report represent the final results of the study. Safety analyses from data collected through 6 months of follow-up are based on a data cutoff date of 08-Aug-2022. A subset of safety analyses was repeated to provide a final

summary of all safety data collected through the last participant's last visit (03-Nov-2022) based on the final database lock on 21-Nov-2022.

Efficacy results summarized in this report are based on a data cutoff date of 28-Mar-2022, after all participants in the primary efficacy analysis population (non-Omicron mFAS) had completed the Day 29 visit, discontinued from study, or missed the Day 29 visit with >34 days on study after dosing, and when all anticipated whole genome sequencing (WGS) results for determination of the baseline SARS-CoV-2 infection isolate were available.

Definitions for the analysis sets used for the analyses of disposition, safety, and efficacy, as well as data cutoff dates for endpoints provided in this report, are summarized in Table 3. This report presents results from the primary and secondary endpoints performed on the primary analysis population (non-Omicron mFAS). Additional analyses of the primary and key secondary endpoints were performed in additional populations, as well as additional analyses to adjust for data handling. Results from these analyses will not be discussed in the report. Details on additional analyses and study populations are included in the SAP.

WGS was used to determine each participant's SARS-CoV-2 infecting variant (eg, Delta, Omicron, and others). The NP sample collected at baseline was to be used for this analysis, but the baseline saliva sample was used if the baseline NP sample was missing or could not be sequenced. If no baseline samples were available, the first available post-baseline NP or saliva sample was to be used. For any participant with a missing WGS result, the SARS-CoV-2 infecting variant was classified as either "suspected non-Omicron" or "suspected Omicron" based on: (1) comparison of the participant's randomization date with the date of the first participant enrolled from the same country with a WGS-confirmed Omicron infection, or (2) if there was no participant with WGS-confirmed Omicron enrolled from the same country in the study, the date of emergence of Omicron in the country based on publicly available epidemiology data.

When applicable, the following prognostic factors were included as baseline covariates in the analysis model for the efficacy endpoints: age (continuous), sex (categorical), baseline qualitative serostatus (categorical as positive; negative), body mass index (BMI; continuous), and baseline viral load from the NP sample (continuous).

In the efficacy analyses, participants were analyzed based on the treatment to which they were randomized. In the safety analyses, participants were analyzed based on the study drug received. No participant received the wrong study drug.

**Table 3: Participant Populations Analyzed With Endpoint Cutoff Dates**

| Defined Analysis Data Sets (in-text abbreviation) | Description | Endpoint/Data Output | Data Cutoff Date |
|---|---|---|---|
| Full Analysis Set **(FAS)** | All randomized participants regardless of whether the participant received study drug | Disposition | 21-Nov-2022 |
| | | Demographics/baseline characteristics | 28-Mar-2022 |
| Modified Full Analysis Set with confirmed or suspected non-Omicron SARS-CoV-2 variant (**non-Omicron mFAS**)[a] | All randomized participants with COVID-19 due to WGS-confirmed or suspected non-Omicron SARS-CoV-2 variants, regardless of whether the participant received study drug | All primary and secondary efficacy endpoints (Table 2) | 28-Mar-2022 |
| Safety Analysis Set **(Safety Set)** | All participants who received any amount of study drug | • Solicited AEs (ISRs)<br>• Vital signs<br>• Laboratory tests | 08-Aug-2022 |
| | | • TEAEs<br>• Deaths<br>• SAEs | 21-Nov-2022 |
| Immunogenicity Set | All participants in the Safety Set who had a valid immunogenicity test result before the dose of study drug, and at least 1 valid result after the dose of study drug | Incidence of ADAs against adintrevimab | 08-Aug-2022 |
| PK Set | All participants in the Safety Set who had at least 1 measurable adintrevimab concentration post administration of study drug | Assessment of serum concentrations and PK parameters of adintrevimab | 08-Aug-2022 |

ADA=antidrug antibody; AE=adverse event; COVID-19=coronavirus disease 2019; FAS=full analysis set; ISR=injection site reaction; mFAS=modified full analysis set; PK=pharmacokinetic(s); SAE=serious adverse event; SARS-CoV-2=severe acute respiratory syndrome coronavirus 2; TEAE=treatment-emergent adverse event.

[a] The abbreviation S (saliva) or NP (nasopharyngeal) was appended to the name of this analysis set indicate the sampling method; these sets included participants with both baseline and postdose samples using that method.

# STUDY PARTICIPANTS

## Participant Disposition

A total of 399 participants were randomized in the study: 198 in the adintrevimab arm and 201 in the placebo arm, comprising the FAS (Table 14.1.1.2). A total of 7 (1.8%) participants did not receive study drug (adintrevimab: n=6; placebo: n=1) and were not included in the Safety Set. Most of the participants randomized to the study (84.2%) were included in the primary efficacy population (the non-Omicron mFAS). Approximately 96% of participants discontinued from the study, primarily (89%) due to study termination by the Sponsor. Besides study termination, the most common reason for study discontinuation was withdrawal of consent (4.5%) in the adintrevimab arm and death (3.5%) in the placebo arm. Most participants completed the Day 29 visit (95.5% and 92.0% in the adintrevimab and placebo arms, respectively) and 6 months of follow-up (86.4% and 89.6%, respectively).

Participant disposition in the primary analysis population (non-Omicron mFAS) was similar to the FAS and balanced between treatment arms (Table 14.1.1.2.1).

## Demographics and Baseline Characteristics

Demographics and baseline characteristics were well-balanced between treatment arms in the FAS (Table 14.1.3.1). Most participants were female (54.4%), White (91.2%), and not Hispanic or Latino (99.5%). One adolescent was enrolled in the adintrevimab arm. The median age was 54 years, with 24.1% over age 65 years and 7.0% over age 75 years, and the median BMI was 30.5 kg/m$^2$. Demographics were similar between the FAS and the non-Omicron mFAS (Table 14.1.3.1.1).

At baseline, 53.4% of participants in the FAS had investigator-determined mild COVID-19 while 46.4% had moderate COVID-19 (Table 14.1.3.2.2). The incidence of mild COVID-19 at baseline was higher in the adintrevimab arm compared with the placebo arm (58.1% vs 48.8%). The most common signs and symptoms of COVID-19 across both treatment arms at baseline were cough (78.4%), fatigue (77.4%), and fever (71.7%). The 3 most common predefined risk factors for progression of COVID-19 were obesity (57.5%), age ≥55 years (48.7%), cardiac disease (13.6%), and Type 1 or Type 2 diabetes (13.6%) (Table 14.1.3.2.4). SARS-CoV-2 serostatus and viral load were also balanced across treatment arms (Table 14.1.3.2.1). A total of 32.8% of participants in the adintrevimab arm and 35.3% in the placebo arm were seropositive for SARS-CoV-2 at baseline based on all available tests, including 18.7% and 17.4% who were seropositive only on a qualitative assay.

COVID-19 severity/associated symptoms (Table 14.1.3.2.2.1), baseline risk factors for disease progression (Table 14.1.3.2.4.1), and SARS-CoV-2 serostatus and viral load (Table 14.1.3.2.1.1) were similar between the FAS and the non-Omicron mFAS.

Of all participants with available WGS results (n=361), 86.7% had SARS-CoV-2 infection due to the Delta variant, with B.1.617.2-like sublineages being the most common (64.3%) (Table 14.1.3.2.5). The remaining participants were infected with the Omicron variant (13.3%), predominantly BA.1 (12.7%). The proportion of participants infected with each VOC was

balanced across the treatment arms. All participants in the non-Omicron mFAS had SARS CoV-2 infection due to the Delta variant or related sublineages.

### Exposure

A total of 192 participants received adintrevimab (Table 14.1.6). All participants received the full IM dose of adintrevimab (300 mg) as planned.

## EFFICACY RESULTS

All efficacy analyses presented below were performed in the primary analysis set (non-Omicron mFAS).

### Primary Endpoint: COVID-19-Related Hospitalization or All-Cause Death Through Day 29

Treatment with adintrevimab provided a clinically meaningful and statistically significant reduction in the risk of COVID-19-related hospitalization or all-cause death through Day 29 compared with placebo in participants with mild or moderate COVID-19 due to non-Omicron SARS-CoV-2 variants who were at high risk for disease progression. The proportion of participants with COVID-19-related hospitalization or all-cause death (primary efficacy endpoint) was 4.7% in the adintrevimab arm compared with 13.8% in the placebo arm, a 65.6% relative risk reduction (Table 4). The standardized risk difference (primary estimand) was -8.7% (95% CI: -14.71, -2.67; p=0.0047), demonstrating a 64.4% standardized relative risk reduction in favor of adintrevimab. There was 1 (0.6%) death through Day 29 in the adintrevimab arm compared with 6 (3.6%) deaths in the placebo arm.

The favorable treatment effect for adintrevimab was observed across key subgroups, including participants with moderate COVID-19 at baseline and those aged >65 years (Figure 14.2.1.2.1).

**Table 4: COVID-19-Related Hospitalization or All-Cause Death Through Day 29 (Non-Omicron mFAS)**

| | ADG20 (N=169) | Placebo (N=167) | ADG20 vs. Placebo |
|---|---|---|---|
| COVID-19-Related Hospitalization or All-Cause Death | 8 (4.7) | 23 (13.8) | |
| Death | 1 (0.6) | 6 (3.6) | |
| Hospitalization | 8 (4.7) | 22 (13.2) | |
| Risk Difference[a] | | | -9.0% |
| 95% CI[b] | | | (-15.64, -2.99) |
| Relative Risk Reduction[a] | | | 65.6% |
| Standardized Risk Difference[c] | 4.8% | 13.5% | -8.7% |
| 95% CI | | | (-14.71, -2.67) |
| 2-sided p-value | | | 0.0047 |
| Standardized Relative Risk Reduction[c] | | | 64.4% |
| 95% CI | | | (22.77, 83.59) |
| Alive and No COVID-19-Related Hospitalization | 157 (92.9) | 141 (84.4) | |
| Missing Outcome[d] | 4 (2.4) | 3 (1.8) | |

CI=confidence interval.
Note: Hospitalization is defined as >=24 hours stay in a hospital or acute care facility (includes emergency rooms, intensive care units, acute care facilities created for COVID-19 pandemic hospitalization needs, or other acute care facilities). Missing status on COVID-19-related hospitalization or all-cause death is imputed as not having a COVID-19-related hospitalization or all-cause death.
[a] Based on observed data.
[b] CI from the Miettinen-Nurminen method.
[c] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
[d] Missing outcome is determined for participants who had no reported qualifying event for the primary endpoint through Day 29 and who discontinued from study prior to Day 29.
Source Data: ADSL, ADBL, ADRESP, Listing 16.2.6.3.2, 16.2.7.5
Data cutoff: 28MAR2022 Executed: 30JUN2022

## Key Secondary Endpoints: Clinical Outcomes

### Severe/Critical COVID-19 or All-Cause Death and COVID-19-Related Emergency Room Visits, COVID-19-Related Hospitalizations, or All-Cause Death Through Day 29

Treatment with adintrevimab provided a clinically meaningful and statistically significant reduction compared with placebo in the risk of both severe/critical COVID-19 or all-cause death and COVID-19-related ER visits, COVID-19-related hospitalizations, or all-cause death through Day 29. The proportion of participants in each treatment arm that met criteria were the same for both endpoints (4.7% in the adintrevimab arm compared with 13.8% in the placebo arm), with a 65.6% relative risk reduction (Table 5 and Table 6). The standardized risk difference was -8.7% (95% CI: -14.71, -2.67; p=0.0047), demonstrating a 64.4% standardized relative risk reduction in favor of adintrevimab.

**Table 5: Severe/Critical COVID-19 or All-Cause Death Through Day 29 (Non-Omicron mFAS)**

| | ADG20 (N=169) | Placebo (N=167) | ADG20 vs. Placebo |
|---|---|---|---|
| Severe/Critical COVID-19 or All-Cause Death | 8 (4.7) | 23 (13.8) | |
| Death | 1 (0.6) | 6 (3.6) | |
| Severe/Critical COVID-19 | 8 (4.7) | 22 (13.2) | |
| Imputed Due to COVID-19-Related Hospitalization | 4 (2.4) | 5 (3.0) | |
| Risk Difference[a] | | | -9.0% |
| 95% CI[b] | | | (-15.64, -2.99) |
| Relative Risk Reduction[a] | | | 65.6% |
| Standardized Risk Difference[c] | 4.8% | 13.5% | -8.7% |
| 95% CI | | | (-14.71, -2.67) |
| 2-sided p-value | | | 0.0047 |
| Standardized Relative Risk Reduction[c] | | | 64.4% |
| 95% CI | | | (22.77, 83.59) |
| Alive and No Severe/Critical COVID-19 | 157 (92.9) | 141 (84.4) | |
| Missing Outcome[d] | 4 (2.4) | 3 (1.8) | |

CI=confidence interval.
Note: COVID-19 Severity is based on Investigator's assessment per protocol definition. Regardless of Investigator assessment, if the participant met the primary endpoint, the assessment of COVID-19 severity is imputed as severe/critical COVID-19.
[a] Based on observed data.
[b] CI from the Miettinen-Nurminen method.
[c] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as $\log_{10}$ copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
[d] Missing outcome is determined for participants who had no reported qualifying event for key secondary estimand 2a through Day 29 and who discontinued from study prior to Day 29.
Source Data: ADSL, ADBL, ADRESP, Listing 16.2.6.3.3, 16.2.7.5
Data cutoff: 28MAR2022 Executed: 30JUN2022 19:35

**Table 6: COVID-19-Related Emergency Room Visits, COVID-19-Related Hospitalization, or All-Cause Death Through Day 29 (Non-Omicron mFAS)**

| | ADG20 (N=169) | Placebo (N=167) | ADG20 vs. Placebo |
|---|---|---|---|
| COVID-19-Related Emergency Room Visits, Hospitalization or All-Cause Death | 8 (4.7) | 23 (13.8) | |
| Death | 1 (0.6) | 6 (3.6) | |
| Hospitalization | 8 (4.7) | 22 (13.2) | |
| Emergency Room Visit | 0 | 0 | |
| Risk Difference[a] | | | -9.0% |
| 95% CI[b] | | | (-15.64, -2.99) |
| Relative Risk Reduction[a] | | | 65.6% |
| Standardized Risk Difference[c] | 4.8% | 13.5% | -8.7% |
| 95% CI | | | (-14.71, -2.67) |
| 2-sided p-value | | | 0.0047 |
| Standardized Relative Risk Reduction[c] | | | 64.4% |
| 95% CI | | | (22.77, 83.59) |
| Alive and No COVID-19-Related Hospitalization or COVID-19-Related Emergency Room Visit | 157 (92.9) | 141 (84.4) | |
| Missing Outcome[d] | 4 ( 2.4) | 3 ( 1.8) | |

CI=confidence interval.
Note: COVID-19-related emergency room visits, COVID-19-related hospitalization, or all-cause death through Day 29 is defined as any stay in a hospital or acute care facility regardless of duration (includes emergency rooms, intensive care units, acute care facilities created for COVID-19 pandemic hospitalization needs, or other acute care facilities) for attention to worsening signs or symptoms attributed to COVID-19, in the opinion of the investigator, or all-cause death through Day 29. Missing outcome is imputed as not having a COVID-19-related emergency room visit, COVID-19-related hospitalization or all-cause death.
[a] Based on observed data.
[b] CI from the Miettinen-Nurminen method.
[c] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
[d] Missing outcome is determined for participants who had no reported qualifying event for key secondary estimand 3a through Day 29 and who discontinued from study prior to Day 29.
Source Data: ADSL, ADBL, ADRESP, Listing 16.2.6.3.4, 16.2.7.5
Data cutoff: 28MAR2022 Executed: 30JUN2022 19:35

### COVID-19-Related Medically Attended Visits or All-Cause Death Through Day 29

There was a clinically meaningful reduction in the risk of COVID-19-related medically attended visits or all-cause death through Day 29 following treatment with adintrevimab compared with placebo in participants in the primary efficacy population. The proportion of participants with COVID-19-related medically attended visits or all-cause death was 5.3% in the adintrevimab arm compared with 17.4% in the placebo arm, a 69.3% relative risk reduction (Table 14.2.6.1.1). The standardized risk difference was -11.3% (95% CI: -17.86, -4.81; p=0.0007), demonstrating a 67.3% standardized relative risk reduction in favor of adintrevimab.

### All-Cause Death and COVID-19-Related Death

There was a clinically meaningful reduction in the incidence of all-cause death in participants who received adintrevimab (1 participant [0.6%]) compared with placebo (7 participants [4.2%]) (p=0.0361) (Table 14.2.6.3). Likewise, the incidence of COVID-19-related deaths was numerically lower in participants who received adintrevimab (0.6%) compared with placebo (3.0%). All COVID-19-related deaths and all but 1 of the deaths due to any cause occurred on or prior to Day 29; the remaining death (in the placebo arm) occurred between Days 60 and 90.

### Time to Sustained Resolution and Sustained Recovery of COVID-19 Symptoms

Sustained recovery was defined as either a sustained improvement or resolution of COVID-19 symptoms. The median time to sustained recovery of COVID-19 symptoms through Day 29 was modestly reduced in participants who received adintrevimab (11 days [95% CI: 9, 14]) compared with those who received placebo (14 days [95% CI: 12, 17]) (p=0.0938) (Table 14.2.6.2). The median time to sustained resolution of COVID-19 symptoms was also an independent secondary endpoint. It was numerically lower in the adintrevimab arm at 13 days (95% CI: 10, 15) compared with 16 days (95% CI: 13, 20) in the placebo arm (p=0.0781) (Table 14.2.6.6).

## Other Secondary Endpoint: SARS-CoV-2 Viral Load and Clearance

Median baseline viral load assessed by saliva samples was available for 296 participants in the non-Omicron mFAS-S (adintrevimab: 147; placebo: 149) and was 5.62 $\log_{10}$ copies/mL for adintrevimab and 5.37 $\log_{10}$ copies/mL for placebo (Table 14.2.5.4). Median baseline viral load assessed by NP samples was available for 316 participants in the non-Omicron mFAS-NP (adintrevimab: 157; placebo: 159) and was 7.17 $\log_{10}$ copies/mL for adintrevimab and 7.24 $\log_{10}$ copies/mL for placebo (Table 14.2.5.1).

### Assessments of Viral Load

Treatment with adintrevimab provided a greater reduction in SARS-CoV-2 viral load from baseline to Day 5 compared with placebo as assessed by saliva samples (Table 14.2.5.4), resulting in a mean change from baseline of -2.25 vs -1.30 $\log_{10}$ copies/mL, respectively. The adjusted least square means (LSM) difference was -0.82 (95% CI: -1.33, -0.30; p=0.0019) in favor of adintrevimab. A similar trend was observed in saliva samples on Day 7 (p=0.016). No trends were observed in viral load change from baseline for adintrevimab versus placebo based on NP samples. However, post baseline NP samples to assess viral load change from baseline were only collected on Day 7. The small number of timepoints available limited detection of any meaningful treatment differences in viral load (Table 14.2.5.1).

The proportion of participants with a SARS-CoV-2 viral load >4 or >5 $\log_{10}$ copies/mL as assessed by NP samples at Day 7 was lower in the adintrevimab arm (48.6% and 33.1%, respectively) compared with placebo (58.9% and 43.8%, respectively) (Table 14.2.5.2).

Mean SARS-COV-2 viral load AUC from Day 1 to 29 as assessed by saliva samples was lower in participants who received adintrevimab (49.96 $\log_{10}$ copies/mL ([SD: 36.544]) compared with placebo (57.60 $\log_{10}$ copies/mL [SD: 37.522]); however, the adjusted LSM difference was small and not clinically meaningful (-6.93 $\log_{10}$ copies/mL [SE: 4.349]; p=0.1124) (Table 14.2.5.7).

### Viral Shedding

The median duration of viral shedding of SARS-CoV-2 from Day 1 through Day 29 as assessed by saliva samples was numerically shorter in those who received adintrevimab (14 days [95% CI: 14, 21]) compared with those who received placebo (21 days [95% CI: 14, 21]) (Table 14.2.5.6.1).

### Viral Clearance

The proportion of participants who achieved sustained viral clearance of SARS-CoV-2 as assessed by saliva samples was numerically higher with adintrevimab compared with placebo at each timepoint, most notably on Day 5 (15.3% vs 6.7%, respectively), with a standardized risk difference of 8.2% (95% CI: 1.15, 15.31) on Day 5 (Table 14.2.5.5.1). The same trend was observed when considering the subset of participants with a higher baseline SARS-CoV-2 NP viral load (>5 $\log_{10}$ copies/mL) (n=251) (Table 14.2.5.5.2); whereas no clear trend was observed in participants with a lower baseline SARS-CoV-2 viral load (≤5 $\log_{10}$ copies/mL) (n=44) (Table 14.2.5.5.3).

## Other Secondary Endpoint: Viral Resistance

Genotypic resistance analysis focused on spike amino acid variants associated with loss of SARS-CoV-2 susceptibility to adintrevimab. Three (3.2%) participants in the adintrevimab arm had treatment-emergent variants with substitutions at G504 detected at ≥15% VAF, whereas these variants were not observed in the placebo arm (Table 14.2.8.2).

No other changes associated with reduced adintrevimab binding or activity (ie, known amino acid substitutions at R403, D405, G502, V503, and Y505) were observed at ≥15% VAF in any participant.

## IMMUNOGENICITY RESULTS

Samples were tested for ADA from 137 participants who received adintrevimab and no participants who received placebo. ADAs were infrequent with adintrevimab, and no trends were observed with ADA titers. Overall, 12 (8.8%) participants tested positive for ADAs at any postdose timepoint during the study, including 6 (4.4%) participants who also tested positive at pre dose (Table 14.2.8.1.1). No participant who was positive for ADA at baseline had an increase in titers post dosing (Table 14.2.8.1.2). There were 7 (5.1%) participants who had treatment-emergent ADAs; ADAs were observed by Day 29 in all but 1 of these participants. Two participants (1.5%) continued to be positive for ADAs at Month 6. All participants with treatment-emergent ADAs had titers <90 on all confirmatory assays (Table 14.2.8.1.3). Among participants with treatment-emergent ADAs, there were no reports of immunologically based AEs, such as hypersensitivity reactions (including delayed hypersensitivity), anaphylaxis, or cytokine release syndrome. One participant with treatment-emergent ADA experienced a COVID-19-related hospitalization (SAE: COVID-19 pneumonia) on Day 6; the event was considered recovered on Day 19.

# PHARMACOKINETICS RESULTS

Adintrevimab was well absorbed following a single 300 mg IM injection. The median serum concentration was similar at Day 7 (35.8 µg/mL) and Day 29 (31.7 µg/mL) (Table 14.3.1.3). Due to sparse sampling, other PK parameters cannot be calculated. Estimations based on population PK modeling are reported separately.

# SAFETY RESULTS

The primary safety objective of the study was evaluation of safety and tolerability through Day 29. Long-term safety through the end of study (Month 14) was evaluated as a secondary endpoint. Due to early study termination, the majority of participants were not followed through this time point. The median duration of follow-up at the final analysis was 342 days (range: 1 to 432) (Table 14.1.1.2). An interim analysis of safety was performed after all participants had the opportunity to be followed for 6 months post dose. Vital sign, laboratory tests, and solicited AE (ISRs) data were summarized at this 6-month interim analysis (data cutoff: 08-Aug-2022). A final safety analysis was performed when all participants had completed or discontinued the study. All TEAEs, including deaths and SAEs, were summarized for this final analysis (data cutoff: 21-Nov-2022).

AEs were coded using MedDRA Version 24.0. ISRs through Day 4 were solicited from participants through an e-diary and/or contacts with site personnel. All other AEs were unsolicited, including ISRs reported after Day 4. Hypersensitivity reactions occurring through Day 4 were considered AESIs; hypersensitivity reactions occurring after Day 4 were captured as TEAEs. In this study, worsening or sequelae of the index case of COVID-19 (the primary efficacy endpoint of the study) was to be recorded as an AE only if the event met SAE criteria. Such events are included in the analysis of deaths and SAEs and, thus, may overlap with the primary efficacy endpoint.

## Adverse Events

### Brief Summary of Adverse Events

Adintrevimab was generally safe and well-tolerated in participants with mild or moderate COVID-19. The incidences of TEAEs, Grade 3 to 5 AEs, and SAEs were lower among participants who received adintrevimab compared with placebo (Table 7). Most TEAEs in the adintrevimab arm were mild or moderate in severity. The incidence of solicited ISR AEs was similar in both treatment arms. SAEs occurred in approximately twice as many participants receiving placebo compared with adintrevimab, consistent with the increased hospitalizations due to COVID-19 in placebo participants; there were no drug-related SAEs. There was 1 death (0.5%) due to an AE through 29 days in the adintrevimab arm, compared with 6 (3.0%) deaths in the placebo arm; an additional death due to an AE occurred in each study arm after Day 29. None of the deaths due to AEs were considered related to study drug. No hypersensitivity reactions were reported in the study.

**Table 7: Overall Adverse Event Summary – Final Analysis (Safety Set)**

| Parameter | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192) n (%) | Placebo (N=200) n (%) | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
| Participants with Any TEAE | 47 (24.5) | 62 (31.0) | 75 (39.1) | 87 (43.5) |
| Any Unsolicited TEAE | 29 (15.1) | 44 (22.0) | 60 (31.3) | 74 (37.0) |
| Any Solicited TEAE | 25 (13.0) | 19 (9.5) | 25 (13.0) | 19 (9.5) |
| Any Study Drug-Related TEAE [a] | 26 (13.5) | 19 (9.5) | 26 (13.5) | 19 (9.5) |
| Any ≥ Grade 3 TEAE [b] | 11 (5.7) | 29 (14.5) | 16 (8.3) | 31 (15.5) |
| Any SAE [c] | 9 (4.7) | 28 (14.0) | 14 (7.3) | 29 (14.5) |
| Any Study Drug-Related SAE [a][c] | 0 | 0 | 0 | 0 |
| Any TEAE Leading to Death | 1 (0.5) | 6 (3.0) | 2 (1.0) | 7 (3.5) |
| Any Study Drug-Related TEAE Leading to Death [a] | 0 | 0 | 0 | 0 |
| Any TEAE Leading to Study Drug Discontinuation | 0 | 0 | 0 | 0 |
| Participants with Any MAAE | 13 (6.8) | 29 (14.5) | 27 (14.1) | 42 (21.0) |
| Participants with any Hypersensitivity Reaction | 0 | 0 | 0 | 0 |
| Any Hypersensitivity Reactions through Day 4 (AESI) | 0 | 0 | 0 | 0 |

AESI=Adverse Event of Special Interest; ISR=Injection Site Reaction; MAAE=Medically Attended Adverse Event; TEAE=Treatment-Emergent Adverse Event; SAE=Serious Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Hypersensitivity reactions are determined by medical adjudication based on the narrow and broad terms of the Standardized MedDRA Queries hypersensitivity, anaphylactic reaction, and angioedema. Adverse events are coded using MedDRA Version 24.0.
[a] Missing relationship to study drug is imputed as 'Related'. All solicited AEs (ISRs) were assumed to be 'Related'.
[b] Unsolicited AE severity (Grade) is based on the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017). Solicited AE (ISR) severity is based on the FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007).
[c] Solicited AEs (ISRs) do not have seriousness assigned and are therefore not included in this category.
Source Data: ADSL, ADAE, Listing 16.2.7.1, 16.2.7.2, 16.2.7.3, 16.2.7.4, 16.2.7.5
Database lock: 2022-11-22 EXECUTED: 2022-12-01:13:18:00

### Frequently Reported Adverse Events

The most frequently reported TEAEs were solicited TEAEs (ISRs), which occurred at a slightly higher incidence in the adintrevimab arm (13.0%) compared with placebo (9.5%) (Table 14.3.1.3). All solicited ISRs were mild or moderate in severity. The most frequently reported (>2%) TEAEs (solicited or unsolicited) in each treatment arm are summarized in Table 8. All unsolicited TEAEs were considered unrelated to study drug, except for abdominal pain in 1 participant in the adintrevimab arm (Table 14.3.1.6).

The incidence of Grade 3 to 5 unsolicited TEAEs was lower in the adintrevimab arm than in the placebo arm through Day 29 (5.7% vs 14.5%) and through Month 14 (8.3% vs 15.5%) (Table 7).

All TEAEs reported through the final analysis of the study are summarized in Table 14.3.1.2.1. Nonserious AEs that occurred in greater than 5.0% of participants are presented Table 14.3.1.2.4.

**Table 8: Treatment-Emergent Adverse Events (Solicited and Unsolicited) Occurring in >2% of Participants in Either Arm by Preferred Term Through Day 29 and Through Month 14 (Safety Set)**

| | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| Preferred Term | ADG20 (N=192) n (%) | Placebo (N=200) n (%) | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
| Participants with Any TEAE | 47 (24.5) | 62 (31.0) | 75 (39.1) | 87 (43.5) |
| Injection site pain | 23 (12.0) | 16 ( 8.0) | 23 (12.0) | 16 ( 8.0) |
| COVID-19 pneumonia | 8 ( 4.2) | 24 (12.0) | 8 ( 4.2) | 24 (12.0) |
| COVID-19 | 0 | 0 | 8 ( 4.2) | 3 ( 1.5) |
| Back pain | 2 ( 1.0) | 3 ( 1.5) | 5 ( 2.6) | 4 ( 2.0) |
| Injection site erythema | 3 ( 1.6) | 6 ( 3.0) | 3 ( 1.6) | 6 ( 3.0) |

TEAE=Treatment-Emergent Adverse Event.
Note: Preferred terms are presented by decreasing incidence in the ADG20 arm through Month 14. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once for each applicable Preferred Term. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1
Database lock: 2022-11-22 EXECUTED: 2022-12-01:13:18:13

### Deaths and Serious Adverse Events

#### Deaths

There were no study drug–related deaths due to AEs reported in either treatment arm (Table 7). Overall, 9 deaths due to an AE occurred during the study, 2 (1.0%) in the adintrevimab arm compared with 7 (3.5%) in the placebo arm (Table 14.3.1.9). The leading cause of death was COVID-19, which occurred in 1 (0.5%) participant in the adintrevimab arm and 5 (2.5%) participants in the placebo arm (Table 14.3.1.10). All COVID-19-related deaths occurred by Day 29 (Table 14.3.1.9). The remaining deaths occurred in 2 participants in the placebo arm (1 due to “sudden death” and 1 due to multi-organ dysfunction syndrome) and 1 participant in the adintrevimab arm (cerebrovascular accident).

