

Safety and Efficacy of Pemivibart, a Long-acting Monoclonal Antibody, for Prevention of Symptomatic COVID-19: Final Analysis From a Phase 3 Randomized Clinical Trial (CANOPY)

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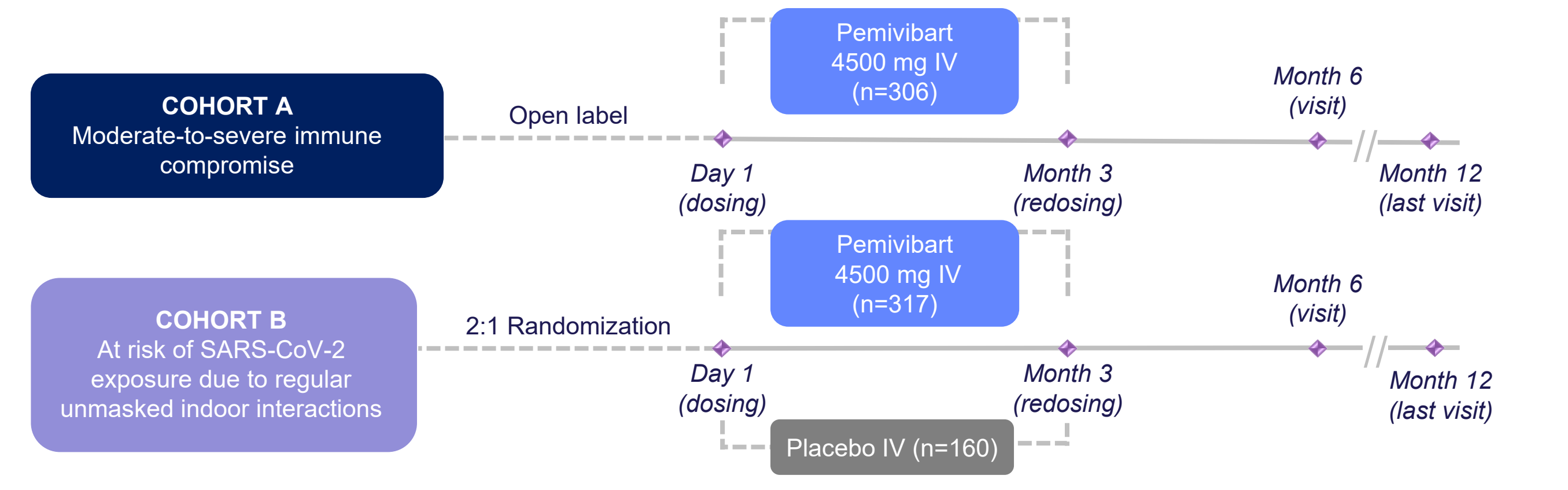
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INTRODUCTION

- Emerging variants of SARS-CoV-2 remain a significant clinical threat, with acute infection associated with severe outcomes, including hospitalization and death. Post-acute sequelae, such as Long COVID, may occur irrespective of initial disease severity and contribute to ongoing impairment in daily activity¹⁻³
- Previous natural exposure and/or vaccination is imperfect for preventing future SARS-CoV-2 infections⁴
- Monoclonal antibodies targeted to SARS-CoV-2 spike protein represent an alternative preventive strategy against COVID-19⁵
- Here we summarize the 12-month analysis of safety and efficacy of pemivibart in individuals with (Cohort A) or without (Cohort B) significant immunocompromise in the phase 3 CANOPY trial

METHODS

Figure 1. CANOPY, a Phase 3 Study to Evaluate Efficacy and Safety of Pemivibart for the Prevention of COVID-19^a



^aOf 482 participants randomized, 480 (99.6%; 320 pemivibart, 160 placebo) comprised the full analysis set (FAS) and 477 (99.0%; 317 pemivibart, 160 placebo) the safety analysis set (SAS). Cohort B modified FAS (mFAS) includes all randomized participants without SARS-CoV-2 infection at baseline who received any amount of pemivibart or placebo.