#### Serious Adverse Events

No study drug–related SAEs were reported in either treatment arm (Table 7). The incidence of SAEs due to any cause was lower among participants who received adintrevimab compared with placebo (4.7% vs 14.0%) (Table 9). The most frequently reported SAE was COVID-19 pneumonia, which occurred at a lower incidence among participants who received adintrevimab (4.2%) compared with placebo (12.0%).

The incidences of non–COVID-19-related SAEs were similar in each treatment arm through the end of the study (3.6% vs 4.0% in the adintrevimab and placebo arms, respectively) (Table 14.3.1.5.1). No trend in the types of events reported was identified.

**Table 9: Serious Treatment-Emergent Adverse Events by System Organ Class and Preferred Term Through Day 29 and Through Month 14 (Safety Set)**

| | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| System Organ Class<br>Preferred Term | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Participants with any serious TEAE | 9 (4.7) | 28 (14.0) | 14 (7.3) | 29 (14.5) |
| Infections and infestations | 8 (4.2) | 24 (12.0) | 10 (5.2) | 24 (12.0) |
| COVID-19 pneumonia | 8 (4.2) | 24 (12.0) | 8 (4.2) | 24 (12.0) |
| Pneumonia bacterial | 1 (0.5) | 0 | 2 (1.0) | 0 |
| Pneumonia | 0 | 0 | 1 (0.5) | 0 |
| Clostridium difficile colitis | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Listeriosis | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Meningitis bacterial | 0 | 0 | 0 | 1 (0.5) |
| Pneumonia klebsiella | 0 | 0 | 0 | 1 (0.5) |
| Cardiac disorders | 0 | 0 | 2 (1.0) | 0 |
| Acute myocardial infarction | 0 | 0 | 1 (0.5) | 0 |
| Angina unstable | 0 | 0 | 1 (0.5) | 0 |
| Gastrointestinal disorders | 1 (0.5) | 0 | 1 (0.5) | 0 |
| Gastrointestinal haemorrhage | 1 (0.5) | 0 | 1 (0.5) | 0 |
| Hiatus hernia | 1 (0.5) | 0 | 1 (0.5) | 0 |
| Injury, poisoning and procedural complications | 0 | 0 | 1 (0.5) | 0 |
| Ankle fracture | 0 | 0 | 1 (0.5) | 0 |
| Metabolism and nutrition disorders | 0 | 0 | 1 (0.5) | 0 |
| Diabetes mellitus inadequate control | 0 | 0 | 1 (0.5) | 0 |
| Nervous system disorders | 0 | 2 (1.0) | 1 (0.5) | 2 (1.0) |
| Cerebrovascular accident | 0 | 0 | 1 (0.5) | 0 |
| Brain oedema | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Syncope | 0 | 1 (0.5) | 0 | 1 (0.5) |
| General disorders and administration site conditions | 0 | 1 (0.5) | 0 | 2 (1.0) |
| Multiple organ dysfunction syndrome | 0 | 0 | 0 | 1 (0.5) |
| Sudden death | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 0 | 1 (0.5) |
| Arthritis | 0 | 0 | 0 | 1 (0.5) |
| Respiratory, thoracic, and mediastinal disorders | 0 | 2 (1.0) | 0 | 2 (1.0) |
| Pulmonary embolism | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Respiratory failure | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Vascular disorders | 0 | 1 (0.5) | 0 | 1 (0.5) |
| Orthostatic hypotension | 0 | 1 (0.5) | 0 | 1 (0.5) |

TEAE=Treatment-Emergent Adverse Event.

Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA Version 24.0.

Source Data: ADSL, ADAE, Listing 16.2.7.3
Database lock: 2022-11-22 EXECUTED: 2022-12-01:13:18:55

### Clinical Laboratory Evaluation

There were no trends in the types or timing of PCS laboratory value changes from baseline indicative of a specific safety risk for adintrevimab based on results reported through the 6-month interim analysis (Table 14.3.2.3).

### Vital Signs Evaluation

There were no trends in the types or timing of PCS vital sign value changes from baseline indicative of a specific safety risk for adintrevimab, including during the postdose monitoring period, based on results reported through the 6-month interim analysis (Table 14.3.3.2).

## CONCLUSIONS

### Efficacy

Treatment with adintrevimab provides a statistically significant and clinically meaningful reduction in the risk of COVID-19-related hospitalization or all-cause death through Day 29 compared with placebo in adults with mild or moderate COVID-19 who are at high risk for disease progression. The following key results were observed:

- The proportion of participants with COVID-19-related hospitalization or all-cause death (primary efficacy endpoint) was 4.7% in the adintrevimab arm compared with 13.8% in the placebo arm, a 65.6% relative risk reduction. The standardized risk difference was -8.7% (95% CI: -14.71, -2.67; p=0.0047), demonstrating a 64.4% standardized relative risk reduction in favor of adintrevimab.
- The favorable treatment effect for adintrevimab was consistent across key subgroups, including participants with moderate COVID-19 at baseline and participants aged >65 years.

### Safety

Adintrevimab administered by IM injection at a dose of 300 mg was generally safe and well-tolerated by adults with mild to moderate COVID-19 at high risk for disease progression. No unexpected safety signals were observed. The following key results were observed:

- The incidences of TEAEs, Grade 3 to 5 AEs, SAEs, and SAEs leading to death were lower among participants who received adintrevimab compared with placebo. This is consistent with the lower incidence of severe COVID-19 and COVID-19-related deaths in the adintrevimab arm.
- The most frequently reported TEAEs attributed to adintrevimab were ISRs, which occurred in 13% of participants. All ISRs were mild to moderate in severity.
- No deaths or SAEs attributed to adintrevimab were reported.
- There were no trends in laboratory or vital sign results that were indicative of a safety risk for adintrevimab.

# PUBLICATIONS

Mahoney K, Narayan K, Betancourt N, et al. Clinical and virologic outcomes with early adintrevimab monoclonal antibody therapy in mild and moderate COVID-19. Poster presented at: IDWeek; October 19-23, 2022; Washington, DC.

Popejoy M, Mahoney K, Betancourt N, et al. Results from the phase 2/3 randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of adintrevimab (ADG20) in the treatment of ambulatory participants with mild or moderate COVID-19 (STAMP). Poster presented at: ASM Microbe; June 9-13, 2022; Washington, DC.

Rubino CM, Cammarata AP, Ambrose PG, et al. Adintrevimab population pharmacokinetics in phase 1 and phase 2/3 COVID-19 prevention and treatment study participants. Poster 591 presented at: IDWeek; October 19-23, 2022; Washington, DC.

Tarbell E, Van Wart SA, Popejoy M, et al. Integrated quantitative systems pharmacology characterizing viral dynamics after intramuscular adintrevimab administration in participants with mild to moderate coronavirus disease (COVID-19). Poster presented at: IDWeek; October 19-23, 2022; Washington, DC.

# SUPPLEMENTAL TABLES AND FIGURES

## Tables

| Output Number | Title |
|---|---|
| 14.1.1.2 | Disposition (Full Analysis Set) |
| 14.1.1.2.1 | Disposition (Non-Omicron mFAS) |
| 14.1.3.1 | Demographics (Full Analysis Set) |
| 14.1.3.1.1 | Demographics (Non-Omicron mFAS) |
| 14.1.3.2.1 | Baseline Disease Characteristics - SARS-CoV-2 Tests and Respiratory Pathogen Assay (Full Analysis Set) |
| 14.1.3.2.2 | Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity (Full Analysis Set) |
| 14.1.3.2.4 | Baseline Disease Characteristics - Protocol-Defined Risk Factors for COVID-19 Progression by Age Group at Baseline (Full Analysis Set) |
| 14.1.3.2.1.1 | Baseline Disease Characteristics - SARS-CoV-2 Tests and Respiratory Pathogen Assay (Non-Omicron mFAS) |
| 14.1.3.2.2.1 | Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity (Non-Omicron mFAS) |
| 14.1.3.2.4.1 | Baseline Disease Characteristics - Protocol-Defined Risk Factors for COVID-19 Progression by Age Group at Baseline (Non-Omicron mFAS) |
| 14.1.3.2.5 | Baseline Disease Characteristics - SARS-CoV-2 Variants (Full Analysis Set) |
| 14.1.6 | Study Drug Exposure (Safety Set) |
| 14.2.5.1 | Change From Baseline in SARS-CoV-2 Viral Load ($log_{10}$ copies/mL) Assessed by RT-qPCR From Day 7 Nasopharyngeal Samples by Timepoint (Non-Omicron mFAS-NP) |
| 14.2.5.2 | Proportion of Participants With High SARS-CoV-2 Viral Load Assessed by RT-qPCR From Day 7 Nasopharyngeal Samples by Timepoint (Non-Omicron mFAS-NP) |
| 14.2.5.4 | Change From Baseline in SARS-CoV-2 Viral Load ($log_{10}$ copies/mL) Assessed by RT-qPCR From Saliva Samples by Timepoint (Non-Omicron mFAS-S) |
| 14.2.5.5.1 | Proportion of Participants With SARS-CoV-2 Viral Clearance Assessed by RT-qPCR From Saliva Samples by Timepoint (Non-Omicron mFAS-S) |
| 14.2.5.5.2 | Proportion of Participants With SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint Within Baseline Subgroup NP Viral Load >5 $log_{10}$ copies/mL (Non-Omicron mFAS-S) |
| 14.2.5.5.3 | Proportion of Participants With SARS-CoV-2 Viral Clearance Assessed by RT-qPCR From Saliva Samples by Timepoint Within Baseline Subgroup NP Viral Load ≤5 $log_{10}$ copies/mL (Non-Omicron mFAS-S) |
| 14.2.5.6.1 | Duration of SARS-CoV-2 Viral Shedding Assessed by RT-qPCR From Saliva Samples From Day 1 Through Day 29 (Non-Omicron mFAS-S) |
| 14.2.5.7 | SARS-CoV-2 Viral Load AUC Assessed by RT-qPCR From Saliva Samples by Timepoint (Non-Omicron mFAS-S) |
| 14.2.6.1.1 | COVID-19-Related Medically Attended Visits or All-Cause Death Through Day 29 (Non-Omicron mFAS) |
| 14.2.6.2 | Time to Sustained Recovery of COVID-19 Symptoms Through Day 29 (Non-Omicron mFAS) |

| Output Number | Title |
|---|---|
| 14.2.6.3 | All-Cause Death and COVID-19-Related Death (Non-Omicron mFAS) |
| 14.2.6.6 | Time to Sustained Resolution of COVID-19 Symptoms Through Day 29 (Non-Omicron mFAS) |
| 14.2.8.1.1 | Anti-Drug Antibodies Confirmatory Assay Results by Timepoint (Immunogenicity Set) |
| 14.2.8.1.2 | Treatment-Emergent Anti-Drug Antibodies by Timepoint (Immunogenicity Set) |
| 14.2.8.1.3 | Summary of Anti-Drug Antibodies Titer Results by Timepoint for Participants Positive for Anti-Drug Antibodies (Immunogenicity Set) |
| 14.2.8.2 | Baseline, Post-Baseline, and Treatment-Emergent Variations at Critical Amino Acid Positions Associated With ADG20 Resistance (>15% Allele Frequencies) (Full Analysis Set) |
| 14.2.9.1 | Summary of ADG20 Serum Concentrations (µg/mL) - Time (PK Analysis Set) |
| 14.3.1.2.1 | Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14 (Safety Set) |
| 14.3.1.2.4 | Non-Serious Treatment-Emergent Adverse Events Occurring in >5% of Participants in ADG20 Group by System Organ Class and Preferred Term (Safety Set) |
| 14.3.1.3 | Solicited Adverse Events of Injection Site Reactions Through Day 4 (Safety Set) |
| 14.3.1.5.1 | Serious Treatment-Emergent Adverse Events (Excluding COVID-19-Related PTs) by System Organ Class and Preferred Term Through Day 29 and Through Month 14 (Safety Set) |
| 14.3.1.6 | Study Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Through Day 29 and Through Month 14 (Safety Set) |
| 14.3.1.9 | Serious Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term Through Day 29 and Through Month 14 (Safety Set) |
| 14.3.1.10 | Summary of Cause of Death Through Day 29 and Through Month 14 (Safety Set) |
| 14.3.2.3 | Potentially Clinically Significant Changes From Baseline in Post-Baseline Laboratory Parameters by Visit (Safety Set) |
| 14.3.3.2 | Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit (Safety Set) |

## Figures

| Output Number | Title |
|---|---|
| 14.2.1.2.1 | Forest Plot of COVID-19-Related Hospitalization or All-Cause Death Through Day 29 (Estimand 1a) by Subgroup (Non-Omicron mFAS) |

Table 14.1.1.2
Disposition
Full Analysis Set

| Parameter | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Number of Participants Randomized | 198 | 201 | 399 |
| mFAS-non-Omicron | 169 (85.4) | 167 (83.1) | 336 (84.2) |
| mFAS-Omicron | 29 (14.6) | 34 (16.9) | 63 (15.8) |
| mFAS-PCR | 184 (92.9) | 193 (96.0) | 377 (94.5) |
| mFAS-NP | 178 (89.9) | 186 (92.5) | 364 (91.2) |
| mFAS-S | 166 (83.8) | 175 (87.1) | 341 (85.5) |
| mFAS-non-Omicron-PCR | 161 (81.3) | 163 (81.1) | 324 (81.2) |
| mFAS-non-Omicron-NP | 157 (79.3) | 159 (79.1) | 316 (79.2) |
| mFAS-non-Omicron-S | 147 (74.2) | 149 (74.1) | 296 (74.2) |
| mFAS-Omicron-PCR | 23 (11.6) | 30 (14.9) | 53 (13.3) |
| mFAS-Omicron-NP | 21 (10.6) | 27 (13.4) | 48 (12.0) |
| mFAS-Omicron-S | 19 ( 9.6) | 26 (12.9) | 45 (11.3) |
| Per-Protocol Set | 163 (82.3) | 158 (78.6) | 321 (80.5) |
| Safety Set | 192 (97.0) | 200 (99.5) | 392 (98.2) |
| Randomized but Not Treated | 6 ( 3.0) | 1 ( 0.5) | 7 ( 1.8) |
| Adverse Event | 0 | 0 | 0 |
| Death | 0 | 0 | 0 |
| Investigator's Discretion | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 |
| Trial Site Terminated by Sponsor | 0 | 0 | 0 |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal by Parent/Guardian | 0 | 0 | 0 |

mFAS=modified Full Analysis Set; NP=nasopharyngeal; S=saliva; PCR=polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a]Calculated as (data cutoff date - randomization date + 1) for participants who were ongoing at the time of data cutoff or (end of study date - randomization date + 1) for participants who discontinued study.
Source Data: ADSL, Listing 16.2.1.2, 16.2.3.1, 16.2.3.2 EXECUTED: 2022-12-01:13:17:27
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_1_1_2_disp.sas

Table 14.1.1.2
Disposition
Full Analysis Set

| Parameter | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Withdrawal by Participant | 3 ( 1.5) | 0 | 3 ( 0.8) |
| Other | 3 ( 1.5) | 1 ( 0.5) | 4 ( 1.0) |

mFAS=modified Full Analysis Set; NP=nasopharyngeal; S=saliva; PCR=polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a]Calculated as (data cutoff date - randomization date + 1) for participants who were ongoing at the time of data cutoff or (end of study date - randomization date + 1) for participants who discontinued study.
Source Data: ADSL, Listing 16.2.1.2, 16.2.3.1, 16.2.3.2 EXECUTED: 2022-12-01:13:17:27
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_1_1_2_disp.sas

Table 14.1.1.2
Disposition
Full Analysis Set

| Parameter | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Received Any Study Treatment | 192 (97.0) | 200 (99.5) | 392 (98.2) |
| Study Treatment Dosing Not Completed | 0 | 0 | 0 |
| Adverse Event | 0 | 0 | 0 |
| Investigator's Discretion | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 |
| Withdrawal by Parent/Guardian | 0 | 0 | 0 |
| Withdrawal by Participant | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Completed Day 29 Visit | 189 (95.5) | 185 (92.0) | 374 (93.7) |
| Completed Day 60 Visit | 187 (94.4) | 188 (93.5) | 375 (94.0) |
| Completed Day 90 Visit | 175 (88.4) | 178 (88.6) | 353 (88.5) |
| Completed Month 6 Visit | 171 (86.4) | 180 (89.6) | 351 (88.0) |
| Completed Month 11 Visit | 129 (65.2) | 141 (70.1) | 270 (67.7) |
| Completed Month 14 Visit (Completed Study) | 3 ( 1.5) | 5 ( 2.5) | 8 ( 2.0) |
| Early Termination from Study | 190 (96.0) | 191 (95.0) | 381 (95.5) |
| Death | 2 ( 1.0) | 7 ( 3.5) | 9 ( 2.3) |
| Participant's Request | 0 | 1 ( 0.5) | 1 ( 0.3) |
| Withdrawal of Consent | 9 ( 4.5) | 6 ( 3.0) | 15 ( 3.8) |
| Lost to Follow-up | 1 ( 0.5) | 0 | 1 ( 0.3) |
| Other | 178 (89.9) | 177 (88.1) | 355 (89.0) |
| Duration of Follow-up (days)[a] | | | |
| n | 198 | 201 | 399 |

mFAS=modified Full Analysis Set; NP=nasopharyngeal; S=saliva; PCR=polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a]Calculated as (data cutoff date - randomization date + 1) for participants who were ongoing at the time of data cutoff or (end of study date - randomization date + 1) for participants who discontinued study.
Source Data: ADSL, Listing 16.2.1.2, 16.2.3.1, 16.2.3.2 EXECUTED: 2022-12-01:13:17:27
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_1_1_2_disp.sas

Table 14.1.1.2
Disposition
Full Analysis Set

| Parameter | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Median | 344.5 | 341.0 | 342.0 |
| Min, Max | 1, 432 | 1, 428 | 1, 432 |

mFAS=modified Full Analysis Set; NP=nasopharyngeal; S=saliva; PCR=polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a]Calculated as (data cutoff date - randomization date + 1) for participants who were ongoing at the time of data cutoff or (end of study date - randomization date + 1) for participants who discontinued study.
Source Data: ADSL, Listing 16.2.1.2, 16.2.3.1, 16.2.3.2 EXECUTED: 2022-12-01:13:17:27
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_1_1_2_disp.sas

Table 14.1.1.2.1
Disposition
mFAS-non-Omicron

| Parameter | ADG20 (N=169) n (%) | Placebo (N=167) n (%) | Overall (N=336) n (%) |
|---|---|---|---|
| mFAS-non-Omicron | 169 ( 100) | 167 ( 100) | 336 ( 100) |
| mFAS-non-Omicron-PCR | 161 (95.3) | 163 (97.6) | 324 (96.4) |
| mFAS-non-Omicron-NP | 157 (92.9) | 159 (95.2) | 316 (94.0) |
| mFAS-non-Omicron-S | 147 (87.0) | 149 (89.2) | 296 (88.1) |
| Per-Protocol Set | 163 (96.4) | 158 (94.6) | 321 (95.5) |
| Randomized but Not Treated | 3 ( 1.8) | 0 | 3 ( 0.9) |
| Adverse Event | 0 | 0 | 0 |
| Death | 0 | 0 | 0 |
| Investigator's Discretion | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 |
| Trial Site Terminated by Sponsor | 0 | 0 | 0 |
| Study Terminated by Sponsor | 0 | 0 | 0 |
| Withdrawal by Parent/Guardian | 0 | 0 | 0 |
| Withdrawal by Participant | 3 ( 1.8) | 0 | 3 ( 0.9) |
| Other | 0 | 0 | 0 |
| Received Any Study Treatment | 166 (98.2) | 167 ( 100) | 333 (99.1) |
| Study Treatment Dosing Not Completed | 0 | 0 | 0 |
| Adverse Event | 0 | 0 | 0 |
| Investigator's Discretion | 0 | 0 | 0 |
| Protocol Deviation | 0 | 0 | 0 |

mFAS=modified Full Analysis Set; NP=nasopharyngeal; S=saliva; PCR=polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a]Calculated as (data cutoff date - randomization date + 1) for participants who were ongoing at the time of data cutoff or (end of study date - randomization date + 1) for participants who discontinued study.
Source Data: ADSL, Listing 16.2.1.2, 16.2.3.1, 16.2.3.2 EXECUTED: 2022-12-01:13:17:18
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_1_1_2_1_disp.sas

Table 14.1.1.2.1
Disposition
mFAS-non-Omicron

| Parameter | ADG20 (N=169) n (%) | Placebo (N=167) n (%) | Overall (N=336) n (%) |
|---|---|---|---|
| Withdrawal by Parent/Guardian | 0 | 0 | 0 |
| Withdrawal by Participant | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Completed Day 29 Visit | 163 (96.4) | 154 (92.2) | 317 (94.3) |
| Completed Day 60 Visit | 162 (95.9) | 157 (94.0) | 319 (94.9) |
| Completed Day 90 Visit | 156 (92.3) | 151 (90.4) | 307 (91.4) |
| Completed Month 6 Visit | 152 (89.9) | 151 (90.4) | 303 (90.2) |
| Completed Month 11 Visit | 118 (69.8) | 124 (74.3) | 242 (72.0) |
| Completed Month 14 Visit (Completed Study) | 3 ( 1.8) | 5 ( 3.0) | 8 ( 2.4) |
| Early Termination from Study | 161 (95.3) | 157 (94.0) | 318 (94.6) |
| Death | 2 ( 1.2) | 7 ( 4.2) | 9 ( 2.7) |
| Participant's Request | 0 | 1 ( 0.6) | 1 ( 0.3) |
| Withdrawal of Consent | 8 ( 4.7) | 4 ( 2.4) | 12 ( 3.6) |
| Lost to Follow-up | 1 ( 0.6) | 0 | 1 ( 0.3) |
| Other | 150 (88.8) | 145 (86.8) | 295 (87.8) |
| Duration of Follow-up (days)[a] | | | |
| n | 169 | 167 | 336 |
| Median | 348.0 | 347.0 | 347.5 |
| Min, Max | 1, 432 | 1, 428 | 1, 432 |

mFAS=modified Full Analysis Set; NP=nasopharyngeal; S=saliva; PCR=polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a]Calculated as (data cutoff date - randomization date + 1) for participants who were ongoing at the time of data cutoff or (end of study date - randomization date + 1) for participants who discontinued study.
Source Data: ADSL, Listing 16.2.1.2, 16.2.3.1, 16.2.3.2 EXECUTED: 2022-12-01:13:17:18
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_1_1_2_1_disp.sas

Table 14.1.3.1
Demographics
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Age (years) | | | |
| n | 198 | 201 | 399 |
| Mean | 54.1 | 52.6 | 53.3 |
| SD | 15.25 | 16.16 | 15.71 |
| Median | 55.0 | 53.0 | 54.0 |
| Q1, Q3 | 43.0, 65.0 | 41.0, 65.0 | 42.0, 65.0 |
| Min, Max | 15, 93 | 18, 91 | 15, 93 |
| Age Categories (years) | | | |
| 12 - 17 | 1 ( 0.5) | 0 | 1 ( 0.3) |
| 18 - 65 | 150 (75.8) | 152 (75.6) | 302 (75.7) |
| > 65 | 47 (23.7) | 49 (24.4) | 96 (24.1) |
| >= 50 | 123 (62.1) | 117 (58.2) | 240 (60.2) |
| > 55 | 97 (49.0) | 95 (47.3) | 192 (48.1) |
| > 70 | 31 (15.7) | 26 (12.9) | 57 (14.3) |
| > 75 | 15 ( 7.6) | 13 ( 6.5) | 28 ( 7.0) |
| Sex | | | |
| Male | 85 (42.9) | 97 (48.3) | 182 (45.6) |
| Female | 113 (57.1) | 104 (51.7) | 217 (54.4) |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14010301.sas Executed: 30JUN2022 19:25

Table 14.1.3.1
Demographics
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Country | | | |
| Brazil | 0 | 2 ( 1.0) | 2 ( 0.5) |
| Bulgaria | 101 (51.0) | 100 (49.8) | 201 (50.4) |
| Germany | 1 ( 0.5) | 1 ( 0.5) | 2 ( 0.5) |
| Greece | 9 ( 4.5) | 11 ( 5.5) | 20 ( 5.0) |
| Poland | 13 ( 6.6) | 13 ( 6.5) | 26 ( 6.5) |
| Romania | 18 ( 9.1) | 18 ( 9.0) | 36 ( 9.0) |
| South Africa | 20 (10.1) | 20 (10.0) | 40 (10.0) |
| Ukraine | 36 (18.2) | 36 (17.9) | 72 (18.0) |
| Race | | | |
| White | 183 (92.4) | 181 (90.0) | 364 (91.2) |
| Black or African American | 14 ( 7.1) | 17 ( 8.5) | 31 ( 7.8) |
| Asian | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 1 ( 0.5) | 3 ( 1.5) | 4 ( 1.0) |
| Ethnicity | | | |
| Hispanic or Latino | 0 | 2 ( 1.0) | 2 ( 0.5) |
| Not Hispanic or Latino | 198 ( 100) | 199 (99.0) | 397 (99.5) |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14010301.sas Executed: 30JUN2022 19:25

Table 14.1.3.1
Demographics
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Weight (kg) | | | |
| n | 198 | 201 | 399 |
| Mean | 83.63 | 88.37 | 86.02 |
| SD | 16.880 | 18.612 | 17.909 |
| Median | 84.00 | 88.00 | 85.00 |
| Q1, Q3 | 73.00, 94.00 | 76.00, 98.00 | 74.20, 95.00 |
| Min, Max | 46.0, 150.0 | 50.0, 154.0 | 46.0, 154.0 |
| Height (cm) | | | |
| n | 198 | 201 | 399 |
| Mean | 168.58 | 169.94 | 169.26 |
| SD | 8.558 | 9.637 | 9.132 |
| Median | 168.00 | 170.00 | 169.00 |
| Q1, Q3 | 162.00, 175.00 | 162.00, 176.00 | 162.00, 176.00 |
| Min, Max | 150.0, 193.0 | 145.0, 198.0 | 145.0, 198.0 |
| Body Mass Index (BMI) (kg/m^2) | | | |
| n | 198 | 201 | 399 |
| Mean | 29.37 | 30.47 | 29.93 |
| SD | 5.200 | 5.099 | 5.173 |
| Median | 30.40 | 30.67 | 30.47 |
| Q1, Q3 | 25.56, 32.00 | 27.58, 32.79 | 26.64, 32.41 |
| Min, Max | 16.9, 46.5 | 15.6, 45.7 | 15.6, 46.5 |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14010301.sas Executed: 30JUN2022 19:25

Table 14.1.3.1
Demographics
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| BMI Subgroups (Adult) (kg/m^2) [a] | 197 | 201 | 398 |
| >= 25 | 154 (78.2) | 172 (85.6) | 326 (81.9) |
| >= 30 | 110 (55.8) | 119 (59.2) | 229 (57.5) |
| >= 40 | 4 ( 2.0) | 10 ( 5.0) | 14 ( 3.5) |
| BMI Subgroup (Adolescent) [b] | 1 | 0 | 1 |
| >= 85th percentile for Age and Sex | 1 ( 100) | 0 | 1 ( 100) |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14010301.sas Executed: 30JUN2022 19:25

Table 14.1.3.1.1
Demographics
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Age (years) | | | |
| n | 169 | 167 | 336 |
| Mean | 56.1 | 54.9 | 55.5 |
| SD | 14.82 | 14.93 | 14.87 |
| Median | 58.0 | 56.0 | 57.0 |
| Q1, Q3 | 46.0, 67.0 | 45.0, 66.0 | 45.0, 66.0 |
| Min, Max | 22, 93 | 18, 90 | 18, 93 |
| Age Categories (years) | | | |
| 12 - 17 | 0 | 0 | 0 |
| 18 - 65 | 122 (72.2) | 121 (72.5) | 243 (72.3) |
| > 65 | 47 (27.8) | 46 (27.5) | 93 (27.7) |
| >= 50 | 114 (67.5) | 110 (65.9) | 224 (66.7) |
| > 55 | 93 (55.0) | 89 (53.3) | 182 (54.2) |
| > 70 | 31 (18.3) | 23 (13.8) | 54 (16.1) |
| > 75 | 15 ( 8.9) | 11 ( 6.6) | 26 ( 7.7) |
| Sex | | | |
| Male | 70 (41.4) | 82 (49.1) | 152 (45.2) |
| Female | 99 (58.6) | 85 (50.9) | 184 (54.8) |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030101.sas Executed: 30JUN2022 19:33

Table 14.1.3.1.1
Demographics
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Country | | | |
| Brazil | 0 | 1 ( 0.6) | 1 ( 0.3) |
| Bulgaria | 95 (56.2) | 92 (55.1) | 187 (55.7) |
| Germany | 1 ( 0.6) | 1 ( 0.6) | 2 ( 0.6) |
| Greece | 8 ( 4.7) | 10 ( 6.0) | 18 ( 5.4) |
| Poland | 12 ( 7.1) | 12 ( 7.2) | 24 ( 7.1) |
| Romania | 16 ( 9.5) | 13 ( 7.8) | 29 ( 8.6) |
| South Africa | 3 ( 1.8) | 3 ( 1.8) | 6 ( 1.8) |
| Ukraine | 34 (20.1) | 35 (21.0) | 69 (20.5) |
| Race | | | |
| White | 167 (98.8) | 164 (98.2) | 331 (98.5) |
| Black or African American | 1 ( 0.6) | 1 ( 0.6) | 2 ( 0.6) |
| Asian | 0 | 0 | 0 |
| American Indian or Alaska Native | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 |
| Other | 1 ( 0.6) | 2 ( 1.2) | 3 ( 0.9) |
| Ethnicity | | | |
| Hispanic or Latino | 0 | 1 ( 0.6) | 1 ( 0.3) |
| Not Hispanic or Latino | 169 ( 100) | 166 (99.4) | 335 (99.7) |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030101.sas Executed: 30JUN2022 19:33

Table 14.1.3.1.1
Demographics
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Weight (kg) | | | |
| n | 169 | 167 | 336 |
| Mean | 82.92 | 89.06 | 85.97 |
| SD | 15.297 | 18.856 | 17.407 |
| Median | 84.00 | 88.90 | 85.00 |
| Q1, Q3 | 73.00, 93.00 | 76.00, 98.00 | 74.95, 95.00 |
| Min, Max | 46.0, 122.0 | 50.0, 154.0 | 46.0, 154.0 |
| Height (cm) | | | |
| n | 169 | 167 | 336 |
| Mean | 168.16 | 170.16 | 169.15 |
| SD | 8.677 | 9.116 | 8.941 |
| Median | 167.00 | 170.00 | 169.00 |
| Q1, Q3 | 162.00, 174.00 | 163.00, 176.00 | 162.00, 175.00 |
| Min, Max | 150.0, 193.0 | 150.0, 192.0 | 150.0, 193.0 |
| Body Mass Index (BMI) (kg/m^2) | | | |
| n | 169 | 167 | 336 |
| Mean | 29.29 | 30.60 | 29.94 |
| SD | 4.757 | 5.043 | 4.938 |
| Median | 30.41 | 30.71 | 30.47 |
| Q1, Q3 | 25.66, 32.00 | 27.58, 33.46 | 26.90, 32.61 |
| Min, Max | 16.9, 42.2 | 15.6, 45.7 | 15.6, 45.7 |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030101.sas Executed: 30JUN2022 19:33

Table 14.1.3.1.1
Demographics
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| BMI Subgroups (Adult) (kg/m^2) [a] | 169 | 167 | 336 |
| >= 25 | 133 (78.7) | 143 (85.6) | 276 (82.1) |
| >= 30 | 96 (56.8) | 98 (58.7) | 194 (57.7) |
| >= 40 | 1 ( 0.6) | 9 ( 5.4) | 10 ( 3.0) |
| BMI Subgroup (Adolescent) [b] | 0 | 0 | 0 |
| >= 85th percentile for Age and Sex | 0 | 0 | 0 |

BMI=body mass index; Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group, except where noted.
BMI=(body weight in kilograms)/(height in meters)^2
[a] Based on calculated BMI. Percentages are based on the number of participants age >=18 years in each treatment group.
[b] Based on CDC growth charts. Percentages are based on the number of participants age 12-17 years in each treatment group.
Source Data: ADSL, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030101.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Was a local SARS-CoV-2 test performed? | | | |
| Yes | 198 ( 100) | 201 ( 100) | 399 ( 100) |
| No | 0 | 0 | 0 |
| Local Sample Specimen Type | | | |
| Nasopharyngeal | 182 (91.9) | 185 (92.0) | 367 (92.0) |
| Nasal | 15 ( 7.6) | 16 ( 8.0) | 31 ( 7.8) |
| Oral/Oropharyngeal | 1 ( 0.5) | 0 | 1 ( 0.3) |
| Buccal | 0 | 0 | 0 |
| Saliva | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Local SARS-CoV-2 Assay Type | | | |
| RT-PCR | 56 (28.3) | 71 (35.3) | 127 (31.8) |
| Antigen Test | 142 (71.7) | 130 (64.7) | 272 (68.2) |
| Other | 0 | 0 | 0 |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics – SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Local SARS-CoV-2 Test Result | | | |
| Positive | 198 ( 100) | 201 ( 100) | 399 ( 100) |
| Negative | 0 | 0 | 0 |
| Inconclusive | 0 | 0 | 0 |
| Number of Days from Local Test Sample Collected to Randomization [a] | | | |
| 0 Days | 127 (64.1) | 114 (56.7) | 241 (60.4) |
| 1-2 Days | 55 (27.8) | 64 (31.8) | 119 (29.8) |
| 3-5 Days | 16 ( 8.1) | 23 (11.4) | 39 ( 9.8) |
| >5 Days | 0 | 0 | 0 |
| n | 198 | 201 | 399 |
| Mean | 0.7 | 0.9 | 0.8 |
| SD | 1.12 | 1.21 | 1.17 |
| Median | 0.0 | 0.0 | 0.0 |
| Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 | 0.0, 1.0 |
| Min, Max | 0, 5 | 0, 5 | 0, 5 |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Central Lab SARS-CoV-2 RT-qPCR NP Swab | | | |
| Positive | 180 (90.9) | 186 (92.5) | 366 (91.7) |
| Negative | 12 ( 6.1) | 14 ( 7.0) | 26 ( 6.5) |
| Missing | 6 ( 3.0) | 1 ( 0.5) | 7 ( 1.8) |
| Viral load (log10 copies/mL) | | | |
| n | 192 | 200 | 392 |
| Mean | 6.35 | 6.44 | 6.40 |
| SD | 2.300 | 2.343 | 2.319 |
| Median | 7.01 | 7.05 | 7.04 |
| Q1, Q3 | 5.29, 7.85 | 5.45, 8.17 | 5.42, 8.05 |
| Min, Max | 0, 10.0 | 0, 10.1 | 0, 10.1 |
| >5 log10 copies/mL | 151 (76.3) | 156 (77.6) | 307 (76.9) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Central Lab SARS-CoV-2 RT-qPCR Saliva Sample | | | |
| Positive | 168 (84.8) | 175 (87.1) | 343 (86.0) |
| Negative | 20 (10.1) | 17 ( 8.5) | 37 ( 9.3) |
| Missing | 10 ( 5.1) | 9 ( 4.5) | 19 ( 4.8) |
| Viral load (log10 copies/mL) | | | |
| n | 188 | 192 | 380 |
| Mean | 4.89 | 4.78 | 4.84 |
| SD | 2.219 | 2.004 | 2.111 |
| Median | 5.35 | 5.09 | 5.21 |
| Q1, Q3 | 3.78, 6.40 | 3.88, 6.05 | 3.81, 6.20 |
| Min, Max | 0, 9.3 | 0, 9.0 | 0, 9.3 |
| >5 log10 copies/mL | 105 (53.0) | 104 (51.7) | 209 (52.4) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics – SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Central Lab Baseline Serology Status (SARS-CoV-2 antibody) | | | |
| Overall [b] | | | |
| Positive | 65 (32.8) | 71 (35.3) | 136 (34.1) |
| Negative | 128 (64.6) | 129 (64.2) | 257 (64.4) |
| Missing | 5 ( 2.5) | 1 ( 0.5) | 6 ( 1.5) |
| Qualitative Assay | | | |
| Positive | 37 (18.7) | 35 (17.4) | 72 (18.0) |
| Negative | 156 (78.8) | 164 (81.6) | 320 (80.2) |
| Missing | 5 ( 2.5) | 2 ( 1.0) | 7 ( 1.8) |
| IgG Assay | | | |
| Positive | 62 (31.3) | 59 (29.4) | 121 (30.3) |
| Negative | 131 (66.2) | 141 (70.1) | 272 (68.2) |
| Missing | 5 ( 2.5) | 1 ( 0.5) | 6 ( 1.5) |
| IgA Assay | | | |
| Positive | 29 (14.6) | 32 (15.9) | 61 (15.3) |
| Negative | 164 (82.8) | 168 (83.6) | 332 (83.2) |
| Missing | 5 ( 2.5) | 1 ( 0.5) | 6 ( 1.5) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| MNT Assay | | | |
| Detected (>=10 AU/mL) | 155 (78.3) | 156 (77.6) | 311 (77.9) |
| Not Detected (<10 AU/mL) | 32 (16.2) | 41 (20.4) | 73 (18.3) |
| Missing | 11 ( 5.6) | 4 ( 2.0) | 15 ( 3.8) |
| MNT Detected (AU/mL) | | | |
| n | 155 | 156 | 311 |
| Mean | 350.22 | 608.87 | 479.96 |
| SD | 1725.849 | 2592.002 | 2203.562 |
| Geometric Mean | 35.74 | 35.78 | 35.76 |
| Geometric SD | 4.861 | 5.889 | 5.352 |
| Median | 16.00 | 16.00 | 16.00 |
| Min, Max | 10.0, 18593.0 | 10.0, 17863.0 | 10.0, 18593.0 |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Respiratory Pathogen Panel | | | |
| Participants with: | | | |
| Adenovirus | 0 | 0 | 0 |
| Chlamydophila pneumoniae | 0 | 0 | 0 |
| Human Rhinovirus/Enterovirus | 5 ( 2.5) | 2 ( 1.0) | 7 ( 1.8) |
| Influenza A | 0 | 0 | 0 |
| Influenza B | 0 | 0 | 0 |
| Bordetella pertussis | 0 | 0 | 0 |
| Human Coronavirus 229E | 0 | 0 | 0 |
| Human Coronavirus HKU1 | 0 | 0 | 0 |
| Human Coronavirus NL63 | 0 | 0 | 0 |
| Human Coronavirus OC43 | 0 | 0 | 0 |
| Human Metapneumovirus | 1 ( 0.5) | 0 | 1 ( 0.3) |
| Human Parainfluenza Virus 1 | 0 | 0 | 0 |
| Human Parainfluenza Virus 2 | 0 | 0 | 0 |
| Human Parainfluenza Virus 3 | 0 | 0 | 0 |
| Human Parainfluenza Virus 4 | 1 ( 0.5) | 0 | 1 ( 0.3) |
| Influenza A subtype H1/2009 | 0 | 0 | 0 |
| Influenza A subtype H1 | 0 | 0 | 0 |
| Influenza A subtype H3 | 0 | 0 | 0 |
| Mycoplasma pneumoniae | 0 | 0 | 0 |
| Respiratory Syncytial Virus | 1 ( 0.5) | 0 | 1 ( 0.3) |
| None | 191 (96.5) | 199 (99.0) | 390 (97.7) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030201.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.2
Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Duration (days) from Symptom Onset to Randomization | | | |
| n | 198 | 201 | 399 |
| Mean | 2.4 | 2.4 | 2.4 |
| SD | 1.34 | 1.35 | 1.34 |
| Median | 2.0 | 2.0 | 2.0 |
| Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 | 2.0, 3.0 |
| Min, Max | 0, 8 | 0, 5 | 0, 8 |
| 0-3 days | 156 (78.8) | 156 (77.6) | 312 (78.2) |
| 4-5 days | 41 (20.7) | 45 (22.4) | 86 (21.6) |
| >5 days | 1 ( 0.5) | 0 | 1 ( 0.3) |
| Duration (days) from Symptom Onset to Study Drug Administration | | | |
| n | 192 | 200 | 392 |
| Mean | 2.4 | 2.4 | 2.4 |
| SD | 1.37 | 1.35 | 1.36 |
| Median | 2.0 | 2.0 | 2.0 |
| Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 | 2.0, 3.0 |
| Min, Max | 0, 8 | 0, 5 | 0, 8 |
| 0-3 days | 150 (75.8) | 155 (77.1) | 305 (76.4) |
| 4-5 days | 41 (20.7) | 45 (22.4) | 86 (21.6) |
| >5 days | 1 ( 0.5) | 0 | 1 ( 0.3) |

Note: Percentages are based on the number of participants in each treatment group.
[a] Based on participant response to the question "In the past 24 hours, what was the severity of your overall COVID-19-related symptoms at their worst?"
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t1401030202.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.2
Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Diary: Day 1 COVID-19 Symptoms (Baseline) | | | |
| Any Symptom | 186 (93.9) | 194 (96.5) | 380 (95.2) |
| Any Severe Symptom | 80 (40.4) | 76 (37.8) | 156 (39.1) |
| Any Moderate Symptom and No Severe Symptoms | 93 (47.0) | 96 (47.8) | 189 (47.4) |
| Any Mild Symptom and No Severe/Moderate Symptoms | 13 ( 6.6) | 22 (10.9) | 35 ( 8.8) |
| Cough | 147 (74.2) | 166 (82.6) | 313 (78.4) |
| Fatigue | 152 (76.8) | 157 (78.1) | 309 (77.4) |
| Fever | 134 (67.7) | 152 (75.6) | 286 (71.7) |
| Muscle or Body Aches | 123 (62.1) | 131 (65.2) | 254 (63.7) |
| Congestion | 124 (62.6) | 124 (61.7) | 248 (62.2) |
| Headache | 120 (60.6) | 124 (61.7) | 244 (61.2) |
| Chills | 91 (46.0) | 101 (50.2) | 192 (48.1) |
| Sore Throat | 70 (35.4) | 92 (45.8) | 162 (40.6) |
| Loss of Sense of Smell | 80 (40.4) | 80 (39.8) | 160 (40.1) |
| Loss of Sense of Taste | 81 (40.9) | 78 (38.8) | 159 (39.8) |
| Shortness of Breath or Difficulty Breathing with Exertion | 52 (26.3) | 63 (31.3) | 115 (28.8) |
| Nausea | 44 (22.2) | 48 (23.9) | 92 (23.1) |
| Diarrhea | 36 (18.2) | 31 (15.4) | 67 (16.8) |
| Shortness of Breath or Difficulty Breathing at Rest | 24 (12.1) | 19 ( 9.5) | 43 (10.8) |
| Vomiting | 12 ( 6.1) | 16 ( 8.0) | 28 ( 7.0) |

Note: Percentages are based on the number of participants in each treatment group.
[a] Based on participant response to the question "In the past 24 hours, what was the severity of your overall COVID-19-related symptoms at their worst?"
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t1401030202.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.2
Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Diary: Day 1 Overall Severity of COVID-19-Related Symptoms [a] | | | |
| None | 7 ( 3.5) | 4 ( 2.0) | 11 ( 2.8) |
| Mild | 86 (43.4) | 80 (39.8) | 166 (41.6) |
| Moderate | 87 (43.9) | 107 (53.2) | 194 (48.6) |
| Severe | 6 ( 3.0) | 4 ( 2.0) | 10 ( 2.5) |
| Investigator-Determined Baseline COVID-19 Severity | | | |
| SARS-CoV-2 Infection without Symptoms | 0 | 0 | 0 |
| Mild COVID-19 | 115 (58.1) | 98 (48.8) | 213 (53.4) |
| Moderate COVID-19 | 83 (41.9) | 102 (50.7) | 185 (46.4) |
| Severe COVID-19 | 0 | 0 | 0 |
| Critical COVID-19 | 0 | 0 | 0 |
| Missing | 0 | 1 ( 0.5) | 1 ( 0.3) |
| Programmatically-Determined Baseline COVID-19 Severity | | | |
| SARS-CoV-2 Infection without Symptoms | 0 | 1 ( 0.5) | 1 ( 0.3) |
| Mild COVID-19 | 93 (47.0) | 87 (43.3) | 180 (45.1) |
| Moderate COVID-19 | 74 (37.4) | 91 (45.3) | 165 (41.4) |
| Severe COVID-19 | 24 (12.1) | 19 ( 9.5) | 43 (10.8) |
| Critical COVID-19 | 0 | 0 | 0 |
| Missing | 7 ( 3.5) | 3 ( 1.5) | 10 ( 2.5) |

Note: Percentages are based on the number of participants in each treatment group.
[a] Based on participant response to the question "In the past 24 hours, what was the severity of your overall COVID-19-related symptoms at their worst?"
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t1401030202.sas Executed: 30JUN2022 19:33

Table 14.1.3.2.4
Baseline Disease Characteristics – Protocol-Defined Risk Factors for COVID-19 Progression by Age Group at Baseline
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Adults (Age >=18 years) | 197 | 201 | 398 |
| Age >55 years | 98 (49.7) | 96 (47.8) | 194 (48.7) |
| Obesity (BMI >=30 kg/m2) [a] | 110 (55.8) | 119 (59.2) | 229 (57.5) |
| Diabetes (Type 1 or Type 2) | 28 (14.2) | 26 (12.9) | 54 (13.6) |
| Chronic Kidney Disease | 1 ( 0.5) | 2 ( 1.0) | 3 ( 0.8) |
| Chronic Lung Disease | 16 ( 8.1) | 18 ( 9.0) | 34 ( 8.5) |
| Cardiac Disease | 24 (12.2) | 30 (14.9) | 54 (13.6) |
| Sickle Cell Disease or Thalassemia | 0 | 0 | 0 |
| Solid Organ or Blood Stem Cell Transplant Recipients | 0 | 0 | 0 |
| Other Immunodeficiency Due to Underlying Illness or Immunosuppressant Medication | 9 ( 4.6) | 7 ( 3.5) | 16 ( 4.0) |
| Down Syndrome | 0 | 0 | 0 |
| Stroke or Cerebrovascular Disease Affecting Blood Flow to the Brain | 5 ( 2.5) | 9 ( 4.5) | 14 ( 3.5) |
| Substance Use Disorder | 4 ( 2.0) | 6 ( 3.0) | 10 ( 2.5) |
| Pregnant | 0 | 0 | 0 |
| >=1 Protocol-Defined Risk Factor | 197 ( 100) | 201 ( 100) | 398 ( 100) |
| >=2 Protocol-Defined Risk Factors | 74 (37.6) | 81 (40.3) | 155 (38.9) |
| >=3 Protocol-Defined Risk Factors | 21 (10.7) | 24 (11.9) | 45 (11.3) |

BMI=body mass index.
Note: Percentages for each risk factor are based on the number of participants in each age group (Adults or Adolescents) within each treatment group. Adolescents and pregnant participants were enrolled in the Phase 3 portion of the study only. Age at Screening was used for categorization as Adult or Adolescent.
[a] BMI=(body weight in kilograms)/(height in meters)^2.
[b] Based on CDC growth charts.
Source Data: ADSL, ADMH, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t1401030204.sas Executed: 30JUN2022 19:34

Table 14.1.3.2.4
Baseline Disease Characteristics — Protocol-Defined Risk Factors for COVID-19 Progression by Age Group at Baseline
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) | Overall (N=399) |
|---|---|---|---|
| Adolescents (Age 12-17 years) | 1 | 0 | 1 |
| BMI >85th Percentile for Age and Sex [a][b] | 1 ( 100) | | 1 ( 100) |
| Diabetes (Type 1 or Type 2) | 0 | | 0 |
| Chronic Kidney Disease | 0 | | 0 |
| Sickle Cell Disease or Thalassemia | 0 | | 0 |
| Congenital or Acquired Heart Disease | 0 | | 0 |
| Neurodevelopmental Disorders | 0 | | 0 |
| Medically-Related Technological Dependence | 0 | | 0 |
| Asthma, Reactive Airway or Other Chronic Respiratory Disease | 0 | | 0 |
| Solid Organ or Blood Stem Cell Transplant Recipients | 0 | | 0 |
| Other Immunodeficiency Due to Underlying Illness or Immunosuppressant Medication | 0 | | 0 |
| Substance Use Disorder | 0 | | 0 |
| Pregnant | 0 | | 0 |
| >=1 Protocol-Defined Risk Factor | 1 ( 100) | | 1 ( 100) |
| >=2 Protocol-Defined Risk Factors | 0 | | 0 |
| >=3 Protocol-Defined Risk Factors | 0 | | 0 |

BMI=body mass index.
Note: Percentages for each risk factor are based on the number of participants in each age group (Adults or Adolescents) within each treatment group. Adolescents and pregnant participants were enrolled in the Phase 3 portion of the study only. Age at Screening was used for categorization as Adult or Adolescent.
[a] BMI=(body weight in kilograms)/(height in meters)^2.
[b] Based on CDC growth charts.
Source Data: ADSL, ADMH, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t1401030204.sas Executed: 30JUN2022 19:34

Table 14.1.3.2.1.1
Baseline Disease Characteristics – SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Was a local SARS-CoV-2 test performed? | | | |
| Yes | 169 ( 100) | 167 ( 100) | 336 ( 100) |
| No | 0 | 0 | 0 |
| Local Sample Specimen Type | | | |
| Nasopharyngeal | 158 (93.5) | 157 (94.0) | 315 (93.8) |
| Nasal | 11 ( 6.5) | 10 ( 6.0) | 21 ( 6.3) |
| Oral/Oropharyngeal | 0 | 0 | 0 |
| Buccal | 0 | 0 | 0 |
| Saliva | 0 | 0 | 0 |
| Other | 0 | 0 | 0 |
| Local SARS-CoV-2 Assay Type | | | |
| RT-PCR | 42 (24.9) | 53 (31.7) | 95 (28.3) |
| Antigen Test | 127 (75.1) | 114 (68.3) | 241 (71.7) |
| Other | 0 | 0 | 0 |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T140103020101.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.1.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Local SARS-CoV-2 Test Result | | | |
| Positive | 169 ( 100) | 167 ( 100) | 336 ( 100) |
| Negative | 0 | 0 | 0 |
| Inconclusive | 0 | 0 | 0 |
| Number of Days from Local Test Sample Collected to Randomization [a] | | | |
| 0 Days | 112 (66.3) | 99 (59.3) | 211 (62.8) |
| 1-2 Days | 46 (27.2) | 52 (31.1) | 98 (29.2) |
| 3-5 Days | 11 ( 6.5) | 16 ( 9.6) | 27 ( 8.0) |
| >5 Days | 0 | 0 | 0 |
| n | 169 | 167 | 336 |
| Mean | 0.6 | 0.8 | 0.7 |
| SD | 1.06 | 1.20 | 1.13 |
| Median | 0.0 | 0.0 | 0.0 |
| Q1, Q3 | 0.0, 1.0 | 0.0, 1.0 | 0.0, 1.0 |
| Min, Max | 0, 5 | 0, 5 | 0, 5 |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T140103020101.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.1.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Central Lab SARS-CoV-2 RT-qPCR NP Swab | | | |
| Positive | 158 (93.5) | 159 (95.2) | 317 (94.3) |
| Negative | 7 ( 4.1) | 8 ( 4.8) | 15 ( 4.5) |
| Missing | 4 ( 2.4) | 0 | 4 ( 1.2) |
| Viral load (log10 copies/mL) | | | |
| n | 165 | 167 | 332 |
| Mean | 6.60 | 6.71 | 6.66 |
| SD | 2.085 | 2.168 | 2.125 |
| Median | 7.14 | 7.16 | 7.16 |
| Q1, Q3 | 5.79, 7.96 | 6.00, 8.34 | 5.88, 8.17 |
| Min, Max | 0, 10.0 | 0, 10.1 | 0, 10.1 |
| >5 log10 copies/mL | 137 (81.1) | 137 (82.0) | 274 (81.5) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T140103020101.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.1.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Central Lab SARS-CoV-2 RT-qPCR Saliva Sample | | | |
| Positive | 148 (87.6) | 149 (89.2) | 297 (88.4) |
| Negative | 13 ( 7.7) | 12 ( 7.2) | 25 ( 7.4) |
| Missing | 8 ( 4.7) | 6 ( 3.6) | 14 ( 4.2) |
| Viral load (log10 copies/mL) | | | |
| n | 161 | 161 | 322 |
| Mean | 5.08 | 4.89 | 4.99 |
| SD | 2.061 | 1.930 | 1.996 |
| Median | 5.52 | 5.20 | 5.36 |
| Q1, Q3 | 4.24, 6.40 | 4.12, 6.10 | 4.13, 6.26 |
| Min, Max | 0, 9.3 | 0, 9.0 | 0, 9.3 |
| >5 log10 copies/mL | 96 (56.8) | 94 (56.3) | 190 (56.5) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T140103020101.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.1.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Central Lab Baseline Serology Status (SARS-CoV-2 antibody) | | | |
| Overall [b] | | | |
| Positive | 43 (25.4) | 48 (28.7) | 91 (27.1) |
| Negative | 123 (72.8) | 119 (71.3) | 242 (72.0) |
| Missing | 3 ( 1.8) | 0 | 3 ( 0.9) |
| Qualitative Assay | | | |
| Positive | 19 (11.2) | 23 (13.8) | 42 (12.5) |
| Negative | 147 (87.0) | 143 (85.6) | 290 (86.3) |
| Missing | 3 ( 1.8) | 1 ( 0.6) | 4 ( 1.2) |
| IgG Assay | | | |
| Positive | 41 (24.3) | 38 (22.8) | 79 (23.5) |
| Negative | 125 (74.0) | 129 (77.2) | 254 (75.6) |
| Missing | 3 ( 1.8) | 0 | 3 ( 0.9) |
| IgA Assay | | | |
| Positive | 17 (10.1) | 21 (12.6) | 38 (11.3) |
| Negative | 149 (88.2) | 146 (87.4) | 295 (87.8) |
| Missing | 3 ( 1.8) | 0 | 3 ( 0.9) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T140103020101.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.1.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| MNT Assay | | | |
| Detected (>=10 AU/mL) | 130 (76.9) | 125 (74.9) | 255 (75.9) |
| Not Detected (<10 AU/mL) | 32 (18.9) | 39 (23.4) | 71 (21.1) |
| Missing | 7 ( 4.1) | 3 ( 1.8) | 10 ( 3.0) |
| MNT Detected (AU/mL) | | | |
| n | 130 | 125 | 255 |
| Mean | 275.60 | 475.41 | 373.55 |
| SD | 1683.109 | 2332.505 | 2026.026 |
| Geometric Mean | 29.80 | 28.64 | 29.23 |
| Geometric SD | 4.130 | 4.923 | 4.500 |
| Median | 15.00 | 16.00 | 16.00 |
| Min, Max | 10.0, 18593.0 | 10.0, 17122.0 | 10.0, 18593.0 |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T140103020101.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.1.1
Baseline Disease Characteristics — SARS-CoV-2 Tests and Respiratory Pathogen Assay
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Respiratory Pathogen Panel | | | |
| Participants with: | | | |
| Adenovirus | 0 | 0 | 0 |
| Chlamydophila pneumoniae | 0 | 0 | 0 |
| Human Rhinovirus/Enterovirus | 3 ( 1.8) | 1 ( 0.6) | 4 ( 1.2) |
| Influenza A | 0 | 0 | 0 |
| Influenza B | 0 | 0 | 0 |
| Bordetella pertussis | 0 | 0 | 0 |
| Human Coronavirus 229E | 0 | 0 | 0 |
| Human Coronavirus HKU1 | 0 | 0 | 0 |
| Human Coronavirus NL63 | 0 | 0 | 0 |
| Human Coronavirus OC43 | 0 | 0 | 0 |
| Human Metapneumovirus | 1 ( 0.6) | 0 | 1 ( 0.3) |
| Human Parainfluenza Virus 1 | 0 | 0 | 0 |
| Human Parainfluenza Virus 2 | 0 | 0 | 0 |
| Human Parainfluenza Virus 3 | 0 | 0 | 0 |
| Human Parainfluenza Virus 4 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| Influenza A subtype H1/2009 | 0 | 0 | 0 |
| Influenza A subtype H1 | 0 | 0 | 0 |
| Influenza A subtype H3 | 0 | 0 | 0 |
| Mycoplasma pneumoniae | 0 | 0 | 0 |
| Respiratory Syncytial Virus | 1 ( 0.6) | 0 | 1 ( 0.3) |
| None | 164 (97.0) | 166 (99.4) | 330 (98.2) |

IgA=immunoglobulin A; IgG=immunoglobulin G; MNT=microneutralization test; NP=nasopharyngeal; Q1=first quartile; Q3=third quartile; RT-PCR=reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each treatment group.
[a] Number of Days from Local Test Sample Collected to Randomization is defined as (date of randomization – the date test performed).
[b] Overall baseline serologic status is positive if any of the three component assays (qualitative, IgG, IgA) are positive, missing if all three component assays are missing, and negative otherwise.
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.1, 16.2.4.1.2.3
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Table 14.1.3.2.2.1
Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Duration (days) from Symptom Onset to Randomization | | | |
| n | 169 | 167 | 336 |
| Mean | 2.4 | 2.5 | 2.4 |
| SD | 1.24 | 1.33 | 1.28 |
| Median | 2.0 | 2.0 | 2.0 |
| Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 | 2.0, 3.0 |
| Min, Max | 0, 5 | 0, 5 | 0, 5 |
| 0-3 days | 136 (80.5) | 128 (76.6) | 264 (78.6) |
| 4-5 days | 33 (19.5) | 39 (23.4) | 72 (21.4) |
| >5 days | 0 | 0 | 0 |
| Duration (days) from Symptom Onset to Study Drug Administration | | | |
| n | 166 | 167 | 333 |
| Mean | 2.4 | 2.5 | 2.4 |
| SD | 1.25 | 1.33 | 1.29 |
| Median | 2.0 | 2.0 | 2.0 |
| Q1, Q3 | 2.0, 3.0 | 2.0, 3.0 | 2.0, 3.0 |
| Min, Max | 0, 5 | 0, 5 | 0, 5 |
| 0-3 days | 133 (78.7) | 128 (76.6) | 261 (77.7) |
| 4-5 days | 33 (19.5) | 39 (23.4) | 72 (21.4) |
| >5 days | 0 | 0 | 0 |

Note: Percentages are based on the number of participants in each treatment group.
[a] Based on participant response to the question "In the past 24 hours, what was the severity of your overall COVID-19-related symptoms at their worst?"
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t140103020201.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.2.1
Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Diary: Day 1 COVID-19 Symptoms (Baseline) | | | |
| Any Symptom | 160 (94.7) | 164 (98.2) | 324 (96.4) |
| Any Severe Symptom | 71 (42.0) | 64 (38.3) | 135 (40.2) |
| Any Moderate Symptom and No Severe Symptoms | 80 (47.3) | 81 (48.5) | 161 (47.9) |
| Any Mild Symptom and No Severe/Moderate Symptoms | 9 ( 5.3) | 19 (11.4) | 28 ( 8.3) |
| Cough | 130 (76.9) | 140 (83.8) | 270 (80.4) |
| Fatigue | 132 (78.1) | 135 (80.8) | 267 (79.5) |
| Fever | 112 (66.3) | 132 (79.0) | 244 (72.6) |
| Muscle or Body Aches | 104 (61.5) | 111 (66.5) | 215 (64.0) |
| Congestion | 105 (62.1) | 102 (61.1) | 207 (61.6) |
| Headache | 104 (61.5) | 102 (61.1) | 206 (61.3) |
| Chills | 75 (44.4) | 88 (52.7) | 163 (48.5) |
| Loss of Sense of Smell | 74 (43.8) | 67 (40.1) | 141 (42.0) |
| Loss of Sense of Taste | 73 (43.2) | 64 (38.3) | 137 (40.8) |
| Sore Throat | 56 (33.1) | 76 (45.5) | 132 (39.3) |
| Shortness of Breath or Difficulty Breathing with Exertion | 47 (27.8) | 58 (34.7) | 105 (31.3) |
| Nausea | 38 (22.5) | 38 (22.8) | 76 (22.6) |
| Diarrhea | 30 (17.8) | 21 (12.6) | 51 (15.2) |
| Shortness of Breath or Difficulty Breathing at Rest | 21 (12.4) | 16 ( 9.6) | 37 (11.0) |
| Vomiting | 12 ( 7.1) | 12 ( 7.2) | 24 ( 7.1) |