Study Design

- CANOPY (NCT06039449) was a Phase 3, randomized, placebo-controlled trial (conducted in the United States during 2023-2024) that evaluated the safety, tolerability, pharmacokinetics, and efficacy of pemivibart for pre-exposure prophylaxis of COVID-19 in adults aged ≥18 years (**Figure 1**)
- CANOPY Cohort A:** open-label, single-arm cohort that enrolled adults with significant immune compromise to receive pemivibart
- CANOPY Cohort B:** randomized, double-blind, placebo-controlled cohort of non-immunocompromised participants at risk of acquiring SARS-CoV-2 due to regular unmasked face-to-face interactions in indoor settings (e.g., workplace, gym facility, public transportation). Participants were randomized (2:1) to receive either pemivibart or placebo.
- Participants received a dose of study drug via intravenous infusion on Day 1 and then another equivalent dose at Month 3
 - Participants were followed through Month 12; no additional doses were administered following the Month 3 dose

Objectives and Assessments

Cohort A Primary Objectives:

- Evaluation of safety and tolerability of pemivibart in all treated participants
- Evaluation of protection against symptomatic COVID-19 based on sVNA titers against SARS-CoV-2 after receiving pemivibart (immunobridging data reported previously⁶)

Cohort B Primary Objective:

- Evaluation of safety and tolerability of pemivibart compared with placebo in all treated participants

Additional Objectives Include:

- Evaluation of sVNA titers against SARS-CoV-2 after receiving pemivibart via csVNA and measured sVNA titers against relevant SARS-CoV-2 variants (i.e., pseudotyped JN.1 SARS-CoV-2 variant) (Cohort A and B)
- Evaluation of pemivibart in the prevention of reverse transcriptase polymerase chain reaction (RT-PCR)-confirmed symptomatic COVID-19 (Cohort A)
- Evaluation of the clinical efficacy of pemivibart compared with placebo in the prevention of severe/critical COVID-19 via a composite of RT-PCR-confirmed symptomatic COVID-19 with onset of symptoms ≤14 days from positive sample collection, COVID-19-related hospitalization, or all-cause mortality (Cohort B)
- Data were analyzed through 365 days
- TEAEs were recorded through the last follow-up visit before data cutoff

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DISCLOSURES

Funding for this research was provided by Inviyd, Inc. ML, KN, and IY are employees of Inviyd, Inc. and may own stock. DW is a paid consultant of Inviyd, Inc. CW was on an Inviyd Advisory Board.

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RESULTS

Participants

- The 12-month analysis included 306 participants in Cohort A and 480 in Cohort B (320 pemivibart, 160 placebo; **Table 1**)
- In Cohort B, baseline characteristics between pemivibart (n=320) and placebo (n=160) arms were generally well balanced