Note: Percentages are based on the number of participants in each treatment group.
[a] Based on participant response to the question "In the past 24 hours, what was the severity of your overall COVID-19-related symptoms at their worst?"
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t140103020201.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.2.1
Baseline Disease Characteristics - COVID-19 Symptoms and COVID-19 Severity
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Diary: Day 1 Overall Severity of COVID-19-Related Symptoms [a] | | | |
| None | 7 ( 4.1) | 2 ( 1.2) | 9 ( 2.7) |
| Mild | 71 (42.0) | 67 (40.1) | 138 (41.1) |
| Moderate | 77 (45.6) | 92 (55.1) | 169 (50.3) |
| Severe | 5 ( 3.0) | 3 ( 1.8) | 8 ( 2.4) |
| Investigator-Determined Baseline COVID-19 Severity | | | |
| SARS-CoV-2 Infection without Symptoms | 0 | 0 | 0 |
| Mild COVID-19 | 97 (57.4) | 76 (45.5) | 173 (51.5) |
| Moderate COVID-19 | 72 (42.6) | 91 (54.5) | 163 (48.5) |
| Severe COVID-19 | 0 | 0 | 0 |
| Critical COVID-19 | 0 | 0 | 0 |
| Programmatically-Determined Baseline COVID-19 Severity | | | |
| SARS-CoV-2 Infection without Symptoms | 0 | 0 | 0 |
| Mild COVID-19 | 77 (45.6) | 68 (40.7) | 145 (43.2) |
| Moderate COVID-19 | 66 (39.1) | 81 (48.5) | 147 (43.8) |
| Severe COVID-19 | 21 (12.4) | 16 ( 9.6) | 37 (11.0) |
| Critical COVID-19 | 0 | 0 | 0 |
| Missing | 5 ( 3.0) | 2 ( 1.2) | 7 ( 2.1) |

Note: Percentages are based on the number of participants in each treatment group.
[a] Based on participant response to the question "In the past 24 hours, what was the severity of your overall COVID-19-related symptoms at their worst?"
Source Data: ADSL, ADBL, Listing 16.2.4.1.2.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t140103020201.sas Executed: 30JUN2022 19:46

Table 14.1.3.2.4.1
Baseline Disease Characteristics – Protocol-Defined Risk Factors for COVID-19 Progression by Age Group at Baseline
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Adults (Age >=18 years) | 169 | 167 | 336 |
| Age >55 years | 94 (55.6) | 90 (53.9) | 184 (54.8) |
| Obesity (BMI >=30 kg/m2) [a] | 96 (56.8) | 98 (58.7) | 194 (57.7) |
| Diabetes (Type 1 or Type 2) | 23 (13.6) | 21 (12.6) | 44 (13.1) |
| Chronic Kidney Disease | 1 ( 0.6) | 1 ( 0.6) | 2 ( 0.6) |
| Chronic Lung Disease | 14 ( 8.3) | 16 ( 9.6) | 30 ( 8.9) |
| Cardiac Disease | 23 (13.6) | 26 (15.6) | 49 (14.6) |
| Sickle Cell Disease or Thalassemia | 0 | 0 | 0 |
| Solid Organ or Blood Stem Cell Transplant Recipients | 0 | 0 | 0 |
| Other Immunodeficiency Due to Underlying Illness or Immunosuppressant Medication | 5 ( 3.0) | 4 ( 2.4) | 9 ( 2.7) |
| Down Syndrome | 0 | 0 | 0 |
| Stroke or Cerebrovascular Disease Affecting Blood Flow to the Brain | 4 ( 2.4) | 9 ( 5.4) | 13 ( 3.9) |
| Substance Use Disorder | 2 ( 1.2) | 1 ( 0.6) | 3 ( 0.9) |
| Pregnant | 0 | 0 | 0 |
| >=1 Protocol-Defined Risk Factor | 169 ( 100) | 167 ( 100) | 336 ( 100) |
| >=2 Protocol-Defined Risk Factors | 69 (40.8) | 71 (42.5) | 140 (41.7) |
| >=3 Protocol-Defined Risk Factors | 21 (12.4) | 21 (12.6) | 42 (12.5) |

BMI=body mass index.
Note: Percentages for each risk factor are based on the number of participants in each age group (Adults or Adolescents) within each treatment group. Adolescents and pregnant participants were enrolled in the Phase 3 portion of the study only. Age at Screening was used for categorization as Adult or Adolescent.
[a] BMI=(body weight in kilograms)/(height in meters)^2.
[b] Based on CDC growth charts.
Source Data: ADSL, ADMH, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t140103020401.sas Executed: 30JUN2022 19:47

Table 14.1.3.2.4.1
Baseline Disease Characteristics – Protocol-Defined Risk Factors for COVID-19 Progression by Age Group at Baseline
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | Overall (N=336) |
|---|---|---|---|
| Adolescents (Age 12-17 years) | 0 | 0 | 0 |
| BMI >85th Percentile for Age and Sex [a][b] | | | |
| Diabetes (Type 1 or Type 2) | | | |
| Chronic Kidney Disease | | | |
| Sickle Cell Disease or Thalassemia | | | |
| Congenital or Acquired Heart Disease | | | |
| Neurodevelopmental Disorders | | | |
| Medically-Related Technological Dependence | | | |
| Asthma, Reactive Airway or Other Chronic Respiratory Disease | | | |
| Solid Organ or Blood Stem Cell Transplant Recipients | | | |
| Other Immunodeficiency Due to Underlying Illness or Immunosuppressant Medication | | | |
| Substance Use Disorder | | | |
| Pregnant | | | |
| >=1 Protocol-Defined Risk Factor | | | |
| >=2 Protocol-Defined Risk Factors | | | |
| >=3 Protocol-Defined Risk Factors | | | |

BMI=body mass index.
Note: Percentages for each risk factor are based on the number of participants in each age group (Adults or Adolescents) within each treatment group. Adolescents and pregnant participants were enrolled in the Phase 3 portion of the study only. Age at Screening was used for categorization as Adult or Adolescent.
[a] BMI=(body weight in kilograms)/(height in meters)^2.
[b] Based on CDC growth charts.
Source Data: ADSL, ADMH, Listing 16.2.4.1.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t140103020401.sas Executed: 30JUN2022 19:47

Table 14.1.3.2.5
Baseline Disease Characteristics - SARS-CoV-2 Variants
Full Analysis Set

| | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Participants with Any Qualifying Sample Sequenced[a] | 174 (87.9) | 187 (93.0) | 361 (90.5) |
| Participants with Qualifying Baseline Sample Sequenced | 171 (86.4) | 184 (91.5) | 355 (89.0) |
| Participants with Qualifying Post-Baseline Sample Sequenced | 3 ( 1.5) | 3 ( 1.5) | 6 ( 1.5) |
| Variants of Concern [b] | | | |
| Delta | 153 (87.9) | 160 (85.6) | 313 (86.7) |
| Delta (B.1.617.2-like) | 112 (64.4) | 120 (64.2) | 232 (64.3) |
| AY.43 | 27 (15.5) | 30 (16.0) | 57 (15.8) |
| B.1.617.2 | 15 ( 8.6) | 27 (14.4) | 42 (11.6) |
| AY.122 | 15 ( 8.6) | 15 ( 8.0) | 30 ( 8.3) |
| AY.9.2 | 9 ( 5.2) | 9 ( 4.8) | 18 ( 5.0) |

NP=nasopharyngeal; VOC=variant of concern; WGS=whole genome sequencing.
Note: Percentages are based on the number of participants in each treatment group, except where noted. Classification of VOC is based on https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html as of 07MAR2022. Variant classification per WHO is available in Listing 16.2.4.1.2.4.
[a] WGS results available.
[b] WGS confirmed variant is determined by the earliest available baseline or post-baseline sequencing sample data in the following priority order: baseline NP, baseline saliva, earliest post-baseline NP, earliest post-baseline saliva. Percentages are based on number of participants with any qualifying sample sequenced.
[c] Participants without sequencing data are classified as suspected Omicron or non-Omicron variant by comparing randomization date to study/country date of emergence of Omicron variant.
Source Data: ADSL, ADWGS, Listing 16.2.4.1.2.4
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030205.sas Executed: 02AUG2022 19:57

Table 14.1.3.2.5
Baseline Disease Characteristics - SARS-CoV-2 Variants
Full Analysis Set

| | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Variants of Concern [b] | | | |
| Delta | | | |
| Delta (B.1.617.2-like) (cont.) | | | |
| AY.102 | 8 ( 4.6) | 3 ( 1.6) | 11 ( 3.0) |
| AY.125 | 7 ( 4.0) | 4 ( 2.1) | 11 ( 3.0) |
| AY.36 | 4 ( 2.3) | 3 ( 1.6) | 7 ( 1.9) |
| AY.46 | 1 ( 0.6) | 5 ( 2.7) | 6 ( 1.7) |
| AY.127 | 2 ( 1.1) | 3 ( 1.6) | 5 ( 1.4) |
| AY.9.1 | 3 ( 1.7) | 2 ( 1.1) | 5 ( 1.4) |
| AY.121 | 3 ( 1.7) | 1 ( 0.5) | 4 ( 1.1) |
| AY.9 | 2 ( 1.1) | 2 ( 1.1) | 4 ( 1.1) |
| AY.121.1 | 1 ( 0.6) | 2 ( 1.1) | 3 ( 0.8) |
| AY.42 | 1 ( 0.6) | 2 ( 1.1) | 3 ( 0.8) |
| AY.98.1 | 2 ( 1.1) | 1 ( 0.5) | 3 ( 0.8) |
| AY.12 | 1 ( 0.6) | 1 ( 0.5) | 2 ( 0.6) |
| AY.120 | 2 ( 1.1) | 0 | 2 ( 0.6) |
| AY.126 | 1 ( 0.6) | 1 ( 0.5) | 2 ( 0.6) |
| AY.129 | 0 | 2 ( 1.1) | 2 ( 0.6) |

NP=nasopharyngeal; VOC=variant of concern; WGS=whole genome sequencing.
Note: Percentages are based on the number of participants in each treatment group, except where noted. Classification of VOC is based on https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html as of 07MAR2022. Variant classification per WHO is available in Listing 16.2.4.1.2.4.
[a] WGS results available.
[b] WGS confirmed variant is determined by the earliest available baseline or post-baseline sequencing sample data in the following priority order: baseline NP, baseline saliva, earliest post-baseline NP, earliest post-baseline saliva. Percentages are based on number of participants with any qualifying sample sequenced.
[c] Participants without sequencing data are classified as suspected Omicron or non-Omicron variant by comparing randomization date to study/country date of emergence of Omicron variant.
Source Data: ADSL, ADWGS, Listing 16.2.4.1.2.4
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030205.sas Executed: 02AUG2022 19:57

Table 14.1.3.2.5
Baseline Disease Characteristics - SARS-CoV-2 Variants
Full Analysis Set

| | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Variants of Concern [b] | | | |
| Delta | | | |
| Delta (B.1.617.2-like) (cont.) | | | |
| AY.45 | 1 ( 0.6) | 1 ( 0.5) | 2 ( 0.6) |
| AY.5 | 2 ( 1.1) | 0 | 2 ( 0.6) |
| AY.112 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| AY.25 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| AY.32 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| AY.46.1 | 0 | 1 ( 0.5) | 1 ( 0.3) |
| AY.46.6 | 0 | 1 ( 0.5) | 1 ( 0.3) |
| AY.5.4 | 0 | 1 ( 0.5) | 1 ( 0.3) |
| AY.78 | 0 | 1 ( 0.5) | 1 ( 0.3) |
| AY.89 | 0 | 1 ( 0.5) | 1 ( 0.3) |
| AY.92 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| AY.98 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| AY.99.2 | 0 | 1 ( 0.5) | 1 ( 0.3) |

NP=nasopharyngeal; VOC=variant of concern; WGS=whole genome sequencing.
Note: Percentages are based on the number of participants in each treatment group, except where noted. Classification of VOC is based on https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html as of 07MAR2022. Variant classification per WHO is available in Listing 16.2.4.1.2.4.
[a] WGS results available.
[b] WGS confirmed variant is determined by the earliest available baseline or post-baseline sequencing sample data in the following priority order: baseline NP, baseline saliva, earliest post-baseline NP, earliest post-baseline saliva. Percentages are based on number of participants with any qualifying sample sequenced.
[c] Participants without sequencing data are classified as suspected Omicron or non-Omicron variant by comparing randomization date to study/country date of emergence of Omicron variant.
Source Data: ADSL, ADWGS, Listing 16.2.4.1.2.4
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030205.sas Executed: 02AUG2022 19:57

Table 14.1.3.2.5
Baseline Disease Characteristics - SARS-CoV-2 Variants
Full Analysis Set

| | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Variants of Concern [b] | | | |
| Delta (cont.) | | | |
| Delta (AY.4-like) | 31 (17.8) | 30 (16.0) | 61 (16.9) |
| AY.4 | 26 (14.9) | 26 (13.9) | 52 (14.4) |
| AY.4.4 | 4 ( 2.3) | 3 ( 1.6) | 7 ( 1.9) |
| AY.4.3 | 1 ( 0.6) | 0 | 1 ( 0.3) |
| AY.4.5 | 0 | 1 ( 0.5) | 1 ( 0.3) |
| Delta (AY.4.2-like) | 10 ( 5.7) | 10 ( 5.3) | 20 ( 5.5) |
| AY.4.2.1 | 6 ( 3.4) | 6 ( 3.2) | 12 ( 3.3) |
| AY.4.2 | 4 ( 2.3) | 4 ( 2.1) | 8 ( 2.2) |
| Omicron | 21 (12.1) | 27 (14.4) | 48 (13.3) |
| Omicron (BA.1-like) | 21 (12.1) | 25 (13.4) | 46 (12.7) |
| BA.1 | 21 (12.1) | 25 (13.4) | 46 (12.7) |

NP=nasopharyngeal; VOC=variant of concern; WGS=whole genome sequencing.
Note: Percentages are based on the number of participants in each treatment group, except where noted. Classification of VOC is based on https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html as of 07MAR2022. Variant classification per WHO is available in Listing 16.2.4.1.2.4.
[a] WGS results available.
[b] WGS confirmed variant is determined by the earliest available baseline or post-baseline sequencing sample data in the following priority order: baseline NP, baseline saliva, earliest post-baseline NP, earliest post-baseline saliva. Percentages are based on number of participants with any qualifying sample sequenced.
[c] Participants without sequencing data are classified as suspected Omicron or non-Omicron variant by comparing randomization date to study/country date of emergence of Omicron variant.
Source Data: ADSL, ADWGS, Listing 16.2.4.1.2.4
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030205.sas Executed: 02AUG2022 19:57

Table 14.1.3.2.5
Baseline Disease Characteristics - SARS-CoV-2 Variants
Full Analysis Set

| | ADG20 (N=198) n (%) | Placebo (N=201) n (%) | Overall (N=399) n (%) |
|---|---|---|---|
| Variants of Concern [b] | | | |
| Omicron (cont.) | | | |
| Omicron (BA.3-like) | 0 | 2 ( 1.1) | 2 ( 0.6) |
| BA.3 | 0 | 2 ( 1.1) | 2 ( 0.6) |
| Participants with No Qualifying Sample Sequenced [c] | 24 (12.1) | 14 ( 7.0) | 38 ( 9.5) |
| Participants with Suspected Omicron Variant | 8 ( 4.0) | 7 ( 3.5) | 15 ( 3.8) |
| Participants with Suspected non-Omicron Variant | 16 ( 8.1) | 7 ( 3.5) | 23 ( 5.8) |

NP=nasopharyngeal; VOC=variant of concern; WGS=whole genome sequencing.
Note: Percentages are based on the number of participants in each treatment group, except where noted. Classification of VOC is based on https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-surveillance/variant-info.html as of 07MAR2022. Variant classification per WHO is available in Listing 16.2.4.1.2.4.
[a] WGS results available.
[b] WGS confirmed variant is determined by the earliest available baseline or post-baseline sequencing sample data in the following priority order: baseline NP, baseline saliva, earliest post-baseline NP, earliest post-baseline saliva. Percentages are based on number of participants with any qualifying sample sequenced.
[c] Participants without sequencing data are classified as suspected Omicron or non-Omicron variant by comparing randomization date to study/country date of emergence of Omicron variant.
Source Data: ADSL, ADWGS, Listing 16.2.4.1.2.4
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1401030205.sas Executed: 02AUG2022 19:57

Table 14.1.6
Study Drug Exposure
Safety Set

| | ADG20 (N=192) | Placebo (N=200) |
|---|---|---|
| Received Full Dose[a] | | |
| Yes | 192 ( 100) | 200 ( 100) |
| No | 0 | 0 |
| Total Dose Administered (mg) | | |
| n | 192 | NA |
| Mean | 300.0 | |
| SD | 0.00 | |
| Median | 300.0 | |
| Q1, Q3 | 300.0, 300.0 | |
| Min, Max | 300, 300 | |
| Total Volume Administered (mL) | | |
| n | 192 | 200 |
| Mean | 3.0 | 3.0 |
| SD | 0.00 | 0.00 |
| Median | 3.0 | 3.0 |
| Q1, Q3 | 3.0, 3.0 | 3.0, 3.0 |
| Min, Max | 3, 3 | 3, 3 |

Q1=first quartile; Q3=third quartile.
Note: Percentages are based on the number of participants in each treatment group. Total Dose Administered (mg) = 100*total volume administered. Intended full dose is 300 mg.
[a] Based on total volume >= 3 mL.
Source Data: ADSL, ADEX, Listing 16.2.5.1, 16.2.5.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t140106.sas Executed: 30JUN2022 19:25

Table 14.2.6.3
All-Cause Death and COVID-19-Related Death
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) |
|---|---|---|
| All-Cause Death | 1 ( 0.6) | 7 ( 4.2) |
| Through Day 29 | 1 ( 0.6) | 6 ( 3.6) |
| Through Day 60 | 1 ( 0.6) | 6 ( 3.6) |
| Through Day 90 | 1 ( 0.6) | 7 ( 4.2) |
| Log Rank Test p-value[a] | 0.0313 | |
| Hazard Ratio[b] | 0.137 | |
| Hazard Ratio 95% CI[b] | 0.016, 1.162 | |
| Hazard Ratio Score Test p-value[b] | 0.0361 | |
| COVID-19-Related Death | 1 ( 0.6) | 5 ( 3.0) |
| Through Day 29 | 1 ( 0.6) | 5 ( 3.0) |
| Through Day 60 | 1 ( 0.6) | 5 ( 3.0) |
| Through Day 90 | 1 ( 0.6) | 5 ( 3.0) |
| Log Rank Test p-value[a] | 0.0974 | |
| Hazard Ratio[b] | 0.155 | |
| Hazard Ratio 95% CI[b] | 0.017, 1.436 | |
| Hazard Ratio Score Test p-value[b] | 0.0655 | |

Note: Participants who are lost to follow-up are censored at the date last known alive; n/e=not evaluable.
[a] Log Rank test is stratified by age (categorical as 12-17 years, 18-65 years and >65 years).
[b] Cox Proportional Hazard model is used to estimate the hazard ratio where the model includes age (continous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), baseline BMI (continuous) and baseline viral load (continuous as log10 copies/mL) as covariates.
Source Data: ADSL, ADBL, ADTTE, Listing 16.2.7.5
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020603.sas Executed: 30JUN2022 19:26

Table 14.2.6.2
Time to Sustained Recovery of COVID-19-Symptoms through Day 29
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) |
|---|---|---|
| Time to Sustained Recovery of COVID-19-Symptoms through Day 29 | | |
| Events | 134 (79.3) | 126 (75.4) |
| Censored | 35 (20.7) | 41 (24.6) |
| 25th Percentile (95% CI) | 7 (6, 8) | 9 (7, 10) |
| Median (95% CI) | 11 (9, 14) | 14 (12, 17) |
| 75th Percentile (95% CI) | 24 (19, n/e) | 28 (24, n/e) |
| Treatment Comparison | | |
| Log Rank Test p-value[a] | 0.0755 | |
| Hazard Ratio[b] | 1.237 | |
| Hazard Ratio 95% CI[b] | 0.964, 1.586 | |
| Hazard Ratio Score Test p-value[b] | 0.0938 | |

CI=confidence interval; n/e=not evaluable.

Note: Time to sustained recovery of COVID-19 symptoms is the time from the first dose date to the earliest date when sustained improvement or sustained resolution of COVID-19 symptoms is met through Day 29. COVID-19 symptoms assessed include fever, chills, cough, sore throat, congestion, shortness of breath/difficulty breathing at rest, shortness of breath/difficulty breathing with exertion, muscle or body aches, fatigue, headache, nausea, vomiting, and diarrhea. Loss of taste/smell is excluded from this analysis. Participants who were randomized but not treated are censored at Day 1. Participants who had any COVID-related hospitalization (>=24 hours) or all-cause death through Day 29 (as defined in the primary endpoint) are censored at Day 30. Participants who were not followed through the Day 29 visit (due to discontinuation from study or incomplete follow-up at the time of analysis) are censored at the last contact date. Participants who completed the Day 29 visit and did not experience the defined event through Day 29 are censored at Day 30.

[a] Log Rank test is stratified by age (categorical as 12-17 years, 18-65 years and >65 years).

[b] Cox Proportional Hazard model is used to estimate the hazard ratio where the model includes age (categorical as 12-17 years, 18-65 years and >65 years) as a stratification variable and sex (categorical), qualitative baseline serostatus (categorical as positive; negative), baseline BMI (continuous) and baseline viral load (continuous as log10 copies/mL) as covariates.

Source Data: ADSL, ADBL, ADSYMTTE, Listing 16.2.3.9

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020602.sas Executed: 30JUN2022 19:26

Table 14.2.6.6
Time to Sustained Resolution of COVID-19 Symptoms through Day 29
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) |
|---|---|---|
| Time to Resolution of COVID-19 Symptoms through Day 29 | | |
| Events | 130 (76.9) | 123 (73.7) |
| Censored | 39 (23.1) | 44 (26.3) |
| 25th Percentile (95% CI) | 8 (8, 9) | 10 (9, 11) |
| Median (95% CI) | 13 (10, 15) | 16 (13, 20) |
| 75th Percentile (95% CI) | 26 (21, n/e) | n/e (27, n/e) |
| Treatment Comparison | | |
| Log Rank Test p-value[a] | 0.0920 | |
| Hazard Ratio[b] | 1.255 | |
| Hazard Ratio 95% CI[b] | 0.974, 1.617 | |
| Hazard Ratio Score Test p-value[b] | 0.0781 | |

CI=confidence interval; n/e=not evaluable.

Note: COVID-19 symptoms assessed include fever, chills, cough, sore throat, congestion, shortness of breath/difficulty breathing at rest, shortness of breath/difficulty breathing with exertion, muscle or body aches, fatigue, headache, nausea, vomiting, and diarrhea. Loss of taste/smell is excluded from this analysis. Sustained resolution is the time from the first dose date to the first date when all symptoms are scored as absent with no symptom recurrence or new symptoms, except cough, fatigue, and headache which may be mild or absent, through Day 29. Participants who were randomized but not treated are censored at Day 1. Participants who had any COVID-related hospitalization (>=24 hours) or all-cause death through Day 29 (as defined in the primary endpoint) are censored at Day 30. Participants who were not followed through the Day 29 visit (due to discontinuation from study or incomplete follow-up at the time of analysis) are censored at the last contact date. Participants who completed the Day 29 visit and did not experience the defined event through Day 29 are censored at Day 30.

[a] Log Rank test is stratified by age (categorical as 12-17 years, 18-65 years and >65 years).

[b] Cox Proportional Hazard model is used to estimate the hazard ratio where the model includes age (categorical as 12-17 years, 18-65 years and >65 years) as a stratification variable and sex (categorical), qualitative baseline serostatus (categorical as positive; negative), baseline BMI (continuous) and baseline viral load (continuous as log10 copies/mL) as covariates.

Source Data: ADSL, ADBL, ADSYMTTE, Listing 16.2.3.9

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020606.sas Executed: 30JUN2022 19:27

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Baseline | | | | |
| n | 147 | | 149 | |
| Mean | 5.53 | | 5.29 | |
| SD | 1.469 | | 1.389 | |
| Median | 5.62 | | 5.37 | |
| Q1, Q3 | 4.47, 6.50 | | 4.44, 6.26 | |
| Min, Max | 2.6, 9.3 | | 2.6, 9.0 | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

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Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 3 | | | | |
| n | 140 | 140 | 137 | 137 |
| Mean | 4.08 | -1.45 | 4.49 | -0.84 |
| SD | 2.404 | 1.945 | 2.310 | 2.144 |
| Median | 4.48 | -1.39 | 4.63 | -0.54 |
| Q1, Q3 | 2.55, 5.75 | -2.78, -0.08 | 3.39, 6.28 | -1.89, 0.26 |
| Min, Max | 0, 9.0 | -6.4, 4.1 | 0, 9.6 | -6.3, 5.6 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 3 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -1.35 (0.196) | | -0.91 (0.194) |
| 95% CI | | (-1.73, -0.96) | | (-1.29, -0.53) |
| Adjusted LS Mean Difference (SE)[b] | | -0.43 (0.260) | | |
| 95% CI | | (-0.95, 0.08) | | |
| p-value | | 0.0956 | | |
| Unadjusted Mean (SE) | | -1.45 (0.173) | | -0.84 (0.175) |
| 95% CI | | (-1.79, -1.11) | | (-1.18, -0.49) |
| Unadjusted Mean Difference (SE)[c] | | -0.61 (0.246) | | |
| 95% CI | | (-1.10, -0.13) | | |
| p-value | | 0.0136 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 5 | | | | |
| n | 137 | 137 | 134 | 134 |
| Mean | 3.26 | -2.25 | 3.97 | -1.30 |
| SD | 2.460 | 2.069 | 2.231 | 2.154 |
| Median | 3.67 | -1.95 | 4.30 | -1.01 |
| Q1, Q3 | 0.00, 5.00 | -3.56, -0.88 | 2.87, 5.68 | -2.55, 0.16 |
| Min, Max | 0, 7.9 | -7.8, 2.4 | 0, 7.8 | -6.8, 3.9 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 5 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -2.19 (0.197) | | -1.38 (0.195) |
| 95% CI | | (-2.58, -1.81) | | (-1.76, -0.99) |
| Adjusted LS Mean Difference (SE)[b] | | -0.82 (0.261) | | |
| 95% CI | | (-1.33, -0.30) | | |
| p-value | | 0.0019 | | |
| Unadjusted Mean (SE) | | -2.25 (0.180) | | -1.30 (0.182) |
| 95% CI | | (-2.60, -1.89) | | (-1.66, -0.94) |
| Unadjusted Mean Difference (SE)[c] | | -0.95 (0.257) | | |
| 95% CI | | (-1.45, -0.44) | | |
| p-value | | 0.0003 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 7 | | | | |
| n | 135 | 135 | 131 | 131 |
| Mean | 3.02 | -2.51 | 3.58 | -1.74 |
| SD | 2.192 | 1.987 | 2.402 | 2.123 |
| Median | 3.45 | -2.44 | 3.96 | -1.47 |
| Q1, Q3 | 0.00, 4.62 | -4.10, -1.21 | 2.55, 5.58 | -3.18, -0.21 |
| Min, Max | 0, 8.5 | -7.8, 2.6 | 0, 7.9 | -6.8, 3.6 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 7 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -2.41 (0.193) | | -1.79 (0.192) |
| 95% CI | | (-2.79, -2.03) | | (-2.17, -1.41) |
| Adjusted LS Mean Difference (SE)[b] | | -0.62 (0.256) | | |
| 95% CI | | (-1.12, -0.11) | | |
| p-value | | 0.0163 | | |
| Unadjusted Mean (SE) | | -2.51 (0.177) | | -1.74 (0.180) |
| 95% CI | | (-2.86, -2.16) | | (-2.10, -1.39) |
| Unadjusted Mean Difference (SE)[c] | | -0.77 (0.252) | | |
| 95% CI | | (-1.26, -0.27) | | |
| p-value | | 0.0026 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 11 | | | | |
| n | 134 | 134 | 131 | 131 |
| Mean | 1.93 | -3.58 | 2.22 | -3.05 |
| SD | 2.339 | 2.234 | 2.186 | 2.243 |
| Median | 0.00 | -3.68 | 2.55 | -2.98 |
| Q1, Q3 | 0.00, 4.10 | -5.30, -2.09 | 0.00, 3.60 | -4.92, -1.45 |
| Min, Max | 0, 7.5 | -7.9, 2.4 | 0, 7.7 | -7.9, 3.1 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 11 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -3.49 (0.196) | | -3.15 (0.195) |
| 95% CI | | (-3.88, -3.10) | | (-3.53, -2.76) |
| Adjusted LS Mean Difference (SE)[b] | | -0.34 (0.261) | | |
| 95% CI | | (-0.86, 0.17) | | |
| p-value | | 0.1874 | | |
| Unadjusted Mean (SE) | | -3.58 (0.193) | | -3.05 (0.196) |
| 95% CI | | (-3.96, -3.20) | | (-3.44, -2.67) |
| Unadjusted Mean Difference (SE)[c] | | -0.53 (0.275) | | |
| 95% CI | | (-1.07, 0.01) | | |
| p-value | | 0.0538 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 14 | | | | |
| n | 134 | 134 | 128 | 128 |
| Mean | 1.31 | -4.17 | 1.59 | -3.65 |
| SD | 2.016 | 2.108 | 2.181 | 2.311 |
| Median | 0.00 | -4.30 | 0.00 | -3.89 |
| Q1, Q3 | 0.00, 2.93 | -5.77, -3.08 | 0.00, 3.27 | -5.46, -2.24 |
| Min, Max | 0, 7.5 | -7.9, 1.6 | 0, 8.5 | -8.3, 5.2 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 14 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -4.08 (0.186) | | -3.77 (0.187) |
| 95% CI | | (-4.45, -3.71) | | (-4.13, -3.40) |
| Adjusted LS Mean Difference (SE)[b] | | -0.31 (0.247) | | |
| 95% CI | | (-0.80, 0.17) | | |
| p-value | | 0.2053 | | |
| Unadjusted Mean (SE) | | -4.17 (0.191) | | -3.65 (0.195) |
| 95% CI | | (-4.54, -3.79) | | (-4.03, -3.26) |
| Unadjusted Mean Difference (SE)[c] | | -0.52 (0.273) | | |
| 95% CI | | (-1.06, 0.02) | | |
| p-value | | 0.0579 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 21 | | | | |
| n | 139 | 139 | 129 | 129 |
| Mean | 0.75 | -4.71 | 0.93 | -4.36 |
| SD | 1.555 | 1.974 | 1.758 | 2.014 |
| Median | 0.00 | -4.74 | 0.00 | -4.76 |
| Q1, Q3 | 0.00, 0.00 | -6.02, -3.48 | 0.00, 0.00 | -5.77, -2.95 |
| Min, Max | 0, 6.8 | -9.3, 1.7 | 0, 7.6 | -9.0, 2.5 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 21 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -4.63 (0.154) | | -4.45 (0.155) |
| 95% CI | | (-4.94, -4.33) | | (-4.76, -4.15) |
| Adjusted LS Mean Difference (SE)[b] | | -0.18 (0.198) | | |
| 95% CI | | (-0.57, 0.21) | | |
| p-value | | 0.3623 | | |
| Unadjusted Mean (SE) | | -4.71 (0.169) | | -4.36 (0.176) |
| 95% CI | | (-5.04, -4.37) | | (-4.71, -4.01) |
| Unadjusted Mean Difference (SE)[c] | | -0.35 (0.244) | | |
| 95% CI | | (-0.83, 0.13) | | |
| p-value | | 0.1549 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 29 | | | | |
| n | 136 | 136 | 130 | 130 |
| Mean | 0.34 | -5.19 | 0.36 | -4.91 |
| SD | 1.097 | 1.635 | 1.063 | 1.588 |
| Median | 0.00 | -5.39 | 0.00 | -5.08 |
| Q1, Q3 | 0.00, 0.00 | -6.20, -4.27 | 0.00, 0.00 | -5.96, -4.06 |
| Min, Max | 0, 5.7 | -9.3, -0.4 | 0, 5.2 | -8.3, 1.9 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020504.sas Executed: 30JUN2022 19:26

Table 14.2.5.4
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | | Placebo (N=149) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Day 29 | | | | |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -5.11 (0.116) | | -5.01 (0.114) |
| 95% CI | | (-5.34, -4.88) | | (-5.24, -4.79) |
| Adjusted LS Mean Difference (SE)[b] | | -0.10 (0.133) | | |
| 95% CI | | (-0.36, 0.16) | | |
| p-value | | 0.4620 | | |
| Unadjusted Mean (SE) | | -5.19 (0.138) | | -4.91 (0.141) |
| 95% CI | | (-5.46, -4.92) | | (-5.19, -4.63) |
| Unadjusted Mean Difference (SE)[c] | | -0.28 (0.198) | | |
| 95% CI | | (-0.67, 0.11) | | |
| p-value | | 0.1581 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on a mixed model for repeated measures (MMRM) for change from baseline adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). Covariance structure is specified in the following priority order until model converges: unstructured, Toeplitz, compound symmetry.

[c] Based on unadjusted two-sample t-test to compare change from baseline between treatment and placebo at each time point.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2

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Table 14.2.5.1
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Day 7 Nasopharyngeal Samples
mFAS-non-Omicron-NP

| | ADG20 (N=157) | | Placebo (N=159) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Baseline | | | | |
| n | 157 | | 159 | |
| Mean | 6.90 | | 7.05 | |
| SD | 1.587 | | 1.594 | |
| Median | 7.17 | | 7.24 | |
| Q1, Q3 | 6.00, 8.03 | | 6.23, 8.35 | |
| Min, Max | 2.6, 10.0 | | 2.6, 10.1 | |
| Day 7 | | | | |
| n | 148 | 148 | 146 | 146 |
| Mean | 3.84 | -3.11 | 4.03 | -3.05 |
| SD | 2.243 | 2.221 | 2.539 | 2.225 |
| Median | 3.91 | -3.02 | 4.59 | -2.94 |
| Q1, Q3 | 2.55, 5.48 | -4.49, -1.72 | 2.55, 5.95 | -4.41, -1.54 |
| Min, Max | 0, 8.9 | -7.8, 2.1 | 0, 9.1 | -8.5, 5.1 |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on analysis of covariance (ANCOVA) for change from baseline adjusted for prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL).

[c] Based on two-sample t-test to compare change from baseline between treatment and placebo at each time point without covariate adjustment.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.1

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020501.sas Executed: 30JUN2022 19:26

Table 14.2.5.1
Change from Baseline in SARS-CoV-2 Viral Load (log10 copies/mL) Assessed by RT-qPCR from Day 7 Nasopharyngeal Samples
mFAS-non-Omicron-NP

| | ADG20 (N=157) | | Placebo (N=159) | |
|---|---|---|---|---|
| Visit | Actual Value | Change From Baseline[a] | Actual Value | Change From Baseline[a] |
| Treatment Comparison | | | | |
| Adjusted LS Mean (SE) | | -3.61 (0.238) | | -3.44 (0.224) |
| 95% CI | | (-4.08, -3.14) | | (-3.88, -3.00) |
| Adjusted LS Mean Difference (SE)[b] | | -0.17 (0.248) | | |
| 95% CI | | (-0.66, 0.32) | | |
| p-value | | 0.4976 | | |
| Unadjusted Mean (SE) | | -3.11 (0.183) | | -3.05 (0.184) |
| 95% CI | | (-3.47, -2.75) | | (-3.42, -2.69) |
| Unadjusted Mean Difference (SE)[c] | | -0.06 (0.259) | | |
| 95% CI | | (-0.57, 0.45) | | |
| p-value | | 0.8294 | | |

LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Baseline is defined as last non-missing measurement prior to dosing. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.

[a] Change from baseline: post-baseline value – baseline value. For the change from baseline, only participants with a value at both baseline visit and the specific post-baseline visit are included (determination made after imputation).

[b] Based on analysis of covariance (ANCOVA) for change from baseline adjusted for prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL).

[c] Based on two-sample t-test to compare change from baseline between treatment and placebo at each time point without covariate adjustment.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.1

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Table 14.2.5.2
Proportion of Participants with High SARS-CoV-2 Viral Load Assessed by RT-qPCR from Day 7 Nasopharyngeal Samples
mFAS-non-Omicron-NP

| | ADG20 (N=157) | Placebo (N=159) | Risk Diff/ Relative Risk Reduction[a] | Standardized Risk Diff (95% CI) p-value[b] | Standardized Relative Risk Reduction (95% CI)[b] |
|---|---|---|---|---|---|
| Participants with Day 7 NP Samples | 148 | 146 | | | |
| Viral Load >4 (log10 copies/mL) | 72 (48.6) | 86 (58.9) | -10.3%/17.4% | -11.2% (-21.49, -0.96) 0.0321 | 18.9% (1.48, 33.27) |
| Viral Load >5 (log10 copies/mL) | 49 (33.1) | 64 (43.8) | -10.7%/24.5% | -11.1% (-21.42, -0.70) 0.0364 | 25.2% (1.35, 43.22) |

NP=nasopharyngeal; CI=confidence interval; Diff=difference; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Percentages are based on the number of participants in each subgroup. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available. Missing viral load is imputed as not reaching a defined high viral load.

[a] Based on observed data.

[b] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.1

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Table 14.2.5.2
Proportion of Participants with High SARS-CoV-2 Viral Load Assessed by RT-qPCR from Day 7 Nasopharyngeal Samples
mFAS-non-Omicron-NP

| | ADG20 (N=157) | Placebo (N=159) | Risk Diff/ Relative Risk Reduction[a] | Standardized Risk Diff (95% CI) p-value[b] | Standardized Relative Risk Reduction (95% CI)[b] |
|---|---|---|---|---|---|
| Subgroup - Baseline SARS-CoV-2 Viral Load >5 (log10 copies/mL) | | | | | |
| Participants with Day 7 NP Samples | 129 | 126 | | | |
| Viral Load >4 (log10 copies/mL) | 65 (50.4) | 80 (63.5) | -13.1%/20.6% | -13.7% (-24.65, -2.75) 0.0142 | 21.5% (4.36, 35.52) |
| Viral Load >5 (log10 copies/mL) | 43 (33.3) | 60 (47.6) | -14.3%/30.0% | -14.1% (-25.05, -3.07) 0.0121 | 29.6% (6.74, 46.86) |

NP=nasopharyngeal; CI=confidence interval; Diff=difference; RT-qPCR=quantitative reverse transcription polymerase chain reaction.
Note: Percentages are based on the number of participants in each subgroup. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available. Missing viral load is imputed as not reaching a defined high viral load.
[a] Based on observed data.
[b] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.1
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020502.sas Executed: 30JUN2022 19:26

Table 14.2.5.2
Proportion of Participants with High SARS-CoV-2 Viral Load Assessed by RT-qPCR from Day 7 Nasopharyngeal Samples
mFAS-non-Omicron-NP

| | ADG20 (N=157) | Placebo (N=159) | Risk Diff/ Relative Risk Reduction[a] | Standardized Risk Diff (95% CI) p-value[b] | Standardized Relative Risk Reduction (95% CI)[b] |
|---|---|---|---|---|---|
| Subgroup - Baseline SARS-CoV-2 Viral Load <=5 (log10 copies/mL) | | | | | |
| Participants with Day 7 NP Samples | 19 | 20 | | | |
| Viral Load >4 (log10 copies/mL) | 7 (36.8) | 6 (30.0) | 6.8%/-22.8% | 11.7% (-15.45, 38.79) 0.3989 | -41.7% (-220.54, 37.37) |
| Viral Load >5 (log10 copies/mL) | 6 (31.6) | 4 (20.0) | 11.6%/-57.9% | 8.3% (-17.82, 34.50) 0.5322 | -38.7% (-291.87, 50.92) |

NP=nasopharyngeal; CI=confidence interval; Diff=difference; RT-qPCR=quantitative reverse transcription polymerase chain reaction.

Note: Percentages are based on the number of participants in each subgroup. Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available. Missing viral load is imputed as not reaching a defined high viral load.

[a] Based on observed data.

[b] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.1

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Table 14.2.5.7
SARS-CoV-2 Viral Load AUC (log10 copies/mL) Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| AUC | ADG20 (N=147) | Placebo (N=149) |
|---|---|---|
| Day 1 through Day 29 | | |
| n | 131 | 126 |
| Mean | 49.96 | 57.60 |
| SD | 36.544 | 37.522 |
| Median | 43.46 | 49.88 |
| Q1, Q3 | 22.62, 70.97 | 29.38, 77.03 |
| Min, Max | 1.3, 167.2 | 2.6, 178.4 |
| Treatment Comparison | | |
| Adjusted LS Mean Difference (SE)[a] | -6.93 (4.349) | |
| 95% CI[a] | (-15.49, 1.64) | |
| p-value[a] | 0.1124 | |
| Unadjusted Mean Difference (SE)[b] | -7.64 (4.620) | |
| 95% CI[b] | (-16.74, 1.46) | |
| p-value[b] | 0.0995 | |

AUC=area under the concentration-time curve; LS=least squares; SE=standard error; CI=confidence interval; Q1= first quartile; Q3=third quartile; RT-qPCR=quantitative reverse transcription polymerase chain reaction.
Note: Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available. The AUC from Day 1 through Day 29 is calculated according to the linear trapezoidal rule using the measured SARS-CoV-2 viral load. No AUC values are calculated when Day 1 and/or the corresponding Day 29 values are missing, or if there are more than 3 values missing in the profile.
[a] Based on analysis of covariance (ANCOVA) for AUC adjusted for primary analysis prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL) as covariates.
[b] Based on two-sample t-test to compare between treatment and placebo without covariate adjustment.
Source Data: ADSL, ADBL, ADMB, Listing 16.2.6.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T14020507.sas Executed: 30JUN2022 19:26

Table 14.2.5.6.1
Duration of SARS-CoV-2 Viral Shedding Assessed by RT-qPCR from Saliva Samples from Day 1 through Day 29
mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) |
|---|---|---|
| Duration of SARS-CoV-2 Viral Shedding | | |
| Events | 123 (83.7) | 116 (77.9) |
| Censored | 24 (16.3) | 33 (22.1) |
| 25th Percentile (95% CI) | 11 (8, 11) | 11 (11, 14) |
| Median (95% CI) | 14 (14, 21) | 21 (14, 21) |
| 75th Percentile (95% CI) | 29 (22, 30) | 29 (n/e, n/e) |
| Treatment Comparison | | |
| Log Rank Test p-value[a] | 0.3205 | |
| Hazard Ratio[b] | 1.048 | |
| Hazard Ratio 95% CI[b] | 0.806, 1.364 | |
| Hazard Ratio Score Test p-value[b] | 0.7239 | |

CI=confidence interval; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.
Note: Duration of SARS-CoV-2 viral shedding is defined as time from the first dose date to the first date the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants who do not have the defined event are censored at the earlier date of the last viral load assessment or Day 30. Participants who died or discontinued study prior to Day 29 are censored at Day 30.
[a] Log Rank test is stratified by age (categorical) and qualitative baseline serostatus.
[b] Cox Proportional Hazard model is used to estimate the hazard ratio where the model includes age (categorical as 12-17 years, 18-65 years and >65 years) as a stratification variable and sex (categorical), qualitative baseline serostatus (categorical as positive; negative), baseline BMI (continuous) and baseline viral load (continuous as log10 copies/mL) as covariates.
Source Data: ADSL, ADBL, ADVIRTTE, Listing 16.2.6.2
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050601.sas Executed: 30JUN2022 19:37

Table 14.2.6.1.1
COVID-19-Related Medically Attended Visits or All-Cause Death through Day 29
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | ADG20 vs. Placebo |
|---|---|---|---|
| COVID-19-Related Medically Attended Visits or All-Cause Death through Day 29 | 9 ( 5.3) | 29 (17.4) | |
| Death | 1 ( 0.6) | 6 ( 3.6) | |
| COVID-19 Related Visits | 9 ( 5.3) | 28 (16.8) | |
| Hospitalization | 8 ( 4.7) | 22 (13.2) | |
| Emergency Room Visit | 0 | 0 | |
| Urgent Care | 0 | 0 | |
| Physician Office | 1 ( 0.6) | 6 ( 3.6) | |
| Telemedicine | 0 | 1 ( 0.6) | |
| Risk Difference[a] | | | -12.0% |
| 95% CI[b] | | | (-19.11, -5.48) |
| Relative Risk Reduction[a] | | | 69.3% |

CI=confidence interval.
Note: Medically attended visits include telemedicine visits not specified in the protocol, emergency room or urgent care center visits, hospitalization, or visits to a physician's office. COVID-19-related medically attended visits include such visits for attention to worsening signs or symptoms attributed to COVID-19, in the opinion of the investigator. Participants may be counted in more than one visit category.
[a] Based on observed data.
[b] CI from the Miettinen-Nurminen method.
[c] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
[d] Missing outcome is determined for participants who had no reported qualifying event through Day 29 and who discontinued from study prior to Day 29.
Source Data: ADSL, ADBL, ADRESP, Listing 16.2.6.3.2, 16.2.7.5
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402060101.sas Executed: 30JUN2022 19:37

Table 14.2.6.1.1
COVID-19-Related Medically Attended Visits or All-Cause Death through Day 29
mFAS-non-Omicron

| | ADG20 (N=169) | Placebo (N=167) | ADG20 vs. Placebo |
|---|---|---|---|
| Standardized Risk Difference[c] | 5.5% | 16.8% | -11.3% |
| 95% CI | | | (-17.86, -4.81) |
| 2-sided p-value | | | 0.0007 |
| Standardized Relative Risk Reduction[c] | | | 67.3% |
| 95% CI | | | (33.25, 84.01) |
| Alive and No COVID-19-Related Medically Attended Visits | 156 (92.3) | 135 (80.8) | |
| Missing Outcome[d] | 4 ( 2.4) | 3 ( 1.8) | |

CI=confidence interval.
Note: Medically attended visits include telemedicine visits not specified in the protocol, emergency room or urgent care center visits, hospitalization, or visits to a physician's office. COVID-19-related medically attended visits include such visits for attention to worsening signs or symptoms attributed to COVID-19, in the opinion of the investigator. Participants may be counted in more than one visit category.
[a] Based on observed data.
[b] CI from the Miettinen-Nurminen method.
[c] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
[d] Missing outcome is determined for participants who had no reported qualifying event through Day 29 and who discontinued from study prior to Day 29.
Source Data: ADSL, ADBL, ADRESP, Listing 16.2.6.3.2, 16.2.7.5
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402060101.sas Executed: 30JUN2022 19:37

Table 14.2.5.5.1
Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 3 Samples | 140 | 137 | | |
| Participants achieved sustained viral clearance | 12 ( 8.6) | 5 ( 3.6) | 4.9% | n/e (n/e, n/e) n/e |
| Participants with Day 5 Samples | 137 | 134 | | |
| Participants achieved sustained viral clearance | 21 (15.3) | 9 ( 6.7) | 8.6% | 8.2% (1.15, 15.31) 0.0227 |
| Participants with Day 7 Samples | 135 | 131 | | |
| Participants achieved sustained viral clearance | 27 (20.0) | 19 (14.5) | 5.5% | 4.5% (-4.30, 13.22) 0.3185 |

CI=confidence interval; Diff=difference; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050501.sas Executed: 30JUN2022 19:36

Table 14.2.5.5.1
Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 11 Samples | 134 | 131 | | |
| Participants achieved sustained viral clearance | 55 (41.0) | 40 (30.5) | 10.5% | 8.4% (-2.90, 19.61) 0.1456 |
| Participants with Day 14 Samples | 134 | 128 | | |
| Participants achieved sustained viral clearance | 73 (54.5) | 62 (48.4) | 6.0% | 4.0% (-7.94, 15.89) 0.5128 |
| Participants with Day 21 Samples | 139 | 129 | | |
| Participants achieved sustained viral clearance | 98 (70.5) | 83 (64.3) | 6.2% | 4.3% (-6.84, 15.37) 0.4517 |

CI=confidence interval; Diff=difference; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050501.sas Executed: 30JUN2022 19:36

Table 14.2.5.5.1
Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint
mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 29 Samples | 136 | 130 | | |
| Participants achieved sustained viral clearance | 123 (90.4) | 116 (89.2) | 1.2% | 2.2% (-5.02, 9.47) 0.5476 |

CI=confidence interval; Diff=difference; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050501.sas Executed: 30JUN2022 19:36

Table 14.2.5.5.2

Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint within Baseline Subgroup NP Viral Load >5 log10 copies/mL

mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Baseline NP Viral Load >5 log10 copies/mL | 125 | 126 | | |
| Participants with Day 3 Samples | 121 | 116 | | |
| Participants achieved sustained viral clearance | 11 ( 9.1) | 3 ( 2.6) | 6.5% | n/e<br>(n/e, n/e)<br>n/e |
| Participants with Day 5 Samples | 119 | 114 | | |
| Participants achieved sustained viral clearance | 19 (16.0) | 7 ( 6.1) | 9.8% | 10.0%<br>(2.50, 17.60)<br>0.0091 |

CI=confidence interval; Diff=difference; NP=nasopharyngeal; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing the study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

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Table 14.2.5.5.2

Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint within Baseline Subgroup NP Viral Load >5 log10 copies/mL

mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 7 Samples | 115 | 112 | | |
| Participants achieved sustained viral clearance | 23 (20.0) | 14 (12.5) | 7.5% | 7.5% (-1.79, 16.81) 0.1136 |
| Participants with Day 11 Samples | 115 | 112 | | |
| Participants achieved sustained viral clearance | 45 (39.1) | 35 (31.3) | 7.9% | 6.9% (-5.37, 19.21) 0.2696 |
| Participants with Day 14 Samples | 115 | 108 | | |
| Participants achieved sustained viral clearance | 62 (53.9) | 51 (47.2) | 6.7% | 5.4% (-7.66, 18.48) 0.4173 |

CI=confidence interval; Diff=difference; NP=nasopharyngeal; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing the study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050502.sas Executed: 30JUN2022 19:36

Table 14.2.5.5.2

Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint within Baseline Subgroup NP Viral Load >5 log10 copies/mL

mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 21 Samples | 117 | 110 | | |
| Participants achieved sustained viral clearance | 83 (70.9) | 70 (63.6) | 7.3% | 6.0% (-6.14, 18.23) 0.3310 |
| Participants with Day 29 Samples | 116 | 110 | | |
| Participants achieved sustained viral clearance | 105 (90.5) | 98 (89.1) | 1.4% | 2.8% (-5.22, 10.73) 0.4981 |

CI=confidence interval; Diff=difference; NP=nasopharyngeal; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing the study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050502.sas Executed: 30JUN2022 19:36

Table 14.2.5.5.3

Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint within Baseline Subgroup NP Viral Load <=5 log10 copies/mL

mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Baseline NP Viral Load <=5 log10 copies/mL | 21 | 23 | | |
| Participants with Day 3 Samples | 19 | 21 | | |
| Participants achieved sustained viral clearance | 1 ( 5.3) | 2 ( 9.5) | -4.3% | n/e (n/e, n/e) n/e |
| Participants with Day 5 Samples | 18 | 20 | | |
| Participants achieved sustained viral clearance | 2 (11.1) | 2 (10.0) | 1.1% | n/e (n/e, n/e) n/e |

CI=confidence interval; Diff=difference; NP=nasopharyngeal; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable and/or event count <5.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing the study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance. For timepoints with less than 5 total events, only descriptive statistics are presented.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050503.sas Executed: 30JUN2022 19:37

Table 14.2.5.5.3

Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint within Baseline Subgroup NP Viral Load <=5 log10 copies/mL

mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 7 Samples | 19 | 19 | | |
| Participants achieved sustained viral clearance | 3 (15.8) | 5 (26.3) | -10.5% | -8.9% (-34.70, 16.89) 0.4985 |
| Participants with Day 11 Samples | 18 | 19 | | |
| Participants achieved sustained viral clearance | 9 (50.0) | 5 (26.3) | 23.7% | 23.3% (-5.43, 52.04) 0.1119 |
| Participants with Day 14 Samples | 18 | 20 | | |
| Participants achieved sustained viral clearance | 10 (55.6) | 11 (55.0) | 0.6% | -1.6% (-34.55, 31.37) 0.9246 |

CI=confidence interval; Diff=difference; NP=nasopharyngeal; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable and/or event count <5.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing the study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance. For timepoints with less than 5 total events, only descriptive statistics are presented.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050503.sas Executed: 30JUN2022 19:37

Table 14.2.5.5.3

Proportion of Participants with SARS-CoV-2 Viral Clearance Assessed by RT-qPCR from Saliva Samples by Timepoint within Baseline Subgroup NP Viral Load <=5 log10 copies/mL

mFAS-non-Omicron-S

| | ADG20 (N=147) | Placebo (N=149) | Risk Difference | Standardized Risk Diff (95% CI) p-value[a] |
|---|---|---|---|---|
| Participants with Day 21 Samples | 21 | 19 | | |
| Participants achieved sustained viral clearance | 14 (66.7) | 13 (68.4) | -1.8% | -3.8% (-34.11, 26.50) 0.8056 |
| Participants with Day 29 Samples | 19 | 20 | | |
| Participants achieved sustained viral clearance | 17 (89.5) | 18 (90.0) | -0.5% | -9.8% (-30.66, 11.00) 0.3551 |

CI=confidence interval; Diff=difference; NP=nasopharyngeal; RT-qPCR=quantitative reverse transcription polymerase chain reaction; n/e=not evaluable and/or event count <5.

Note: Table summarizes the cumulative proportion of participants who achieved viral clearance at the given timepoint. Viral clearance is defined as the viral load is not detected, i.e., below the limit of detection (LOD), and sustained through Day 29. Participants experiencing death or discontinuing the study before Day 29 are considered to have no viral clearance. Missing viral clearance status is imputed as having no viral clearance. For timepoints with less than 5 total events, only descriptive statistics are presented.

[a] A standardized estimator for a binary outcome is analyzed by treatment with adjustment for the following prognostic factors: age (continuous), sex (categorical), qualitative baseline serostatus (categorical as positive or negative), BMI (continuous) and baseline viral load (continuous as log10 copies/mL). The standard error of the standardized estimator is estimated using the delta method as described in SAP.

Source Data: ADSL, ADBL, ADMB, ADRESP, Listing 16.2.6.2

Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\T1402050503.sas Executed: 30JUN2022 19:37

Table 14.2.8.2
Baseline, Post-Baseline, and Treatment-Emergent Variations at Critical Amino Acid Positions Associated with ADG20 Resistance (>=15% Allele Frequency)
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) |
|---|---|---|
| Participants with Qualifying WGS Data | | |
| Baseline | 171 (86.4) | 184 (91.5) |
| Post-Baseline | 97 (49.0) | 122 (60.7) |
| Baseline and Post-Baseline | 95 (48.0) | 119 (59.2) |
| Participants with any G504 Variant at >=15% Allele Frequency [a] | | |
| Baseline | 0 | 0 |
| Post-Baseline | 4 ( 4.1) | 0 |
| Treatment-Emergent | 3 ( 3.2) | 0 |
| Participants with any R403 Variant at >=15% Allele Frequency [b] | | |
| Baseline | 0 | 0 |
| Post-Baseline | 0 | 0 |
| Treatment-Emergent | 0 | 0 |

WGS = Whole Genome Sequencing.
Note: Qualifying WGS data is data that passed QC. Percentages for "Baseline" sections are based on the number of participants with qualifying data at baseline. Percentages for "Post-Baseline" sections are based on the number of participants with qualifying data at any post-baseline timepoint. Treatment emergent variants are those presented in the post-baseline sample but not in the baseline sample of the same participant and requires available WGS baseline and post-baseline results from the same participant. A participant may have more than one baseline or post-baseline sample. The detection of an amino acid variant(s) in one or more post-baseline samples is only counted as one event for that participant.
[a] Amino acid variants at G504 in the SARS-CoV-2 spike protein were selected in cell culture with loss of susceptibility to ADG20.
[b] Amino acid variants at positions R403, D405 (excluding D405N), G502, V503 (excluding V503V), and Y505 (excluding Y505H) in the SARS-CoV-2 spike protein demonstrated loss of binding affinity and/or reduced activity of ADG20.
Source Data: ADSL, ADWGS, Listing 16.2.6.4.2, 16.2.6.4.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t14020802.sas Executed: 30JUN2022 19:27

Table 14.2.8.2
Baseline, Post-Baseline, and Treatment-Emergent Variations at Critical Amino Acid Positions Associated with ADG20 Resistance (>=15% Allele Frequency)
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) |
|---|---|---|
| Participants with any D405 (excluding D405N) Variant at >=15% Allele Frequency [b] | | |
| Baseline | 0 | 0 |
| Post-Baseline | 0 | 0 |
| Treatment-Emergent | 0 | 0 |
| Participants with any G502 Variant at >=15% Allele Frequency [b] | | |
| Baseline | 0 | 0 |
| Post-Baseline | 0 | 0 |
| Treatment-Emergent | 0 | 0 |
| Participants with any V503 (excluding V503V) Variant at >=15% Allele Frequency [b] | | |
| Baseline | 0 | 0 |
| Post-Baseline | 0 | 0 |
| Treatment-Emergent | 0 | 0 |

WGS = Whole Genome Sequencing.
Note: Qualifying WGS data is data that passed QC. Percentages for "Baseline" sections are based on the number of participants with qualifying data at baseline. Percentages for "Post-Baseline" sections are based on the number of participants with qualifying data at any post-baseline timepoint. Treatment emergent variants are those presented in the post-baseline sample but not in the baseline sample of the same participant and requires available WGS baseline and post-baseline results from the same participant. A participant may have more than one baseline or post-baseline sample. The detection of an amino acid variant(s) in one or more post-baseline samples is only counted as one event for that participant.
[a] Amino acid variants at G504 in the SARS-CoV-2 spike protein were selected in cell culture with loss of susceptibility to ADG20.
[b] Amino acid variants at positions R403, D405 (excluding D405N), G502, V503 (excluding V503V), and Y505 (excluding Y505H) in the SARS-CoV-2 spike protein demonstrated loss of binding affinity and/or reduced activity of ADG20.
Source Data: ADSL, ADWGS, Listing 16.2.6.4.2, 16.2.6.4.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t14020802.sas Executed: 30JUN2022 19:27

Table 14.2.8.2
Baseline, Post-Baseline, and Treatment-Emergent Variations at Critical Amino Acid Positions Associated with ADG20 Resistance (>=15% Allele Frequency)
Full Analysis Set

| | ADG20 (N=198) | Placebo (N=201) |
|---|---|---|
| Participants with any Y505 (excluding Y505H) Variant at >=15% Allele Frequency [b] | | |
| Baseline | 0 | 0 |
| Post-Baseline | 0 | 0 |
| Treatment-Emergent | 0 | 0 |

WGS = Whole Genome Sequencing.
Note: Qualifying WGS data is data that passed QC. Percentages for "Baseline" sections are based on the number of participants with qualifying data at baseline. Percentages for "Post-Baseline" sections are based on the number of participants with qualifying data at any post-baseline timepoint. Treatment emergent variants are those presented in the post-baseline sample but not in the baseline sample of the same participant and requires available WGS baseline and post-baseline results from the same participant. A participant may have more than one baseline or post-baseline sample. The detection of an amino acid variant(s) in one or more post-baseline samples is only counted as one event for that participant.
[a] Amino acid variants at G504 in the SARS-CoV-2 spike protein were selected in cell culture with loss of susceptibility to ADG20.
[b] Amino acid variants at positions R403, D405 (excluding D405N), G502, V503 (excluding V503V), and Y505 (excluding Y505H) in the SARS-CoV-2 spike protein demonstrated loss of binding affinity and/or reduced activity of ADG20.
Source Data: ADSL, ADWGS, Listing 16.2.6.4.2, 16.2.6.4.3
Program Path: \\wilbtib\wilbtib07\Adagio ADG20TRMT001_U\Bios Trunk\TLF\t14020802.sas Executed: 30JUN2022 19:27

Table 14.2.8.1.1
Anti-Drug Antibodies (ADAs) Confirmatory Assay Results by Timepoint
Immunogenicity Set

| | ADG20 (N=137) | Placebo (N=0) |
|---|---|---|
| Any Post-Dose Timepoint | | |
| Positive | 12 ( 8.8) | 0 |
| Negative | 125 (91.2) | 0 |
| Day 1 (pre-dose) | 137 | 0 |
| Positive | 6 ( 4.4) | 0 |
| Negative | 131 (95.6) | 0 |
| Day 29 | 137 | 0 |
| Positive | 11 ( 8.0) | 0 |
| Negative | 126 (92.0) | 0 |
| Day 90 | 107 | 0 |
| Positive | 5 ( 4.7) | 0 |
| Negative | 102 (95.3) | 0 |

ADA=anti-drug antibodies.
Note: Percentages are based on the number of participants with data at the timepoint. ADA status (positive or negative) is determined based on the confirmatory assay. Placebo group has only 10% of samples tested at baseline and no samples tested post-baseline. Nominal visit is used in analysis.
[a] In the event that a participant reports a hypersensitivity reaction after Day 4 and outside of a regularly scheduled in-person visit, an unscheduled ADA sample is collected. The 'Positive' category includes all participants who had positive ADA status at one or more unscheduled visits.
Source Data: ADIS, Listing 16.2.6.4.1 EXECUTED: 2022-09-27:15:44:22
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_2_8_1_1_ADA_CONFIRM.sas

Table 14.2.8.1.1
Anti-Drug Antibodies (ADAs) Confirmatory Assay Results by Timepoint
Immunogenicity Set

| | **ADG20 (N=137)** | **Placebo (N=0)** |
|---|---|---|
| Month 6 | 87 | 0 |
| Positive | 5 ( 5.7) | 0 |
| Negative | 82 (94.3) | 0 |