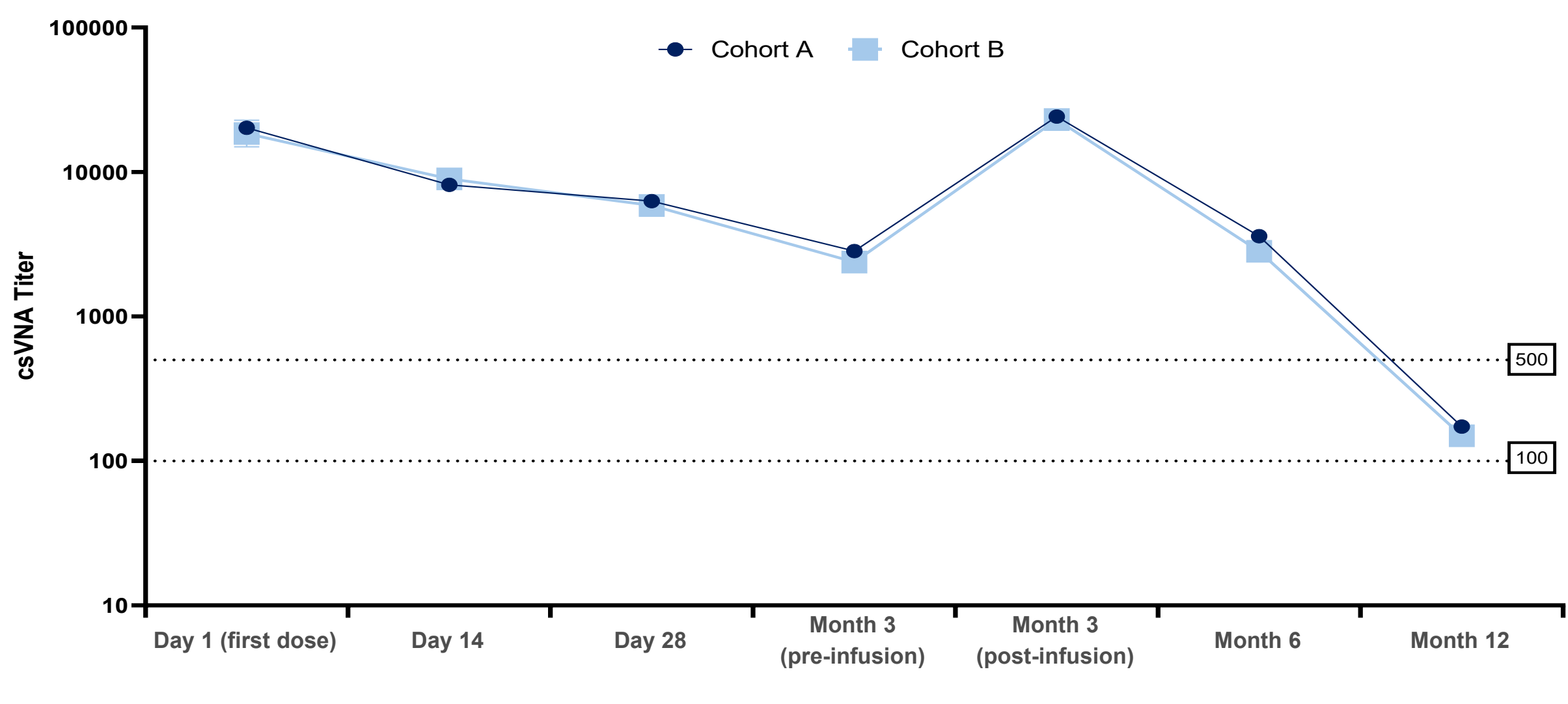
Safety and Tolerability

- Treatment emergent adverse events (TEAEs) were reported in 74.8% of Cohort A participants. TEAEs reported in Cohort B-pemivibart and Cohort B-placebo arms were 45.1% and 46.3%, respectively
 - There were 5 all cause deaths reported in Cohort A
 - There was 1 all cause death reported in Cohort B
- The most common study drug-related TEAEs were infusion-related reactions (Cohort A: 12/306 [3.9%]; Cohort B: 7/320 [2.2%] pemivibart, 0/160 placebo; **Table 2**)
 - Four of 626 (0.6%) pemivibart-receiving participants in Cohort A experienced an anaphylactic reaction (2 serious in Cohort A; study drug was permanently discontinued in both instances. Both anaphylaxis reactions were resolved within 24 hours)

Pemivibart neutralization by sVNA titers against relevant SARS-CoV-2 variants

- Following pemivibart dosing, csVNA titers across both cohorts were elevated to historical levels associated with protection against COVID-19 (**Figure 2**)

Figure 2. csVNA Titer Against JN.1^a in CANOPY



^aJN.1 variant was a predominant variant in the United States during the conduct of CANOPY. The plot displays geometric mean titer (GMT) and 90% confidence interval at each time point. The sVNA titers were calculated based on the serum concentration of pemivibart divided by IC₅₀ value against JN.1 (74.6 ng/mL; pseudotyped VLP neutralization assay). A time-varying Cox proportional hazards model developed using total CANOPY efficacy and csVNA titer data demonstrated a titer threshold of 500 and 100 was associated with a predicted efficacy of 50% & 40% (immunocompromised) and 70% & 58% (non-immunocompromised) for the protection against symptomatic COVID-19.⁷

COVID-19 Assessments

Risk of RT-PCR-confirmed COVID-19 through day 365 (**Figure 3**)