ADA=anti-drug antibodies.
Note: Percentages are based on the number of participants with data at the timepoint. ADA status (positive or negative) is determined based on the confirmatory assay. Placebo group has only 10% of samples tested at baseline and no samples tested post-baseline. Nominal visit is used in analysis.
[a] In the event that a participant reports a hypersensitivity reaction after Day 4 and outside of a regularly scheduled in-person visit, an unscheduled ADA sample is collected. The 'Positive' category includes all participants who had positive ADA status at one or more unscheduled visits.
Source Data: ADIS, Listing 16.2.6.4.1 EXECUTED: 2022-09-27:15:44:22
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_2_8_1_1_ADA_CONFIRM.sas

Table 14.2.8.1.2
Treatment-Emergent Anti-Drug Antibodies (ADA) by Timepoint
Immunogenicity Set

| | ADG20 (N=137) | Placebo (N=0) |
|---|---|---|
| Participants with Treatment-Emergent ADA at Any Post-Baseline Timepoint | 7 ( 5.1) | 0 |
| Baseline Negative/Post-Baseline Positive[a] | 7 ( 5.1) | 0 |
| Baseline Positive/Post-Baseline Positive and High ADA Titer[b] | 0 | 0 |
| Participants with Treatment-Emergent ADA at Day 29 | 6 ( 4.4) | 0 |
| Baseline Negative/Post-Baseline Positive[a] | 6 ( 4.4) | 0 |
| Baseline Positive/Post-Baseline Positive and High ADA Titer[b] | 0 | 0 |
| Participants with Treatment-Emergent ADA at Day 90 | 2 ( 1.5) | 0 |
| Baseline Negative/Post-Baseline Positive[a] | 2 ( 1.5) | 0 |
| Baseline Positive/Post-Baseline Positive and High ADA Titer[b] | 0 | 0 |
| Participants with Treatment-Emergent ADA at Month 6 | 2 ( 1.5) | 0 |

ADA = anti-drug antibodies.
Note: Placebo group has only 10% of samples tested at baseline and no samples tested post-baseline. Nominal visit is used in analysis.
[a] Treatment-emergent ADA based on a negative ADA measurement at baseline and positive ADA post-baseline (Day 29, Day 90, Month 6 or Month 11).
[b] Treatment-emergent ADA based on a positive ADA measurement at baseline and a positive ADA measurement post-baseline (Day 29, Day 90, Month 6 or Month 11) with an ADA titer >=4 times the baseline ADA titer.
[c] In the event that a participant reports a hypersensitivity reaction after Day 4 and outside of a regularly scheduled in-person visit, an unscheduled ADA sample is collected. Counts within each category reflect the number of participants who met the given criteria at one or more unscheduled visits.
Source Data: ADIS, Listing 16.2.6.4.1 EXECUTED: 2022-09-26: 9:16:12
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_2_8_1_2_TEADA.sas

Table 14.2.8.1.2
Treatment-Emergent Anti-Drug Antibodies (ADA) by Timepoint
Immunogenicity Set

| | ADG20 (N=137) | Placebo (N=0) |
|---|---|---|
| Baseline Negative/Post-Baseline Positive[a] | 2 ( 1.5) | 0 |
| Baseline Positive/Post-Baseline Positive and High ADA Titer[b] | 0 | 0 |

ADA = anti-drug antibodies.
Note: Placebo group has only 10% of samples tested at baseline and no samples tested post-baseline. Nominal visit is used in analysis.
[a] Treatment-emergent ADA based on a negative ADA measurement at baseline and positive ADA post-baseline (Day 29, Day 90, Month 6 or Month 11).
[b] Treatment-emergent ADA based on a positive ADA measurement at baseline and a positive ADA measurement post-baseline (Day 29, Day 90, Month 6 or Month 11) with an ADA titer >=4 times the baseline ADA titer.
[c] In the event that a participant reports a hypersensitivity reaction after Day 4 and outside of a regularly scheduled in-person visit, an unscheduled ADA sample is collected. Counts within each category reflect the number of participants who met the given criteria at one or more unscheduled visits.
Source Data: ADIS, Listing 16.2.6.4.1 EXECUTED: 2022-09-26: 9:16:12
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_2_8_1_2_TEADA.sas

Table 14.2.8.1.3
Summary of Anti-Drug Antibodies (ADA) Titer Results by Timepoint for Participants Positive for ADA
Immunogenicity Set

| Visit | Statistics | ADG20 (N=137) | Placebo (N=0) |
|---|---|---|---|
| At Any Timepoint Highest ADA Titer | n | 13 | |
| | Mean | 360.0 | |
| | SD | 776.8 | |
| | Median | 90.0 | |
| | Q1, Q3 | 90.0, 90.0 | |
| | Min, Max | 90, 2880 | |
| Day 1 (pre-dose) ADA Titer | n | 6 | |
| | Mean | 675.0 | |
| | SD | 1108 | |
| | Median | 135.0 | |
| | Q1, Q3 | 90.0, 720.0 | |
| | Min, Max | 90, 2880 | |
| Day 29 ADA Titer | n | 11 | |
| | Mean | 237.3 | |
| | SD | 407.0 | |

ADA = anti-drug antibodies; Q1= first quartile; Q3=third quartile.
Note: Placebo group has only 10% of samples tested at baseline and no samples tested post-baseline. Nominal visit is used in analysis.
[a] In the event that a participant reports a hypersensitivity reaction after Day 4 and outside of a regularly scheduled in-person visit, an unscheduled ADA sample is collected. In the event that a participant was positive for ADA at multiple unscheduled visits, the highest ADA titer is used in the analysis.
Source Data: ADIS, Listing 16.2.6.4.1 EXECUTED: 2022-09-26: 9:16:40
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_2_8_1_3_ADA_TITER.sas

Table 14.2.8.1.3
Summary of Anti-Drug Antibodies (ADA) Titer Results by Timepoint for Participants Positive for ADA
Immunogenicity Set

| Visit | Statistics | ADG20 (N=137) | Placebo (N=0) |
|---|---|---|---|
| | Median | 90.0 | |
| | Q1, Q3 | 90.0, 90.0 | |
| | Min, Max | 90, 1440 | |
| Day 90 ADA Titer | n | 5 | |
| | Mean | 360.0 | |
| | SD | 603.7 | |
| | Median | 90.0 | |
| | Q1, Q3 | 90.0, 90.0 | |
| | Min, Max | 90, 1440 | |
| Month 6 ADA Titer | n | 5 | |
| | Mean | 90.0 | |
| | SD | 0.00 | |
| | Median | 90.0 | |
| | Q1, Q3 | 90.0, 90.0 | |
| | Min, Max | 90, 90 | |

ADA = anti-drug antibodies; Q1= first quartile; Q3=third quartile.
Note: Placebo group has only 10% of samples tested at baseline and no samples tested post-baseline. Nominal visit is used in analysis.
[a] In the event that a participant reports a hypersensitivity reaction after Day 4 and outside of a regularly scheduled in-person visit, an unscheduled ADA sample is collected. In the event that a participant was positive for ADA at multiple unscheduled visits, the highest ADA titer is used in the analysis.
Source Data: ADIS, Listing 16.2.6.4.1 EXECUTED: 2022-09-26: 9:16:40
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_2_8_1_3_ADA_TITER.sas

Table 14.2.9.1
Summary of ADG20 Serum Concentrations(ug/mL) - Time
PK Analysis Set

| Nominal Time Point | Summary Statistic | Treatment Group: ADG20 300 MG IM (N=189) |
|---|---|---|
| Day 1 (Predose) | n | 78 |
| | Arithmetic Mean | 0.0292 |
| | SD | 0.258 |
| | CV(%) | 883.2 |
| | Geometric Mean | . |
| | Geometric CV(%) | . |
| | Median | 0 |
| | Minimum | 0 |
| | Maximum | 2.28 |
| Day 7 | n | 171 |
| | Arithmetic Mean | 36.5 |
| | SD | 15.1 |
| | CV(%) | 41.3 |
| | Geometric Mean | 34.1 |
| | Geometric CV(%) | 46.6 |
| | Median | 35.8 |
| | Minimum | 0 |
| | Maximum | 85.5 |

For the calculation of summary statistics, BLQ values are treated as zero.
BLQ = below the limit of quantification (0.50 ug/mL).
BLQ values are treated as missing for the calculation of geometric mean and geometric CV%.
CV = Coefficient of variation; IM = Intra Muscular; SD = Standard deviation.
Note: As there was only one measurable pre-dose concentration record for Day 1 samples, Geometric Mean and Geometric CV (%) were set to missing.
Source: Listing 16.2.6.5
\\wilbtib\wilbtib07\Adagio ADG20TRMT001_PK\Trunk\TLF\t14020901.SAS  Executed: 22AUG2022 17:01

Table 14.2.9.1
Summary of ADG20 Serum Concentrations(ug/mL) - Time
PK Analysis Set

| Nominal Time Point | Summary Statistic | Treatment Group: ADG20 300 MG IM (N=189) |
|---|---|---|
| Day 29 | n | 138 |
| | Arithmetic Mean | 31.2 |
| | SD | 12.2 |
| | CV(%) | 39.1 |
| | Geometric Mean | 29.4 |
| | Geometric CV(%) | 41.2 |
| | Median | 31.7 |
| | Minimum | 0 |
| | Maximum | 64.4 |
| Day 90 | n | 19 |
| | Arithmetic Mean | 20.9 |
| | SD | 7.57 |
| | CV(%) | 36.3 |
| | Geometric Mean | 19.7 |
| | Geometric CV(%) | 36.5 |
| | Median | 20.6 |
| | Minimum | 9.80 |
| | Maximum | 41.6 |

For the calculation of summary statistics, BLQ values are treated as zero.
BLQ = below the limit of quantification (0.50 ug/mL).
BLQ values are treated as missing for the calculation of geometric mean and geometric CV%.
CV = Coefficient of variation; IM = Intra Muscular; SD = Standard deviation.
Note: As there was only one measurable pre-dose concentration record for Day 1 samples, Geometric Mean and Geometric CV (%) were set to missing.
Source: Listing 16.2.6.5
\\wilbtib\wilbtib07\Adagio ADG20TRMT001_PK\Trunk\TLF\t14020901.SAS Executed: 22AUG2022 17:01

Table 14.2.9.1
Summary of ADG20 Serum Concentrations(ug/mL) - Time
PK Analysis Set

| Nominal Time Point | Summary Statistic | Treatment Group: ADG20 300 MG IM (N=189) |
|---|---|---|
| Month 6 | n | 0 |
| | Arithmetic Mean | . |
| | SD | . |
| | CV(%) | . |
| | Geometric Mean | . |
| | Geometric CV(%) | . |
| | Median | . |
| | Minimum | . |
| | Maximum | . |

For the calculation of summary statistics, BLQ values are treated as zero.
BLQ = below the limit of quantification (0.50 ug/mL).
BLQ values are treated as missing for the calculation of geometric mean and geometric CV%.
CV = Coefficient of variation; IM = Intra Muscular; SD = Standard deviation.
Note: As there was only one measurable pre-dose concentration record for Day 1 samples, Geometric Mean and Geometric CV (%) were set to missing.
Source: Listing 16.2.6.5
\\wilbtib\wilbtib07\Adagio ADG20TRMT001_PK\Trunk\TLF\t14020901.SAS Executed: 22AUG2022 17:01

Table 14.3.1.3
Solicited Adverse Events of Injection Site Reactions Through Day 4
Safety Set

| Injection Site Reaction Maximum Severity | ADG20 (N=192) | Placebo (N=200) |
|---|---|---|
| Any Solicited ISR | 25 (13.0) | 19 ( 9.5) |
| Mild | 17 ( 8.9) | 12 ( 6.0) |
| Moderate | 7 ( 3.6) | 4 ( 2.0) |
| Severe | 0 | 0 |
| Potentially Life-Threatening | 0 | 0 |
| Non-graded [a] | 1 ( 0.5) | 3 ( 1.5) |
| Injection Site Pain | 12 ( 6.3) | 6 ( 3.0) |
| Mild | 12 ( 6.3) | 5 ( 2.5) |
| Moderate | 0 | 1 ( 0.5) |
| Severe | 0 | 0 |
| Potentially Life-Threatening | 0 | 0 |
| Injection Site Tenderness | 20 (10.4) | 14 ( 7.0) |
| Mild | 13 ( 6.8) | 11 ( 5.5) |
| Moderate | 7 ( 3.6) | 3 ( 1.5) |
| Severe | 0 | 0 |
| Potentially Life-Threatening | 0 | 0 |
| Injection Site Redness | 3 ( 1.6) | 6 ( 3.0) |

ISR=infusion site reaction; Q1=first quartile; Q3=third quartile.

Note: Every participant is counted a single time for each type of ISR. Only the maximum reported severity for each ISR type and longest duration of all ISRs reported are counted for each participant. Percentages are based on number of participants in each treatment group. AE severity is determined by FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007).

[a] If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.

[b] All necrosis and exfoliative dermatitis reactions are considered severity Grade 4 (necrosis is considered a Grade 4 erythema/redness or induration/swelling reaction; exfoliative dermatitis is considered a Grade 4 erythema/redness reaction).

[c] Longest duration of ISR is calculated from the date of the first diary report of the ISR to the date of the first diary report not citing the event, if there is no subsequent report of the same event. If an event is reported on a series of non-consecutive days, the duration is calculated from the date of the first diary report of the ISR to the last diary report of the ISR. If events persisted after Day 4, the duration is calculated from the date of the first diary report of the ISR to the date of resolution found on the ISR Resolution CRF. If events persisted after Day 4 and were ongoing at the time of data cutoff, the duration was set to >4 days.

Source Data: ADSL, ADAE, Listing 16.2.7.2 EXECUTED: 2022-09-06:13:57:07
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_3_ISR.sas

Table 14.3.1.3
Solicited Adverse Events of Injection Site Reactions Through Day 4
Safety Set

| Injection Site Reaction<br>Maximum Severity | ADG20<br>(N=192) | Placebo<br>(N=200) |
|---|---|---|
| Mild | 1 ( 0.5) | 0 |
| Moderate | 0 | 0 |
| Severe | 0 | 0 |
| Non-graded [a] | 2 ( 1.0) | 6 ( 3.0) |
| Injection Site Swelling | 1 ( 0.5) | 0 |
| Mild | 0 | 0 |
| Moderate | 0 | 0 |
| Severe | 0 | 0 |
| Non-graded [a] | 1 ( 0.5) | 0 |
| Any Necrosis [b] | 0 | 0 |
| Any Exfoliative Dermatitis [b] | 0 | 0 |
| Time from Injection to Report of First Onset of Any Solicited ISR (days) | | |
| n | 25 | 19 |
| Mean | 1.2 | 1.2 |
| SD | 0.41 | 0.37 |
| Median | 1.0 | 1.0 |

ISR=infusion site reaction; Q1=first quartile; Q3=third quartile.
Note: Every participant is counted a single time for each type of ISR. Only the maximum reported severity for each ISR type and longest duration of all ISRs reported are counted for each participant. Percentages are based on number of participants in each treatment group. AE severity is determined by FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007).
[a] If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.
[b] All necrosis and exfoliative dermatitis reactions are considered severity Grade 4 (necrosis is considered a Grade 4 erythema/redness or induration/swelling reaction; exfoliative dermatitis is considered a Grade 4 erythema/redness reaction).
[c] Longest duration of ISR is calculated from the date of the first diary report of the ISR to the date of the first diary report not citing the event, if there is no subsequent report of the same event. If an event is reported on a series of non-consecutive days, the duration is calculated from the date of the first diary report of the ISR to the last diary report of the ISR. If events persisted after Day 4, the duration is calculated from the date of the first diary report of the ISR to the date of resolution found on the ISR Resolution CRF. If events persisted after Day 4 and were ongoing at the time of data cutoff, the duration was set to >4 days.
Source Data: ADSL, ADAE, Listing 16.2.7.2 EXECUTED: 2022-09-06:13:57:07
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_3_ISR.sas

Table 14.3.1.3
Solicited Adverse Events of Injection Site Reactions Through Day 4
Safety Set

| Injection Site Reaction Maximum Severity | ADG20 (N=192) | Placebo (N=200) |
|---|---|---|
| Q1, Q3 | 1.0, 1.0 | 1.0, 1.0 |
| Min, Max | 1, 2 | 1, 2 |
| Longest Duration of Any Solicited ISR [c] | | |
| 1 day | 19 ( 9.9) | 11 ( 5.5) |
| 2 days | 2 ( 1.0) | 4 ( 2.0) |
| 3 days | 1 ( 0.5) | 2 ( 1.0) |
| 4 days | 1 ( 0.5) | 0 |
| >4 days | 2 ( 1.0) | 2 ( 1.0) |

ISR=infusion site reaction; Q1=first quartile; Q3=third quartile.

Note: Every participant is counted a single time for each type of ISR. Only the maximum reported severity for each ISR type and longest duration of all ISRs reported are counted for each participant. Percentages are based on number of participants in each treatment group. AE severity is determined by FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007).

[a] If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.

[b] All necrosis and exfoliative dermatitis reactions are considered severity Grade 4 (necrosis is considered a Grade 4 erythema/redness or induration/swelling reaction; exfoliative dermatitis is considered a Grade 4 erythema/redness reaction).

[c] Longest duration of ISR is calculated from the date of the first diary report of the ISR to the date of the first diary report not citing the event, if there is no subsequent report of the same event. If an event is reported on a series of non-consecutive days, the duration is calculated from the date of the first diary report of the ISR to the last diary report of the ISR. If events persisted after Day 4, the duration is calculated from the date of the first diary report of the ISR to the date of resolution found on the ISR Resolution CRF. If events persisted after Day 4 and were ongoing at the time of data cutoff, the duration was set to >4 days.

Source Data: ADSL, ADAE, Listing 16.2.7.2 EXECUTED: 2022-09-06:13:57:07
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_3_ISR.sas

Table 14.3.1.6
Study Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term<br>Severity [a] | Through Day 29<br>ADG20 (N=192)<br>n (%) | Through Day 29<br>Placebo (N=200)<br>n (%) | Through Month 14<br>ADG20 (N=192)<br>n (%) | Through Month 14<br>Placebo (N=200)<br>n (%) |
|---|---|---|---|---|
| Number of Study Drug-Related TEAEs [b] | 37 | 26 | 37 | 26 |
| Non-graded | 3 | 6 | 3 | 6 |
| Grade 1 | 27 | 16 | 27 | 16 |
| Grade 2 | 7 | 4 | 7 | 4 |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |
| Participants with Any Study Drug-Related TEAE [b] | 26 (13.5) | 19 ( 9.5) | 26 (13.5) | 19 ( 9.5) |
| Non-graded | 1 ( 0.5) | 3 ( 1.5) | 1 ( 0.5) | 3 ( 1.5) |
| Grade 1 | 18 ( 9.4) | 12 ( 6.0) | 18 ( 9.4) | 12 ( 6.0) |
| Grade 2 | 7 ( 3.6) | 4 ( 2.0) | 7 ( 3.6) | 4 ( 2.0) |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |

DAIDS=Division of Allergy and Infectious Diseases; TEAE=Treatment-Emergent Adverse Event.
Note: The number of AEs counts all study drug-related TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once for the most severe event for each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
[a] Unsolicited TEAEs are graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017). Solicited TEAEs (injection site reactions) are graded using FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007). If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.
[b] Missing relationship to study drug is imputed as 'Related' and all solicited AEs are assumed to be 'Related.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-09-06:11:51:44
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_6_soc_pt_grd.sas

Table 14.3.1.6
Study Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term<br>Severity [a] | Through Day 29<br>ADG20 (N=192)<br>n (%) | Through Day 29<br>Placebo (N=200)<br>n (%) | Through Month 14<br>ADG20 (N=192)<br>n (%) | Through Month 14<br>Placebo (N=200)<br>n (%) |
|---|---|---|---|---|
| General disorders and administration site conditions | 25 (13.0) | 19 ( 9.5) | 25 (13.0) | 19 ( 9.5) |
| Non-graded | 1 ( 0.5) | 3 ( 1.5) | 1 ( 0.5) | 3 ( 1.5) |
| Grade 1 | 17 ( 8.9) | 12 ( 6.0) | 17 ( 8.9) | 12 ( 6.0) |
| Grade 2 | 7 ( 3.6) | 4 ( 2.0) | 7 ( 3.6) | 4 ( 2.0) |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |
| Injection site pain | 23 (12.0) | 16 ( 8.0) | 23 (12.0) | 16 ( 8.0) |
| Grade 1 | 16 ( 8.3) | 12 ( 6.0) | 16 ( 8.3) | 12 ( 6.0) |
| Grade 2 | 7 ( 3.6) | 4 ( 2.0) | 7 ( 3.6) | 4 ( 2.0) |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |
| Injection site erythema | 3 ( 1.6) | 6 ( 3.0) | 3 ( 1.6) | 6 ( 3.0) |
| Non-graded | 2 ( 1.0) | 6 ( 3.0) | 2 ( 1.0) | 6 ( 3.0) |
| Grade 1 | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |

DAIDS=Division of Allergy and Infectious Diseases; TEAE=Treatment-Emergent Adverse Event.
Note: The number of AEs counts all study drug-related TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once for the most severe event for each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
[a] Unsolicited TEAEs are graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017). Solicited TEAEs (injection site reactions) are graded using FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007). If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.
[b] Missing relationship to study drug is imputed as 'Related' and all solicited AEs are assumed to be 'Related.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-09-06:11:51:44
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_6_soc_pt_grd.sas

Table 14.3.1.6
Study Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term<br>Severity [a] | Through Day 29<br>ADG20 (N=192)<br>n (%) | Through Day 29<br>Placebo (N=200)<br>n (%) | Through Month 14<br>ADG20 (N=192)<br>n (%) | Through Month 14<br>Placebo (N=200)<br>n (%) |
|---|---|---|---|---|
| Grade 2 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |
| Injection site swelling | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Non-graded | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Grade 1 | 0 | 0 | 0 | 0 |
| Grade 2 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |
| Gastrointestinal disorders | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Grade 1 | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Grade 2 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 |

DAIDS=Division of Allergy and Infectious Diseases; TEAE=Treatment-Emergent Adverse Event.
Note: The number of AEs counts all study drug-related TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once for the most severe event for each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
[a] Unsolicited TEAEs are graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017). Solicited TEAEs (injection site reactions) are graded using FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007). If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.
[b] Missing relationship to study drug is imputed as 'Related' and all solicited AEs are assumed to be 'Related.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-09-06:11:51:44
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_6_soc_pt_grd.sas

Table 14.3.1.6
Study Drug-Related Treatment Emergent Adverse Events by System Organ Class, Preferred Term, and Maximum Severity Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term<br>Severity [a] | Through Day 29<br>ADG20 (N=192)<br>n (%) | Through Day 29<br>Placebo (N=200)<br>n (%) | Through Month 14<br>ADG20 (N=192)<br>n (%) | Through Month 14<br>Placebo (N=200)<br>n (%) |
|---|---|---|---|---|
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |
| Abdominal pain | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Grade 1 | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Grade 2 | 0 | 0 | 0 | 0 |
| Grade 3 | 0 | 0 | 0 | 0 |
| Grade 4 | 0 | 0 | 0 | 0 |
| Grade 5 | 0 | 0 | 0 | 0 |

DAIDS=Division of Allergy and Infectious Diseases; TEAE=Treatment-Emergent Adverse Event.
Note: The number of AEs counts all study drug-related TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once for the most severe event for each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
[a] Unsolicited TEAEs are graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017). Solicited TEAEs (injection site reactions) are graded using FDA Guidance for Industry: Toxicity Grading Scale for Preventative Vaccine Clinical Trials (DHHS 2007). If the participant reports redness or swelling <2.5 cm, severity was set to non-graded.
[b] Missing relationship to study drug is imputed as 'Related' and all solicited AEs are assumed to be 'Related.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-09-06:11:51:44
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_6_soc_pt_grd.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Number of TEAEs | 80 | 86 | 135 | 136 |
| Participants with Any TEAE | 47 (24.5) | 62 (31.0) | 75 (39.1) | 87 (43.5) |
| General disorders and administration site conditions | 27 (14.1) | 21 (10.5) | 27 (14.1) | 24 (12.0) |
| Injection site pain | 23 (12.0) | 16 ( 8.0) | 23 (12.0) | 16 ( 8.0) |
| Injection site erythema | 3 ( 1.6) | 6 ( 3.0) | 3 ( 1.6) | 6 ( 3.0) |
| Hypothermia | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) |
| Injection site swelling | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Non-cardiac chest pain | 1 ( 0.5) | 0 | 1 ( 0.5) | 1 ( 0.5) |
| Oedema peripheral | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Multiple organ dysfunction syndrome | 0 | 0 | 0 | 1 ( 0.5) |
| Peripheral swelling | 0 | 0 | 0 | 1 ( 0.5) |
| Sudden death | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Infections and infestations | 10 ( 5.2) | 24 (12.0) | 23 (12.0) | 37 (18.5) |
| COVID-19 | 0 | 0 | 8 ( 4.2) | 3 ( 1.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| COVID-19 pneumonia | 8 ( 4.2) | 24 (12.0) | 8 ( 4.2) | 24 (12.0) |
| Pneumonia | 0 | 0 | 2 ( 1.0) | 0 |
| Pneumonia bacterial | 1 ( 0.5) | 0 | 2 ( 1.0) | 0 |
| Ear infection | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Fungal oesophagitis | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Furuncle | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Gastroenteritis | 0 | 0 | 1 ( 0.5) | 1 ( 0.5) |
| Gastrointestinal infection | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Helicobacter infection | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Laryngitis | 0 | 0 | 1 ( 0.5) | 0 |
| Lower respiratory tract infection | 0 | 0 | 1 ( 0.5) | 1 ( 0.5) |
| Pharyngitis | 0 | 0 | 1 ( 0.5) | 2 ( 1.0) |
| Sinusitis | 0 | 0 | 1 ( 0.5) | 0 |
| Tonsillitis bacterial | 0 | 0 | 1 ( 0.5) | 0 |
| Asymptomatic COVID-19 | 0 | 0 | 0 | 1 ( 0.5) |
| Clostridium difficile colitis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Epididymitis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Listeriosis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Meningitis bacterial | 0 | 0 | 0 | 1 ( 0.5) |
| Nasopharyngitis | 0 | 0 | 0 | 1 ( 0.5) |
| Oral fungal infection | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Pneumonia klebsiella | 0 | 0 | 0 | 2 ( 1.0) |
| Pulmonary tuberculosis | 0 | 0 | 0 | 1 ( 0.5) |
| Respiratory tract infection | 0 | 0 | 0 | 1 ( 0.5) |
| Upper respiratory tract infection | 0 | 0 | 0 | 3 ( 1.5) |
| Musculoskeletal and connective tissue disorders | 5 ( 2.6) | 6 ( 3.0) | 11 ( 5.7) | 12 ( 6.0) |
| Back pain | 2 ( 1.0) | 3 ( 1.5) | 5 ( 2.6) | 4 ( 2.0) |
| Neck pain | 1 ( 0.5) | 0 | 3 ( 1.6) | 0 |
| Arthralgia | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | 3 ( 1.5) |
| Muscle spasms | 0 | 0 | 1 ( 0.5) | 0 |
| Muscle tightness | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Osteoarthritis | 0 | 0 | 1 ( 0.5) | 0 |
| Osteoporosis postmenopausal | 0 | 0 | 1 ( 0.5) | 0 |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Arthritis | 0 | 0 | 0 | 1 ( 0.5) |
| Groin pain | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Joint swelling | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Pain in extremity | 0 | 0 | 0 | 2 ( 1.0) |
| Nervous system disorders | 2 ( 1.0) | 4 ( 2.0) | 10 ( 5.2) | 5 ( 2.5) |
| Headache | 0 | 0 | 3 ( 1.6) | 0 |
| Dizziness | 1 ( 0.5) | 1 ( 0.5) | 2 ( 1.0) | 2 ( 1.0) |
| Cerebrovascular accident | 0 | 0 | 1 ( 0.5) | 0 |
| Encephalopathy | 0 | 0 | 1 ( 0.5) | 0 |
| Hypoaesthesia | 0 | 0 | 1 ( 0.5) | 0 |
| Migraine | 0 | 0 | 1 ( 0.5) | 0 |
| Syncope | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) | 2 ( 1.0) |
| Brain oedema | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Cerebral atrophy | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Gastrointestinal disorders | 5 ( 2.6) | 3 ( 1.5) | 8 ( 4.2) | 7 ( 3.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Diarrhoea | 0 | 0 | 2 ( 1.0) | 0 |
| Abdominal hernia | 0 | 0 | 1 ( 0.5) | 0 |
| Abdominal pain | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Abdominal pain upper | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) | 3 ( 1.5) |
| Gastric ulcer | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Gastritis | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Gastrointestinal haemorrhage | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Hiatus hernia | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Toothache | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | 3 ( 1.5) |
| Umbilical hernia | 0 | 0 | 1 ( 0.5) | 0 |
| Abdominal pain lower | 0 | 0 | 0 | 1 ( 0.5) |
| Metabolism and nutrition disorders | 3 ( 1.6) | 2 ( 1.0) | 7 ( 3.6) | 2 ( 1.0) |
| Diabetes mellitus | 2 ( 1.0) | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) |
| Hyperglycaemia | 0 | 1 ( 0.5) | 2 ( 1.0) | 1 ( 0.5) |
| Abnormal loss of weight | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Diabetes mellitus inadequate control | 0 | 0 | 1 ( 0.5) | 0 |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192) n (%) | Placebo (N=200) n (%) | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
| Dyslipidaemia | 0 | 0 | 1 ( 0.5) | 0 |
| Hyperkalaemia | 0 | 0 | 1 ( 0.5) | 0 |
| Investigations | 3 ( 1.6) | 2 ( 1.0) | 4 ( 2.1) | 5 ( 2.5) |
| Alanine aminotransferase increased | 2 ( 1.0) | 0 | 2 ( 1.0) | 0 |
| Aspartate aminotransferase increased | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Blood pressure increased | 0 | 0 | 1 ( 0.5) | 1 ( 0.5) |
| International normalised ratio increased | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Blood cholesterol increased | 0 | 0 | 0 | 1 ( 0.5) |
| Blood pressure decreased | 0 | 0 | 0 | 1 ( 0.5) |
| Hepatic enzyme increased | 0 | 2 ( 1.0) | 0 | 2 ( 1.0) |
| Vascular disorders | 2 ( 1.0) | 2 ( 1.0) | 4 ( 2.1) | 5 ( 2.5) |
| Hypertension | 1 ( 0.5) | 0 | 2 ( 1.0) | 2 ( 1.0) |
| Blood pressure fluctuation | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Thrombosis | 0 | 0 | 1 ( 0.5) | 0 |
| Aortic dilatation | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Essential hypertension | 0 | 0 | 0 | 1 ( 0.5) |
| Orthostatic hypotension | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Cardiac disorders | 1 ( 0.5) | 0 | 3 ( 1.6) | 1 ( 0.5) |
| Acute myocardial infarction | 0 | 0 | 1 ( 0.5) | 0 |
| Angina unstable | 0 | 0 | 1 ( 0.5) | 0 |
| Myocardial ischaemia | 0 | 0 | 1 ( 0.5) | 0 |
| Sinus bradycardia | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Extrasystoles | 0 | 0 | 0 | 1 ( 0.5) |
| Ear and labyrinth disorders | 0 | 0 | 2 ( 1.0) | 2 ( 1.0) |
| Tinnitus | 0 | 0 | 1 ( 0.5) | 0 |
| Vertigo | 0 | 0 | 1 ( 0.5) | 1 ( 0.5) |
| Ear pain | 0 | 0 | 0 | 1 ( 0.5) |
| Injury, poisoning and procedural complications | 1 ( 0.5) | 0 | 2 ( 1.0) | 0 |
| Ankle fracture | 0 | 0 | 1 ( 0.5) | 0 |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Chest injury | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Skin and subcutaneous tissue disorders | 1 ( 0.5) | 0 | 2 ( 1.0) | 0 |
| Rash | 0 | 0 | 1 ( 0.5) | 0 |
| Rash macular | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Blood and lymphatic system disorders | 1 ( 0.5) | 1 ( 0.5) | 1 ( 0.5) | 2 ( 1.0) |
| Leukopenia | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Anaemia | 0 | 1 ( 0.5) | 0 | 2 ( 1.0) |
| Eye disorders | 0 | 0 | 1 ( 0.5) | 0 |
| Conjunctivitis allergic | 0 | 0 | 1 ( 0.5) | 0 |
| Hepatobiliary disorders | 0 | 1 ( 0.5) | 1 ( 0.5) | 2 ( 1.0) |
| Hepatitis alcoholic | 0 | 0 | 1 ( 0.5) | 0 |
| Hepatic steatosis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Hepatitis | 0 | 0 | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Renal and urinary disorders | 0 | 2 ( 1.0) | 1 ( 0.5) | 2 ( 1.0) |
| Dysuria | 0 | 0 | 1 ( 0.5) | 0 |
| Calculus urinary | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Chronic kidney disease | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Hydronephrosis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Psychiatric disorders | 0 | 0 | 0 | 2 ( 1.0) |
| Insomnia | 0 | 0 | 0 | 2 ( 1.0) |
| Reproductive system and breast disorders | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Intermenstrual bleeding | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Respiratory, thoracic and mediastinal disorders | 0 | 2 ( 1.0) | 0 | 4 ( 2.0) |
| Allergic cough | 0 | 0 | 0 | 1 ( 0.5) |
| Oropharyngeal pain | 0 | 0 | 0 | 1 ( 0.5) |
| Pulmonary embolism | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 14.3.1.2.1
Treatment-Emergent Adverse Events (Solicited and Unsolicited) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Respiratory failure | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.1 EXECUTED: 2022-12-01:13:18:13
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_2_1_soc_pt.sas

Table 1
Non-Serious Treatment-Emergent Adverse Events Occurring in >5% of Participants in ADG20 Group by System Organ Class and Preferred Term
(Safety Set)

| System Organ Class<br>Preferred Term | ADG20<br>(N=192) | Placebo<br>(N=200) |
|---|---|---|
| Participants with Any Non-Serious TEAE | 23 (12.0) | 16 ( 8.0) |
| General disorders and administration site conditions | 23 (12.0) | 16 ( 8.0) |
| Injection site pain | 23 (12.0) | 16 ( 8.0) |

Notes: TEAE = Treatment-Emergent Adverse Event. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
PROGRAM PATH: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\Unblind\program\B415-BD361CC2C834\Prod\t_nsae_gt_5pct.sas
DATE: 2022-12-01:15:51:47

Table 14.3.1.9
Serious Treatment-Emergent Adverse Events Leading to Death by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Number of TEAEs Leading to Death | 1 | 6 | 2 | 7 |
| Participants with Any TEAE Leading to Death | 1 ( 0.5) | 6 ( 3.0) | 2 ( 1.0) | 7 ( 3.5) |
| Infections and infestations | 1 ( 0.5) | 5 ( 2.5) | 1 ( 0.5) | 5 ( 2.5) |
| COVID-19 pneumonia | 1 ( 0.5) | 5 ( 2.5) | 1 ( 0.5) | 5 ( 2.5) |
| Nervous system disorders | 0 | 0 | 1 ( 0.5) | 0 |
| Cerebrovascular accident | 0 | 0 | 1 ( 0.5) | 0 |
| General disorders and administration site conditions | 0 | 1 ( 0.5) | 0 | 2 ( 1.0) |
| Multiple organ dysfunction syndrome | 0 | 0 | 0 | 1 ( 0.5) |
| Sudden death | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: The number of TEAEs counts all TEAEs leading to death for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.5 EXECUTED: 2022-12-01:13:19:18
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_9_TEAE_DTH_soc_pt.sas

Table 14.3.1.10
Summary of Cause of Death Through Day 29 and Through Month 14
Safety Set

| | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192) n (%) | Placebo (N=200) n (%) | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
| Participants who Died | 1 ( 0.5) | 6 ( 3.0) | 2 ( 1.0) | 7 ( 3.5) |
| Primary Cause of Death | | | | |
| COVID-19 | 1 ( 0.5) | 5 ( 2.5) | 1 ( 0.5) | 5 ( 2.5) |
| Other Adverse Event | 0 | 0 | 1 ( 0.5) | 1 ( 0.5) |
| Unknown | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| COVID-19 or COVID-19 Complications Contributed to Death [a] | | | | |
| Yes | 1 ( 0.5) | 5 ( 2.5) | 1 ( 0.5) | 5 ( 2.5) |
| No | 0 | 1 ( 0.5) | 1 ( 0.5) | 2 ( 1.0) |
| Death Information Source | | | | |
| Medical Records | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Death Certificate | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Health Care Professional | 0 | 0 | 0 | 1 ( 0.5) |
| Primary or Secondary Personal Contact | 1 ( 0.5) | 3 ( 1.5) | 2 ( 1.0) | 3 ( 1.5) |

Note: Percentages are based on the number of participants in each treatment group.
[a] Did COVID-19 or COVID-19 complications contribute to the death (as determined by the investigator, a formal autopsy report, or death certificate)?
Source Data: ADSL, Listing 16.2.7.5 EXECUTED: 2022-12-01:13:17:48
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_10_Death.sas

Table 14.3.1.10
Summary of Cause of Death Through Day 29 and Through Month 14
Safety Set

| | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192) n (%) | Placebo (N=200) n (%) | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
| Public Source | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Other | 0 | 0 | 0 | 0 |

Note: Percentages are based on the number of participants in each treatment group.
[a] Did COVID-19 or COVID-19 complications contribute to the death (as determined by the investigator, a formal autopsy report, or death certificate)?
Source Data: ADSL, Listing 16.2.7.5 EXECUTED: 2022-12-01:13:17:48
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_10_Death.sas

Table 14.3.1.5.1
Serious Treatment-Emergent Adverse Events (excluding COVID-19-related PTs) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Number of Serious TEAEs | 3 | 8 | 10 | 12 |
| Participants with Any Serious TEAE | 2 ( 1.0) | 7 ( 3.5) | 7 ( 3.6) | 8 ( 4.0) |
| Infections and infestations | 1 ( 0.5) | 2 ( 1.0) | 3 ( 1.6) | 2 ( 1.0) |
| Pneumonia bacterial | 1 ( 0.5) | 0 | 2 ( 1.0) | 0 |
| Pneumonia | 0 | 0 | 1 ( 0.5) | 0 |
| Clostridium difficile colitis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Listeriosis | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Meningitis bacterial | 0 | 0 | 0 | 1 ( 0.5) |
| Pneumonia klebsiella | 0 | 0 | 0 | 1 ( 0.5) |
| Cardiac disorders | 0 | 0 | 2 ( 1.0) | 0 |
| Acute myocardial infarction | 0 | 0 | 1 ( 0.5) | 0 |
| Angina unstable | 0 | 0 | 1 ( 0.5) | 0 |

TEAE=Treatment-Emergent Adverse Event.
Note: COVID-19-related PTs are 'COVID-19' and 'COVID-19 pneumonia'. The number of serious TEAEs counts all serious TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.3 EXECUTED: 2022-12-01:13:18:49
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_5_1_sae_soc_pt.sas

Table 14.3.1.5.1
Serious Treatment-Emergent Adverse Events (excluding COVID-19-related PTs) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Gastrointestinal disorders | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Gastrointestinal haemorrhage | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Hiatus hernia | 1 ( 0.5) | 0 | 1 ( 0.5) | 0 |
| Injury, poisoning and procedural complications | 0 | 0 | 1 ( 0.5) | 0 |
| Ankle fracture | 0 | 0 | 1 ( 0.5) | 0 |
| Metabolism and nutrition disorders | 0 | 0 | 1 ( 0.5) | 0 |
| Diabetes mellitus inadequate control | 0 | 0 | 1 ( 0.5) | 0 |
| Nervous system disorders | 0 | 2 ( 1.0) | 1 ( 0.5) | 2 ( 1.0) |
| Cerebrovascular accident | 0 | 0 | 1 ( 0.5) | 0 |
| Brain oedema | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Syncope | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| General disorders and administration site conditions | 0 | 1 ( 0.5) | 0 | 2 ( 1.0) |

TEAE=Treatment-Emergent Adverse Event.
Note: COVID-19-related PTs are 'COVID-19' and 'COVID-19 pneumonia'. The number of serious TEAEs counts all serious TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.3 EXECUTED: 2022-12-01:13:18:49
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_5_1_sae_soc_pt.sas

Table 14.3.1.5.1
Serious Treatment-Emergent Adverse Events (excluding COVID-19-related PTs) by System Organ Class and Preferred Term Through Day 29 and Through Month 14
Safety Set

| System Organ Class<br>Preferred Term | Through Day 29 | | Through Month 14 | |
|---|---|---|---|---|
| | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) | ADG20 (N=192)<br>n (%) | Placebo (N=200)<br>n (%) |
| Multiple organ dysfunction syndrome | 0 | 0 | 0 | 1 ( 0.5) |
| Sudden death | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Musculoskeletal and connective tissue disorders | 0 | 0 | 0 | 1 ( 0.5) |
| Arthritis | 0 | 0 | 0 | 1 ( 0.5) |
| Respiratory, thoracic and mediastinal disorders | 0 | 2 ( 1.0) | 0 | 2 ( 1.0) |
| Pulmonary embolism | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Respiratory failure | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Vascular disorders | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |
| Orthostatic hypotension | 0 | 1 ( 0.5) | 0 | 1 ( 0.5) |

TEAE=Treatment-Emergent Adverse Event.
Note: COVID-19-related PTs are 'COVID-19' and 'COVID-19 pneumonia'. The number of serious TEAEs counts all serious TEAEs for participants. Percentages are based on the number of participants in each treatment group. Participants with multiple TEAEs are counted only once at each applicable Preferred Term and System Organ Class level. Adverse Events are coded using MedDRA, Version 24.0.
Source Data: ADSL, ADAE, Listing 16.2.7.3 EXECUTED: 2022-12-01:13:18:49
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_14_3_1_5_1_sae_soc_pt.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| At Any Time Post-Baseline | Hematology | Number of Participants with at Least One PCS Assessment | | 5 (2.6) | 7 (3.5) |
| | | Hematocrit (L/L) - H | | 0 | 1 (0.5) |
| | | Hemoglobin (g/L) - L | Any Grade | 0 | 2 (1.0) |
| | | | Grade 2 | 0 | 2 (1.0) |
| | | Leukocytes (10^9/L) - L | Any Grade | 1 (0.5) | 0 |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Lymphocytes (10^9/L) - L | Any Grade | 3 (1.6) | 4 (2.0) |
| | | | Grade 2 | 0 | 2 (1.0) |
| | | | Grade 3 | 2 (1.0) | 2 (1.0) |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Neutrophils (10^9/L) - L | Any Grade | 3 (1.6) | 0 |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 2 | 1 (0.5) | 0 |
| | | | Grade 3 | 1 (0.5) | 0 |
| | | | Grade 4 | 1 (0.5) | 0 |
| | Chemistry | Number of Participants with at Least One PCS Assessment | | 66 (34.4) | 68 (34.0) |
| | | Alanine Aminotransferase (U/L) - H | Any Grade | 6 (3.1) | 10 (5.0) |
| | | | Grade 2 | 3 (1.6) | 6 (3.0) |
| | | | Grade 3 | 2 (1.0) | 4 (2.0) |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Albumin (g/L) - L | Any Grade | 0 | 5 (2.5) |
| | | | Grade 2 | 0 | 5 (2.5) |
| | | Aspartate Aminotransferase (U/L) - H | Any Grade | 1 (0.5) | 2 (1.0) |
| | | | Grade 2 | 1 (0.5) | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 3 | 0 | 1 (0.5) |
| | | Bicarbonate (mmol/L) - L | Any Grade | 2 (1.0) | 1 (0.5) |
| | | | Grade 2 | 2 (1.0) | 1 (0.5) |
| | | Bilirubin (mcmol/L) - H | Any Grade | 1 (0.5) | 2 (1.0) |
| | | | Grade 2 | 1 (0.5) | 1 (0.5) |
| | | | Grade 4 | 0 | 1 (0.5) |
| | | Creatinine (mcmol/L) - H | Any Grade | 26 (13.5) | 23 (11.5) |
| | | | Grade 2 | 19 (9.9) | 13 (6.5) |
| | | | Grade 3 | 7 (3.6) | 9 (4.5) |
| | | | Grade 4 | 0 | 1 (0.5) |
| | | Creatinine Clearance, Estimated (mL/min/1.73m2) - L | Any Grade | 15 (7.8) | 18 (9.0) |
| | | | Grade 3 | 14 (7.3) | 14 (7.0) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
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Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 4 | 1 (0.5) | 4 (2.0) |
| | | Glucose (mmol/L) - H | Any Grade | 12 (6.3) | 16 (8.0) |
| | | | Grade 2 | 8 (4.2) | 10 (5.0) |
| | | | Grade 3 | 3 (1.6) | 4 (2.0) |
| | | | Grade 4 | 1 (0.5) | 2 (1.0) |
| | | Glucose (mmol/L) - L | Any Grade | 2 (1.0) | 1 (0.5) |
| | | | Grade 2 | 2 (1.0) | 1 (0.5) |
| | | Potassium (mmol/L) - H | Any Grade | 2 (1.0) | 1 (0.5) |
| | | | Grade 2 | 2 (1.0) | 1 (0.5) |
| | | Sodium (mmol/L) - H | Any Grade | 2 (1.0) | 2 (1.0) |
| | | | Grade 2 | 2 (1.0) | 1 (0.5) |
| | | | Grade 3 | 0 | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
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Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Sodium (mmol/L) - L | Any Grade | 1 (0.5) | 4 (2.0) |
| | | | Grade 3 | 1 (0.5) | 4 (2.0) |
| | | Urea Nitrogen (mmol/L) - H | | 26 (13.5) | 21 (10.5) |
| | Coagulation | Number of Participants with at Least One PCS Assessment | | 7 (3.6) | 3 (1.5) |
| | | Activated Partial Thromboplastin Time (sec) - H | Any Grade | 1 (0.5) | 0 |
| | | | Grade 3 | 1 (0.5) | 0 |
| | | Prothrombin Intl. Normalized Ratio - H | Any Grade | 5 (2.6) | 1 (0.5) |
| | | | Grade 2 | 1 (0.5) | 1 (0.5) |
| | | | Grade 3 | 1 (0.5) | 0 |
| | | | Grade 4 | 3 (1.6) | 0 |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Prothrombin Time (sec) - H | Any Grade | 7 (3.6) | 3 (1.5) |
| | | | Grade 2 | 2 (1.0) | 1 (0.5) |
| | | | Grade 3 | 2 (1.0) | 2 (1.0) |
| | | | Grade 4 | 3 (1.6) | 0 |
| Day 7 | Hematology | Number of Participants with at Least One PCS Assessment | | 3 (1.6) | 2 (1.0) |
| | | Leukocytes (10^9/L) - L | Any Grade | 1 (0.5) | 0 |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Lymphocytes (10^9/L) - L | Any Grade | 2 (1.0) | 2 (1.0) |
| | | | Grade 2 | 0 | 1 (0.5) |
| | | | Grade 3 | 1 (0.5) | 1 (0.5) |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Neutrophils (10^9/L) - L | Any Grade | 2 (1.0) | 0 |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
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Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 2 | 1 (0.5) | 0 |
| | | | Grade 4 | 1 (0.5) | 0 |
| | Chemistry | Number of Participants with at Least One PCS Assessment | | 36 (18.8) | 38 (19.0) |
| | | Alanine Aminotransferase (U/L) - H | Any Grade | 5 (2.6) | 5 (2.5) |
| | | | Grade 2 | 2 (1.0) | 3 (1.5) |
| | | | Grade 3 | 2 (1.0) | 2 (1.0) |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Albumin (g/L) - L | Any Grade | 0 | 2 (1.0) |
| | | | Grade 2 | 0 | 2 (1.0) |
| | | Aspartate Aminotransferase (U/L) - H | Any Grade | 1 (0.5) | 0 |
| | | | Grade 2 | 1 (0.5) | 0 |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Creatinine (mcmol/L) - H | Any Grade | 12 (6.3) | 11 (5.5) |
| | | | Grade 2 | 9 (4.7) | 5 (2.5) |
| | | | Grade 3 | 3 (1.6) | 6 (3.0) |
| | | Creatinine Clearance, Estimated (mL/min/1.73m2) - L | Any Grade | 7 (3.6) | 9 (4.5) |
| | | | Grade 3 | 6 (3.1) | 6 (3.0) |
| | | | Grade 4 | 1 (0.5) | 3 (1.5) |
| | | Glucose (mmol/L) - H | Any Grade | 10 (5.2) | 8 (4.0) |
| | | | Grade 2 | 7 (3.6) | 5 (2.5) |
| | | | Grade 3 | 2 (1.0) | 3 (1.5) |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Potassium (mmol/L) - H | Any Grade | 2 (1.0) | 1 (0.5) |
| | | | Grade 2 | 2 (1.0) | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Sodium (mmol/L) - L | Any Grade | 1 (0.5) | 1 (0.5) |
| | | | Grade 3 | 1 (0.5) | 1 (0.5) |
| | | Urea Nitrogen (mmol/L) - H | | 15 (7.8) | 19 (9.5) |
| | Coagulation | Number of Participants with at Least One PCS Assessment | | 3 (1.6) | 0 |
| | | Prothrombin Intl. Normalized Ratio - H | Any Grade | 2 (1.0) | 0 |
| | | | Grade 4 | 2 (1.0) | 0 |
| | | Prothrombin Time (sec) - H | Any Grade | 3 (1.6) | 0 |
| | | | Grade 2 | 1 (0.5) | 0 |
| | | | Grade 4 | 2 (1.0) | 0 |
| Day 29 | Hematology | Number of Participants with at Least One PCS Assessment | | 2 (1.0) | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Hemoglobin (g/L) - L | Any Grade | 0 | 1 (0.5) |
| | | | Grade 2 | 0 | 1 (0.5) |
| | | Lymphocytes (10^9/L) - L | Any Grade | 1 (0.5) | 0 |
| | | | Grade 3 | 1 (0.5) | 0 |
| | | Neutrophils (10^9/L) - L | Any Grade | 1 (0.5) | 0 |
| | | | Grade 3 | 1 (0.5) | 0 |
| | Chemistry | Number of Participants with at Least One PCS Assessment | | 19 (9.9) | 24 (12.0) |
| | | Alanine Aminotransferase (U/L) - H | Any Grade | 1 (0.5) | 2 (1.0) |
| | | | Grade 2 | 1 (0.5) | 2 (1.0) |
| | | Albumin (g/L) - L | Any Grade | 0 | 3 (1.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
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Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 2 | 0 | 3 (1.5) |
| | | Bicarbonate (mmol/L) - L | Any Grade | 0 | 1 (0.5) |
| | | | Grade 2 | 0 | 1 (0.5) |
| | | Bilirubin (mcmol/L) - H | Any Grade | 1 (0.5) | 0 |
| | | | Grade 2 | 1 (0.5) | 0 |
| | | Creatinine (mcmol/L) - H | Any Grade | 7 (3.6) | 8 (4.0) |
| | | | Grade 2 | 4 (2.1) | 7 (3.5) |
| | | | Grade 3 | 3 (1.6) | 1 (0.5) |
| | | Creatinine Clearance, Estimated (mL/min/1.73m2) - L | Any Grade | 3 (1.6) | 3 (1.5) |
| | | | Grade 3 | 3 (1.6) | 3 (1.5) |
| | | Glucose (mmol/L) - H | Any Grade | 2 (1.0) | 5 (2.5) |

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Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 2 | 2 (1.0) | 2 (1.0) |
| | | | Grade 3 | 0 | 1 (0.5) |
| | | | Grade 4 | 0 | 2 (1.0) |
| | | Sodium (mmol/L) - H | Any Grade | 1 (0.5) | 1 (0.5) |
| | | | Grade 2 | 1 (0.5) | 0 |
| | | | Grade 3 | 0 | 1 (0.5) |
| | | Sodium (mmol/L) - L | Any Grade | 0 | 2 (1.0) |
| | | | Grade 3 | 0 | 2 (1.0) |
| | | Urea Nitrogen (mmol/L) - H | | 7 (3.6) | 4 (2.0) |
| | Coagulation | Number of Participants with at Least One PCS Assessment | | 2 (1.0) | 2 (1.0) |
| | | Prothrombin Intl. Normalized Ratio - H | Any Grade | 1 (0.5) | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
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If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
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Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 2 | 0 | 1 (0.5) |
| | | | Grade 4 | 1 (0.5) | 0 |
| | | Prothrombin Time (sec) - H | Any Grade | 2 (1.0) | 2 (1.0) |
| | | | Grade 2 | 1 (0.5) | 1 (0.5) |
| | | | Grade 3 | 0 | 1 (0.5) |
| | | | Grade 4 | 1 (0.5) | 0 |
| Day 90 | Hematology | Number of Participants with at Least One PCS Assessment | | 0 | 3 (1.5) |
| | | Hematocrit (L/L) - H | | 0 | 1 (0.5) |
| | | Hemoglobin (g/L) - L | Any Grade | 0 | 1 (0.5) |
| | | | Grade 2 | 0 | 1 (0.5) |
| | | Lymphocytes (10^9/L) - L | Any Grade | 0 | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 3 | 0 | 1 (0.5) |
| | Chemistry | Number of Participants with at Least One PCS Assessment | | 14 (7.3) | 15 (7.5) |
| | | Alanine Aminotransferase (U/L) - H | Any Grade | 0 | 1 (0.5) |
| | | | Grade 3 | 0 | 1 (0.5) |
| | | Creatinine (mcmol/L) - H | Any Grade | 7 (3.6) | 6 (3.0) |
| | | | Grade 2 | 4 (2.1) | 5 (2.5) |
| | | | Grade 3 | 3 (1.6) | 1 (0.5) |
| | | Creatinine Clearance, Estimated (mL/min/1.73m2) - L | Any Grade | 4 (2.1) | 3 (1.5) |
| | | | Grade 3 | 4 (2.1) | 3 (1.5) |
| | | Glucose (mmol/L) - H | Any Grade | 0 | 3 (1.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 2 | 0 | 3 (1.5) |
| | | Glucose (mmol/L) - L | Any Grade | 2 (1.0) | 0 |
| | | | Grade 2 | 2 (1.0) | 0 |
| | | Urea Nitrogen (mmol/L) - H | | 5 (2.6) | 5 (2.5) |
| | Coagulation | Number of Participants with at Least One PCS Assessment | | 2 (1.0) | 0 |
| | | Activated Partial Thromboplastin Time (sec) - H | Any Grade | 1 (0.5) | 0 |
| | | | Grade 3 | 1 (0.5) | 0 |
| | | Prothrombin Intl. Normalized Ratio - H | Any Grade | 2 (1.0) | 0 |
| | | | Grade 4 | 2 (1.0) | 0 |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Prothrombin Time (sec) - H | Any Grade | 2 (1.0) | 0 |
| | | | Grade 4 | 2 (1.0) | 0 |
| Month 6 | Hematology | Number of Participants with at Least One PCS Assessment | | 0 | 1 (0.5) |
| | | Hemoglobin (g/L) - L | Any Grade | 0 | 1 (0.5) |
| | | | Grade 3 | 0 | 1 (0.5) |
| | Chemistry | Number of Participants with at Least One PCS Assessment | | 15 (7.8) | 20 (10.0) |
| | | Alanine Aminotransferase (U/L) - H | Any Grade | 0 | 2 (1.0) |
| | | | Grade 3 | 0 | 2 (1.0) |
| | | Aspartate Aminotransferase (U/L) - H | Any Grade | 0 | 2 (1.0) |
| | | | Grade 2 | 0 | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 3 | 0 | 1 (0.5) |
| | | Bicarbonate (mmol/L) - L | Any Grade | 2 (1.0) | 0 |
| | | | Grade 2 | 2 (1.0) | 0 |
| | | Bilirubin (mcmol/L) - H | Any Grade | 0 | 1 (0.5) |
| | | | Grade 4 | 0 | 1 (0.5) |
| | | Creatinine (mcmol/L) - H | Any Grade | 11 (5.7) | 12 (6.0) |
| | | | Grade 2 | 6 (3.1) | 7 (3.5) |
| | | | Grade 3 | 5 (2.6) | 4 (2.0) |
| | | | Grade 4 | 0 | 1 (0.5) |
| | | Creatinine Clearance, Estimated (mL/min/1.73m2) - L | Any Grade | 8 (4.2) | 8 (4.0) |
| | | | Grade 3 | 8 (4.2) | 7 (3.5) |
| | | | Grade 4 | 0 | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | Glucose (mmol/L) - H | Any Grade | 0 | 3 (1.5) |
| | | | Grade 2 | 0 | 3 (1.5) |
| | | Glucose (mmol/L) - L | Any Grade | 0 | 1 (0.5) |
| | | | Grade 2 | 0 | 1 (0.5) |
| | | Sodium (mmol/L) - H | Any Grade | 0 | 1 (0.5) |
| | | | Grade 2 | 0 | 1 (0.5) |
| | | Urea Nitrogen (mmol/L) - H | | 2 (1.0) | 3 (1.5) |
| | Coagulation | Number of Participants with at Least One PCS Assessment | | 3 (1.6) | 1 (0.5) |
| | | Prothrombin Intl. Normalized Ratio - H | Any Grade | 2 (1.0) | 0 |
| | | | Grade 2 | 1 (0.5) | 0 |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.2.3
Potentially Clinically Significant Changes from Baseline in Post-Baseline Laboratory Parameters by Visit
Safety Set

| Visit | Category | Parameter | Grade | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|---|---|
| | | | Grade 3 | 1 (0.5) | 0 |
| | | Prothrombin Time (sec) - H | Any Grade | 3 (1.6) | 1 (0.5) |
| | | | Grade 2 | 1 (0.5) | 0 |
| | | | Grade 3 | 2 (1.0) | 1 (0.5) |

L=Low; H=High; DAIDS=Division of Allergy and Infectious Diseases; PCS=potentially clinically significant.
Note: Percentages are based on the number of participants in each treatment group. Laboratory values were graded using the DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events (NIAID 2017) if applicable.
Potentially clinically significant laboratory values are defined as: any DAIDS Grade 4 post-baseline value; any DAIDS increase of 2 or more grades post-baseline (except for Creatinine Clearance); any DAIDS grade shift from 0 to 3 post-baseline for Creatinine Clearance; or as follows for laboratory parameters not outlined in DAIDS: Basophils (%) >4.00 x ULN, Eosinophils (%) >4.00 x ULN, Monocytes (%) >4.00 x ULN, Hematocrit (%) <0.6 x baseline or >4.00 x ULN, Blood Urea Nitrogen (mmol/L) >1.3 x ULN, Chloride (mmol/L) <0.8 x LLN or >1.1 x ULN, Total Protein (g/L) <0.8 x LLN or >1.2 x ULN.
If a participant has multiple toxicity grades at the same or multiple visits for each parameter, the first occurrence of toxicity grade meeting the PCS criteria was used in the summary at any time post-baseline.
Source Data: ADSL, ADLB, Listing 16.2.8.1, 16.2.8.2 EXECUTED: 2022-09-06:12:52:59
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_lb_pcs.sas

Table 14.3.3.2
Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit
Safety Set

| Visit | Parameter | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|
| At Any Time Post-Baseline | Participants with Assessment | 157 (81.8) | 162 (81.0) |
| | SBP <=90 mmHg or Decrease >=20 mmHg | 17 ( 8.9) | 23 (11.5) |
| | SBP >=180 mmHg or Increase >=20 mmHg | 29 (15.1) | 26 (13.0) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 25 (13.0) | 26 (13.0) |
| | DBP >=105 mmHg or Increase >=15 mmHg | 24 (12.5) | 31 (15.5) |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 78 (40.6) | 96 (48.0) |
| | HR >120 bpm or Increase >=15 bpm | 20 (10.4) | 25 (12.5) |
| | Temp <35 C or Decrease >=1 C [b] | 60 (31.3) | 56 (28.0) |
| | Temp >=38 C or Increase >=1 C [c] | 5 ( 2.6) | 17 ( 8.5) |
| | RR <=8 breaths/min or Decrease >=4 bpm | 20 (10.4) | 25 (12.5) |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 2 ( 1.0) | 2 ( 1.0) |
| | SpO2 <=93% or Decrease >=3% | 14 ( 7.3) | 19 ( 9.5) |
| During Post Study Drug Administration Vital Signs Monitoring | Participants with Assessment | 31 (16.1) | 41 (20.5) |
| | SBP <=90 mmHg or Decrease >=20 mmHg | 4 ( 2.1) | 4 ( 2.0) |
| | SBP >=180 mmHg or Increase >=20 mmHg | 3 ( 1.6) | 1 ( 0.5) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 5 ( 2.6) | 6 ( 3.0) |