- Cohort A: 10.1% (95% CI, 6.6%-14.5%)
- Cohort B:
 - Pemivibart:** 5.3% (95% CI, 3.1%–8.7%)
 - Placebo:** 19.0% (95% CI, 13.2%-26.9%)

Incidence of RT-PCR-confirmed symptomatic COVID-19 through day 365 (**Table 3**)

- Cohort A: 25 (8.4%) had confirmed COVID-19 and 4 (1.3%) had all-cause death
- Cohort B:
 - Pemivibart:** 14 (4.4%) confirmed COVID-19, 1 (0.3%) death not related to COVID-19
 - Placebo:** 29 (18.4%) confirmed COVID-19
 - SRR with pemivibart:** 74.1% (95% CI: 53.1–85.7, p<0.0001)

Figure 3: Cumulative Incidence of RT-PCR-confirmed COVID-19 A) Cohort A (FAS), and B) Cohort B (mFAS)

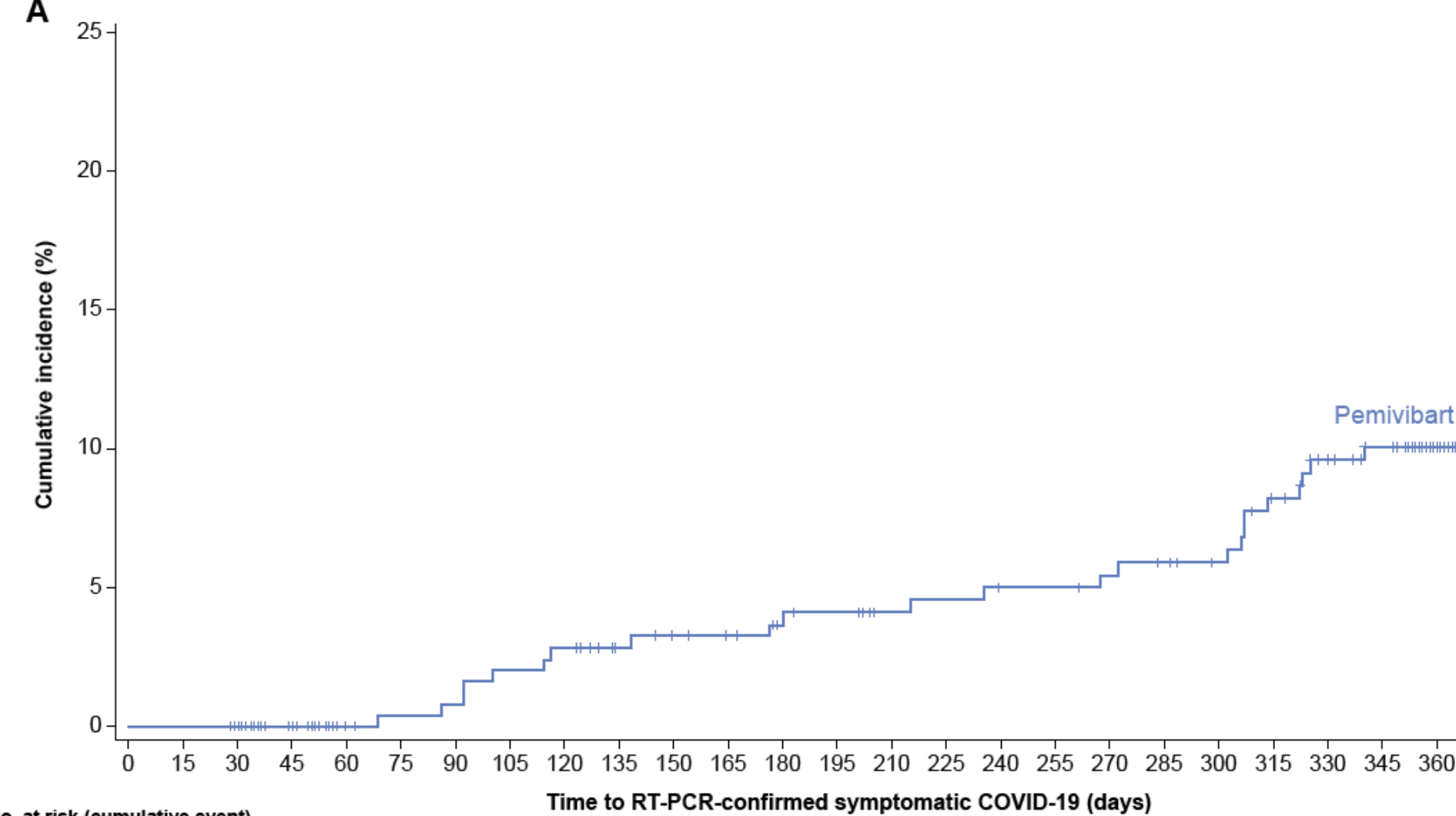


Table 1: Demographic and Baseline Characteristics in Cohorts A and B

Characteristic	Cohort A (SAS)	Cohort B (FAS)	
	Pemivibart n=306	Pemivibart n=320	Placebo n=160
Median age (range), years	59 (22–83)	47.0 (18–84)	48.0 (19–78)
Female, n (%)	187 (61.1)	166 (51.9)	91 (56.9)
BMI, mean (SD), kg/m ²	29.5 (7.8)	29.4 (6.6)	29.5 (6.7)
Negative baseline SARS-CoV-2 central RT-PCR test, n (%)	302 (98.7)	312 (97.5)	157 (98.1)
Baseline serology, (%)			
N-protein positive	49.0	84.7	85.6
N-protein negative	49.3	14.4	14.4
S-protein positive	97.7	98.4	99.4
S-protein negative	0.7	0.6	0.6
Immunocompromising condition ^a , n (%)			
Taking other immunosuppressive medications ^b	202 (66.0)	-	-
Acute leukemia, CLL, NHL, multiple myeloma	40 (13.1)	-	-
Moderate/severe primary immunodeficiency	37 (12.1)	-	-
SOT recipient taking immunosuppressive therapy	33 (10.8)	-	-
Advanced HIV (CD4 <350 cells/mm ³)	27 (8.8)	-	-
Actively treated solid tumor or hematologic malignancies	20 (6.5)	-	-
Risk factor for COVID-19 progression, ^a n (%)			
Age ≥55 years	306 (100)	212 (66.3)	99 (61.9)
Cardiac disease	179 (58.5)	117 (36.6)	59 (36.9)
Obesity (BMI >30 kg/m ²)	129 (42.2)	68 (21.3)	40 (25.0)
Chronic lung disease	116 (37.9)	128 (40.0)	65 (40.6)
Diabetes (type 1 or 2)	58 (19.0)	8 (2.5)	7 (4.4)
Solid organ or blood stem cell transplant recipient	54 (17.6)	29 (9.1)	15 (9.4)
Chronic kidney disease	33 (10.8)	0	0
Stroke or cerebrovascular disease	31 (10.1)	1 (0.3)	2 (1.3)
Substance use disorder	9 (2.9)	0	1 (0.6)
Sickle cell disease or thalassemia	6 (2.0)	4 (1.3)	3 (1.9)
	1 (0.3)	0	0

Abbreviations: BMI, body mass index; CLL, chronic lymphocytic leukemia; COVID-19, coronavirus disease 2019; FAS, full analysis set; HIV, human immunodeficiency virus; NHL, non-Hodgkin lymphoma; RT-PCR, reverse-transcription polymerase chain reaction; SAS, safety analysis set; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2; SD, standard deviation; SOT, solid organ transplant.
^aParticipants may have >1 immunocompromising condition or medication or risk factor for COVID-19 progression.
^bTaking high-dose corticosteroids (≥20 mg of prednisone or equivalent per day for ≥2 weeks), B-cell-depleting agents (within the past year), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, TNF blockers, or other immunosuppressive/immunomodulatory biologic agents.