Bpm=Beats per minute; DBP=Diastolic Blood Pressure; HR=heart rate; PCS=potentially clinically significant; RR=respiratory rate; SBP=Systolic Blood Pressure; SpO2=Oxygen Saturation; Temp=temperature.
Note: Percentages are based on the number of participants in each treatment group.
[a] Participants with a heart rate >120 bpm at baseline are not reported as a PCS decrease unless HR <=50 bpm.
[b] Participants with fever (>=38 C) at baseline are not reported as PCS decrease unless temperature <35 C.
[c] Participants with fever (>=38 C) at baseline are not reported as a PCS increase unless temperature increase is >=1 C.
[d] Participants with a respiratory rate >20 breaths/minute at baseline are not reported as a PCS decrease unless RR <=8 breaths/minute.
Source Data: ADSL, ADVS, Listing 16.2.9.1 EXECUTED: 2022-09-06:12:53:46
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_vs_pcs.sas

Table 14.3.3.2
Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit
Safety Set

| Visit | Parameter | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|
| | DBP >=105 mmHg or Increase >=15 mmHg | 3 ( 1.6) | 7 ( 3.5) |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 6 ( 3.1) | 6 ( 3.0) |
| | HR >120 bpm or Increase >=15 bpm | 2 ( 1.0) | 8 ( 4.0) |
| | Temp <35 C or Decrease >=1 C [b] | 6 ( 3.1) | 3 ( 1.5) |
| | Temp >=38 C or Increase >=1 C [c] | 3 ( 1.6) | 11 ( 5.5) |
| | RR <=8 breaths/min or Decrease >=4 bpm | 0 | 3 ( 1.5) |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 1 ( 0.5) | 2 ( 1.0) |
| | SpO2 <=93% or Decrease >=3% | 10 ( 5.2) | 7 ( 3.5) |
| Day 7 | Participants with Assessment | 79 (41.1) | 80 (40.0) |
| | SBP <=90 mmHg or Decrease >=20 mmHg | 7 ( 3.6) | 12 ( 6.0) |
| | SBP >=180 mmHg or Increase >=20 mmHg | 9 ( 4.7) | 5 ( 2.5) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 5 ( 2.6) | 9 ( 4.5) |
| | DBP >=105 mmHg or Increase >=15 mmHg | 4 ( 2.1) | 6 ( 3.0) |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 32 (16.7) | 36 (18.0) |
| | HR >120 bpm or Increase >=15 bpm | 8 ( 4.2) | 5 ( 2.5) |
| | Temp <35 C or Decrease >=1 C [b] | 24 (12.5) | 17 ( 8.5) |
| | Temp >=38 C or Increase >=1 C [c] | 0 | 3 ( 1.5) |

Bpm=Beats per minute; DBP=Diastolic Blood Pressure; HR=heart rate; PCS=potentially clinically significant; RR=respiratory rate; SBP=Systolic Blood Pressure; SpO2=Oxygen Saturation; Temp=temperature.
Note: Percentages are based on the number of participants in each treatment group.
[a] Participants with a heart rate >120 bpm at baseline are not reported as a PCS decrease unless HR <=50 bpm.
[b] Participants with fever (>=38 C) at baseline are not reported as PCS decrease unless temperature <35 C.
[c] Participants with fever (>=38 C) at baseline are not reported as a PCS increase unless temperature increase is >=1 C.
[d] Participants with a respiratory rate >20 breaths/minute at baseline are not reported as a PCS decrease unless RR <=8 breaths/minute.
Source Data: ADSL, ADVS, Listing 16.2.9.1 EXECUTED: 2022-09-06:12:53:46
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_vs_pcs.sas

Table 14.3.3.2
Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit
Safety Set

| Visit | Parameter | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|
| | RR <=8 breaths/min or Decrease >=4 bpm | 5 ( 2.6) | 5 ( 2.5) |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 1 ( 0.5) | 0 |
| | SpO2 <=93% or Decrease >=3% | 3 ( 1.6) | 9 ( 4.5) |
| Day 29 | Participants with Assessment | 91 (47.4) | 105 (52.5) |
| | SBP <=90 mmHg or Decrease >=20 mmHg | 4 ( 2.1) | 9 ( 4.5) |
| | SBP >=180 mmHg or Increase >=20 mmHg | 9 ( 4.7) | 8 ( 4.0) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 6 ( 3.1) | 13 ( 6.5) |
| | DBP >=105 mmHg or Increase >=15 mmHg | 10 ( 5.2) | 5 ( 2.5) |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 41 (21.4) | 57 (28.5) |
| | HR >120 bpm or Increase >=15 bpm | 5 ( 2.6) | 7 ( 3.5) |
| | Temp <35 C or Decrease >=1 C [b] | 33 (17.2) | 38 (19.0) |
| | Temp >=38 C or Increase >=1 C [c] | 1 ( 0.5) | 0 |
| | RR <=8 breaths/min or Decrease >=4 bpm | 13 ( 6.8) | 9 ( 4.5) |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 0 | 0 |
| | SpO2 <=93% or Decrease >=3% | 2 ( 1.0) | 4 ( 2.0) |
| Day 90 | Participants with Assessment | 83 (43.2) | 89 (44.5) |

Bpm=Beats per minute; DBP=Diastolic Blood Pressure; HR=heart rate; PCS=potentially clinically significant; RR=respiratory rate; SBP=Systolic Blood Pressure; SpO2=Oxygen Saturation; Temp=temperature.
Note: Percentages are based on the number of participants in each treatment group.
[a] Participants with a heart rate >120 bpm at baseline are not reported as a PCS decrease unless HR <=50 bpm.
[b] Participants with fever (>=38 C) at baseline are not reported as PCS decrease unless temperature <35 C.
[c] Participants with fever (>=38 C) at baseline are not reported as a PCS increase unless temperature increase is >=1 C.
[d] Participants with a respiratory rate >20 breaths/minute at baseline are not reported as a PCS decrease unless RR <=8 breaths/minute.
Source Data: ADSL, ADVS, Listing 16.2.9.1 EXECUTED: 2022-09-06:12:53:46
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_vs_pcs.sas

Table 14.3.3.2
Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit
Safety Set

| Visit | Parameter | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|
| | SBP <=90 mmHg or Decrease >=20 mmHg | 3 ( 1.6) | 4 ( 2.0) |
| | SBP >=180 mmHg or Increase >=20 mmHg | 13 ( 6.8) | 15 ( 7.5) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 7 ( 3.6) | 5 ( 2.5) |
| | DBP >=105 mmHg or Increase >=15 mmHg | 7 ( 3.6) | 13 ( 6.5) |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 41 (21.4) | 52 (26.0) |
| | HR >120 bpm or Increase >=15 bpm | 5 ( 2.6) | 7 ( 3.5) |
| | Temp <35 C or Decrease >=1 C [b] | 33 (17.2) | 28 (14.0) |
| | Temp >=38 C or Increase >=1 C [c] | 0 | 1 ( 0.5) |
| | RR <=8 breaths/min or Decrease >=4 bpm | 8 ( 4.2) | 9 ( 4.5) |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 0 | 0 |
| | SpO2 <=93% or Decrease >=3% | 2 ( 1.0) | 1 ( 0.5) |
| Month 6 | Participants with Assessment | 72 (37.5) | 84 (42.0) |
| | SBP <=90 mmHg or Decrease >=20 mmHg | 1 ( 0.5) | 6 ( 3.0) |
| | SBP >=180 mmHg or Increase >=20 mmHg | 11 ( 5.7) | 10 ( 5.0) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 4 ( 2.1) | 6 ( 3.0) |
| | DBP >=105 mmHg or Increase >=15 mmHg | 10 ( 5.2) | 10 ( 5.0) |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 39 (20.3) | 54 (27.0) |

Bpm=Beats per minute; DBP=Diastolic Blood Pressure; HR=heart rate; PCS=potentially clinically significant; RR=respiratory rate; SBP=Systolic Blood Pressure; SpO2=Oxygen Saturation; Temp=temperature.
Note: Percentages are based on the number of participants in each treatment group.
[a] Participants with a heart rate >120 bpm at baseline are not reported as a PCS decrease unless HR <=50 bpm.
[b] Participants with fever (>=38 C) at baseline are not reported as PCS decrease unless temperature <35 C.
[c] Participants with fever (>=38 C) at baseline are not reported as a PCS increase unless temperature increase is >=1 C.
[d] Participants with a respiratory rate >20 breaths/minute at baseline are not reported as a PCS decrease unless RR <=8 breaths/minute.
Source Data: ADSL, ADVS, Listing 16.2.9.1 EXECUTED: 2022-09-06:12:53:46
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_vs_pcs.sas

Table 14.3.3.2
Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit
Safety Set

| Visit | Parameter | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|
| | HR >120 bpm or Increase >=15 bpm | 3 ( 1.6) | 3 ( 1.5) |
| | Temp <35 C or Decrease >=1 C [b] | 27 (14.1) | 30 (15.0) |
| | Temp >=38 C or Increase >=1 C [c] | 0 | 2 ( 1.0) |
| | RR <=8 breaths/min or Decrease >=4 bpm | 10 ( 5.2) | 13 ( 6.5) |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 0 | 0 |
| | SpO2 <=93% or Decrease >=3% | 0 | 3 ( 1.5) |
| Month 11 | Participants with Assessment | 1 ( 0.5) | 1 ( 0.5) |
| | SBP <=90 mmHg or Decrease >=20 mmHg | 0 | 0 |
| | SBP >=180 mmHg or Increase >=20 mmHg | 0 | 1 ( 0.5) |
| | DBP <=50 mmHg or Decrease >=15 mmHg | 0 | 0 |
| | DBP >=105 mmHg or Increase >=15 mmHg | 0 | 0 |
| | HR <=50 bpm or Decrease >=15 bpm [a] | 1 ( 0.5) | 0 |
| | HR >120 bpm or Increase >=15 bpm | 0 | 0 |
| | Temp <35 C or Decrease >=1 C [b] | 0 | 0 |
| | Temp >=38 C or Increase >=1 C [c] | 0 | 0 |
| | RR <=8 breaths/min or Decrease >=4 bpm | 0 | 0 |
| | RR >=30 breaths/min or Increase >=10 bpm [d] | 0 | 0 |

Bpm=Beats per minute; DBP=Diastolic Blood Pressure; HR=heart rate; PCS=potentially clinically significant; RR=respiratory rate; SBP=Systolic Blood Pressure; SpO2=Oxygen Saturation; Temp=temperature.
Note: Percentages are based on the number of participants in each treatment group.
[a] Participants with a heart rate >120 bpm at baseline are not reported as a PCS decrease unless HR <=50 bpm.
[b] Participants with fever (>=38 C) at baseline are not reported as PCS decrease unless temperature <35 C.
[c] Participants with fever (>=38 C) at baseline are not reported as a PCS increase unless temperature increase is >=1 C.
[d] Participants with a respiratory rate >20 breaths/minute at baseline are not reported as a PCS decrease unless RR <=8 breaths/minute.
Source Data: ADSL, ADVS, Listing 16.2.9.1 EXECUTED: 2022-09-06:12:53:46
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_vs_pcs.sas

Table 14.3.3.2
Potentially Clinically Significant Changes in Post-Baseline Vital Signs by Visit
Safety Set

| Visit | Parameter | ADG20 (N=192) n (%) | Placebo (N=200) n (%) |
|---|---|---|---|
| | SpO2 <=93% or Decrease >=3% | 0 | 0 |

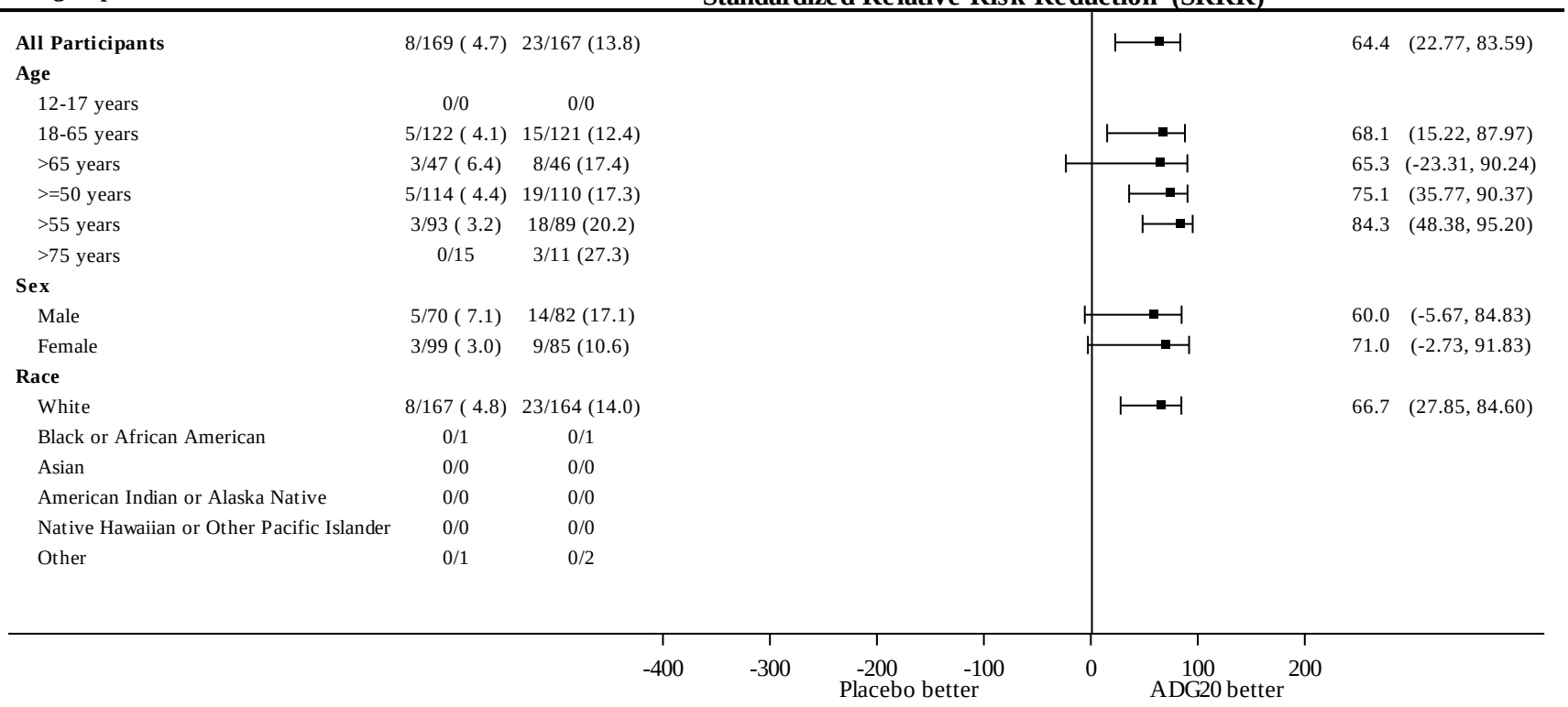
Bpm=Beats per minute; DBP=Diastolic Blood Pressure; HR=heart rate; PCS=potentially clinically significant; RR=respiratory rate; SBP=Systolic Blood Pressure; SpO2=Oxygen Saturation; Temp=temperature.
Note: Percentages are based on the number of participants in each treatment group.
[a] Participants with a heart rate >120 bpm at baseline are not reported as a PCS decrease unless HR <=50 bpm.
[b] Participants with fever (>=38 C) at baseline are not reported as PCS decrease unless temperature <35 C.
[c] Participants with fever (>=38 C) at baseline are not reported as a PCS increase unless temperature increase is >=1 C.
[d] Participants with a respiratory rate >20 breaths/minute at baseline are not reported as a PCS decrease unless RR <=8 breaths/minute.
Source Data: ADSL, ADVS, Listing 16.2.9.1 EXECUTED: 2022-09-06:12:53:46
Program Path: G:\ADG20\ADG_TRMT_001_Ph_1_3_Rx\program\INhouse_CSR\tlf\prod\t_vs_pcs.sas

Figure 14.2.1.2.1
Forest Plot of Standardized Relative Risk Reduction for Primary Estimand 1a – COVID-19-Related Hospitalization or All-Cause Death through Day 29 by Subgroup
mFAS-non-Omicron

CI=confidence interval.
Note: Viral load values reported as detected but BLQ of the PCR assay (<714 copies/mL) are imputed with half of lower limit of quantification of the PCR assay (ie, 2.55 log10 copies/mL). Viral load values reported as not detected are imputed with 0 log10 copies/mL. Viral load values reported as >7.1x10^7 copies/mL are imputed to 7.1x10^7 copies/mL (ie, 7.85 log10 copies/mL) if no reflex result from sample dilution is available.
Hospitalization is defined as >=24 hours stay in a hospital or acute care facility (includes emergency rooms, intensive care units, acute care facilities created for COVID 19 pandemic hospitalization needs, or other acute care facilities).
Missing status on COVID-19-related hospitalization or all-cause death is imputed as not having a COVID-19-related hospitalization or all-cause death. For subgroups with less than 5 total events, only descriptive statistics are presented.
A standardized estimator for a binary outcome is analyzed with treatment and adjustment for age (continuous). The standard error of the standardized estimator is estimated using the delta method as described in SAP.
Missing outcome is determined for participants who had no reported qualifying event for the primary endpoint through Day 29 and who had either discontinued from study prior to Day 29 or were still on study with an unknown survival status on Day 29 at the time of analysis.

Figure 14.2.1.2.1
Forest Plot of Standardized Relative Risk Reduction for Primary Estimand 1a – COVID-19-Related Hospitalization or All-Cause Death through Day 29 by Subgroup
mFAS-non-Omicron

| Subgroup | ADG20 | Placebo | SRRR | 95% CI |
|---|---|---|---|---|
| **All Participants** | 8/169 ( 4.7) | 23/167 (13.8) | 64.4 | (22.77, 83.59) |
| **Age** | | | | |
| 12-17 years | 0/0 | 0/0 | | |
| 18-65 years | 5/122 ( 4.1) | 15/121 (12.4) | 68.1 | (15.22, 87.97) |
| >65 years | 3/47 ( 6.4) | 8/46 (17.4) | 65.3 | (-23.31, 90.24) |
| >=50 years | 5/114 ( 4.4) | 19/110 (17.3) | 75.1 | (35.77, 90.37) |
| >55 years | 3/93 ( 3.2) | 18/89 (20.2) | 84.3 | (48.38, 95.20) |
| >75 years | 0/15 | 3/11 (27.3) | | |
| **Sex** | | | | |
| Male | 5/70 ( 7.1) | 14/82 (17.1) | 60.0 | (-5.67, 84.83) |
| Female | 3/99 ( 3.0) | 9/85 (10.6) | 71.0 | (-2.73, 91.83) |
| **Race** | | | | |
| White | 8/167 ( 4.8) | 23/164 (14.0) | 66.7 | (27.85, 84.60) |
| Black or African American | 0/1 | 0/1 | | |
| Asian | 0/0 | 0/0 | | |
| American Indian or Alaska Native | 0/0 | 0/0 | | |
| Native Hawaiian or Other Pacific Islander | 0/0 | 0/0 | | |
| Other | 0/1 | 0/2 | | |




Notes are listed on page 1.
Source Data: ADSL, ADBL, ADRESP, Table 14.2.1.1.1, 14.2.1.2.1
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Figure 14.2.1.2.1
Forest Plot of Standardized Relative Risk Reduction for Primary Estimand 1a – COVID-19-Related Hospitalization or All-Cause Death through Day 29 by Subgroup
mFAS-non-Omicron

| Subgroup | ADG20 | Placebo | SRRR | 95% CI |
|---|---|---|---|---|
| **Time from symptom onset to study drug administration** | | | | |
| 0-3 days | 4/133 ( 3.0) | 15/128 (11.7) | 74.6 | (25.66, 91.35) |
| 4-5 days | 4/33 (12.1) | 8/39 (20.5) | 45.6 | (-59.48, 81.42) |
| >5 days | 0/0 | 0/0 | | |
| **Time from local SARS-CoV-2 test to study drug administration** | | | | |
| 0 days | 6/109 ( 5.5) | 14/99 (14.1) | 62.3 | (5.91, 84.86) |
| 1-2 days | 1/45 ( 2.2) | 8/52 (15.4) | 85.8 | (-8.81, 98.14) |
| 3-5 days | 1/12 ( 8.3) | 1/16 ( 6.3) | | |
| >5 days | 0/0 | 0/0 | | |
| **Baseline NP central RT-PCR status** | | | | |
| Positive | 8/158 ( 5.1) | 22/159 (13.8) | 64.3 | (22.64, 83.55) |
| Negative | 0/7 | 1/8 (12.5) | | |
| **Baseline NP viral load** | | | | |
| >5 log10 copies/mL | 6/137 ( 4.4) | 21/137 (15.3) | 73.2 | (36.11, 88.79) |
| <=5 log10 copies/mL | 2/28 ( 7.1) | 2/30 ( 6.7) | | |
| **Baseline qualitative serologic status** | | | | |
| Positive | 0/19 | 1/23 ( 4.3) | | |
| Negative | 7/147 ( 4.8) | 22/143 (15.4) | 71.4 | (35.35, 87.34) |

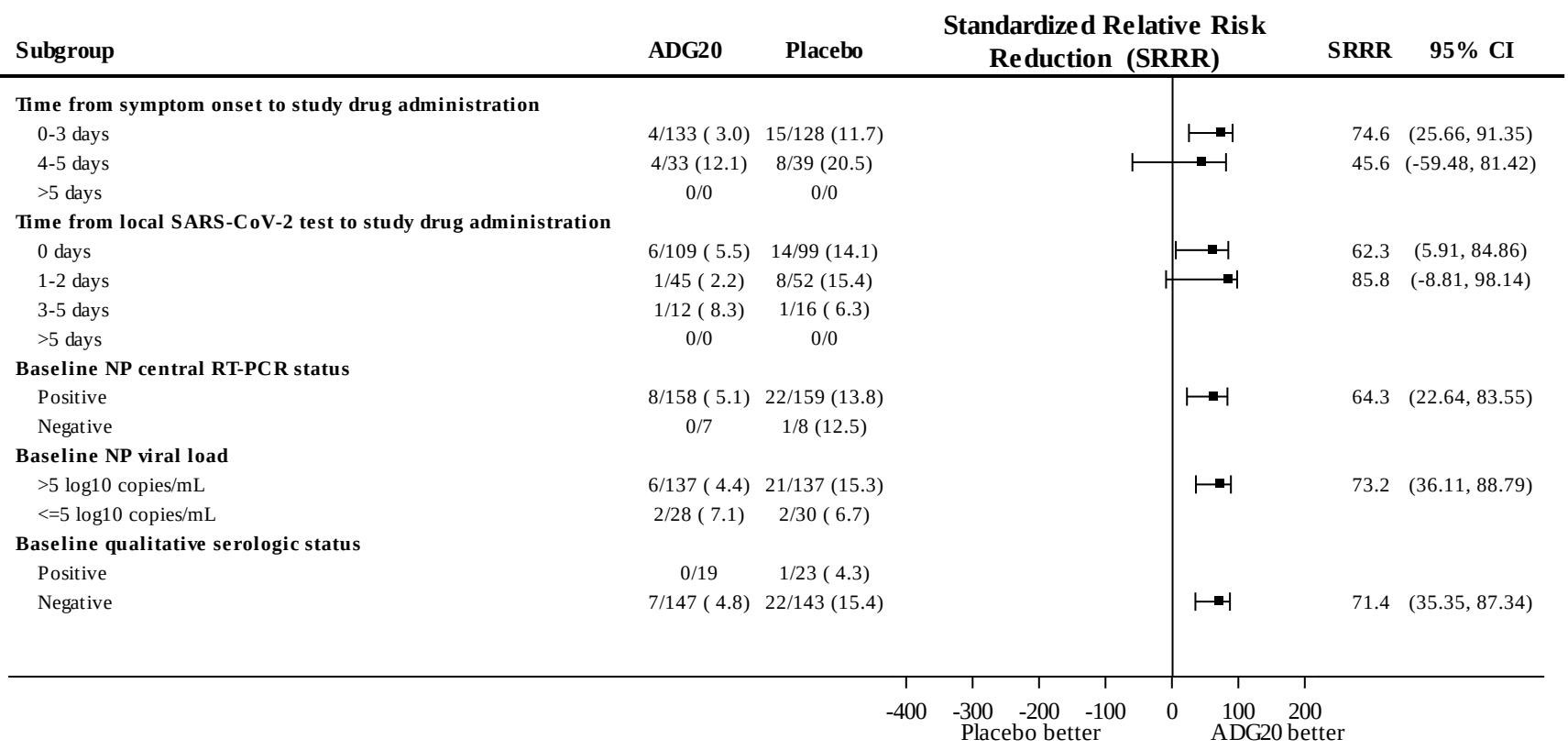


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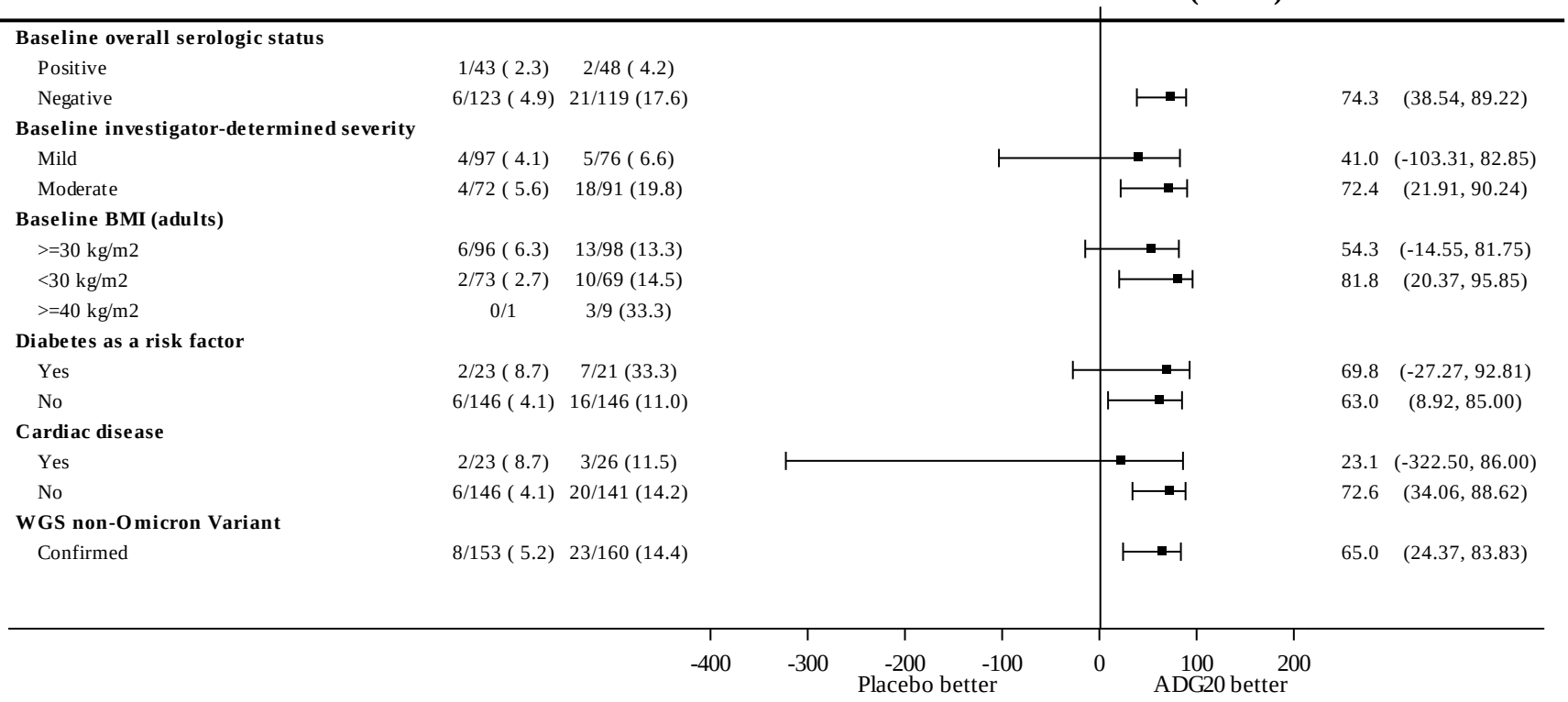
Figure 14.2.1.2.1
Forest Plot of Standardized Relative Risk Reduction for Primary Estimand 1a – COVID-19-Related Hospitalization or All-Cause Death through Day 29 by Subgroup
mFAS-non-Omicron

| Subgroup | ADG20 | Placebo | SRRR | 95% CI |
|---|---|---|---|---|
| **Baseline overall serologic status** | | | | |
| Positive | 1/43 ( 2.3) | 2/48 ( 4.2) | | |
| Negative | 6/123 ( 4.9) | 21/119 (17.6) | 74.3 | (38.54, 89.22) |
| **Baseline investigator-determined severity** | | | | |
| Mild | 4/97 ( 4.1) | 5/76 ( 6.6) | 41.0 | (-103.31, 82.85) |
| Moderate | 4/72 ( 5.6) | 18/91 (19.8) | 72.4 | (21.91, 90.24) |
| **Baseline BMI (adults)** | | | | |
| >=30 kg/m2 | 6/96 ( 6.3) | 13/98 (13.3) | 54.3 | (-14.55, 81.75) |
| <30 kg/m2 | 2/73 ( 2.7) | 10/69 (14.5) | 81.8 | (20.37, 95.85) |
| >=40 kg/m2 | 0/1 | 3/9 (33.3) | | |
| **Diabetes as a risk factor** | | | | |
| Yes | 2/23 ( 8.7) | 7/21 (33.3) | 69.8 | (-27.27, 92.81) |
| No | 6/146 ( 4.1) | 16/146 (11.0) | 63.0 | (8.92, 85.00) |
| **Cardiac disease** | | | | |
| Yes | 2/23 ( 8.7) | 3/26 (11.5) | 23.1 | (-322.50, 86.00) |
| No | 6/146 ( 4.1) | 20/141 (14.2) | 72.6 | (34.06, 88.62) |
| **WGS non-Omicron Variant** | | | | |
| Confirmed | 8/153 ( 5.2) | 23/160 (14.4) | 65.0 | (24.37, 83.83) |





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# SIGNATURE PAGE

**Document:** ADG20-TRMT-001 Clinical Study Report Synopsis - Version 1.0, 18 April 2023

**Document ID:** VV-CLIN-000377

I have hereby read this document and confirm that, to the best of my knowledge, all content herein is complete and accurate.

| Document Approvals | |
|---|---|
| Approval Task | Myra Popejoy<br>Senior Director, Clinical Research<br>Approved<br>19-Apr-2023 18:36:36 GMT+0000 |