Table 2. Summary of Treatment-Emergent Adverse Events (SAS)^{*}

Adverse Event Category, n (%)	Cohort A Pemivibart n = 306	Cohort B Pemivibart n = 317	Cohort B Placebo n = 160
Any TEAEs	229 (74.8)	143 (45.1)	74 (46.3)
Serious TEAEs	47 (15.4)	6 (1.9)	3 (1.9)
Any TEAEs leading to death	5 (1.6)	1 (0.3)	0
Any study drug-related TEAEs ^a	34 (11.1)	15 (4.7)	0
Study drug-related serious TEAEs	2 (0.7)	0	0
Study-drug related TEAEs leading to death	0	0	0
Study drug-related TEAEs leading to study treatment interruption ^b	14 (4.6)	4 (1.3)	0
Study drug-related TEAEs leading to study treatment discontinuation ^c	7 (2.3)	3 (0.9)	0

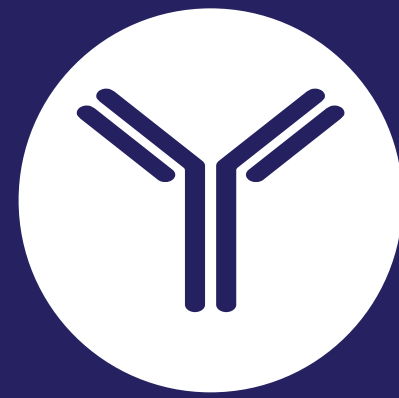
SAS, safety analysis set.
^aData cutoff February 3, 2025.
^bMissing relationship assessments were assumed to be "Related."
^cTreatment interruption included any participant who received a partial dose or who had a dose interrupted but restarted and completed the dose.
^dStudy treatment discontinuation included any participant who began dosing on day 1 but did not finish and was not re-dosed at month 3, or received a full dose on day 1 but was not re-dosed at month 3, or received a full dose on day 1 and began redosing at month 3 but did not finish. Does not include participants who had a dose interrupted but restarted and completed the dose or had the day 1 dose interrupted/discontinued but was subsequently re-dosed fully at month 3.

Table 3. RT-PCR-Confirmed Symptomatic COVID-19^a

Cohort A ^b	Pemivibart (n = 298)	
Composite RT-PCR-confirmed symptomatic COVID-19 through day 365, n (%)	29 (9.7)	
Symptomatic COVID-19	25 (8.4)	
All-cause death ^c	4 (1.3)	
Cohort B ^d	Pemivibart (n = 315)	Placebo (n = 158)
Composite RT-PCR-confirmed symptomatic COVID-19 through day 365, n (%)	15 (4.8)	29 (18.4)
Observed risk difference, %	−13.6	
SRR (95% CI), %; 2-sided P-value	74.1 (53.1–85.7); <0.0001	
Symptomatic COVID-19	14 (4.4)	29 (18.4)
All-cause death through day 365 ^e , n (%)	1 (0.3)	0

CI, confidence interval; FAS, full analysis set; mFAS, modified full analysis set; SRR, standardized relative risk reduction.
^aCentral laboratory conducted confirmatory testing using RT-PCR on nasopharyngeal swabs and saliva samples collected from participants with self-reported symptoms of COVID-19-like illness.
^bCohort A FAS includes all participants who received a full dose of pemivibart at initial dosing.
^cDue to suicide (n=1), unknown cause (n=1), cerebrovascular accident (n=1), and cardiac arrest (n=1), as assessed by the investigator. The participant who died after day 365 in cohort A did not contribute to composite COVID-19 endpoint through 365 days.
^dCohort B mFAS includes all randomized participants without SARS-CoV-2 infection at baseline who received any amount of pemivibart or placebo.
^eDue to congestive heart failure, as assessed by the investigator.

KEY FINDINGS



Two intravenous infusions of pemivibart administered 90 days apart were well tolerated; the majority of drug-related TEAEs with pemivibart (in both cohorts) were mild/moderate in severity. Anaphylaxis was an important identified safety risk.



csVNA titers were elevated to protective levels from symptomatic COVID-19 through 12 months



There was a 74.1% standardized relative risk reduction in composite COVID-19 incidence through 12 months with pemivibart (4.8%) versus placebo (18.4%)

CONCLUSIONS

- Pemivibart was well tolerated and provided prophylactic efficacy against contemporary COVID-19 variants in individuals with or without immune compromise
- Overall, these data further support the durability of pemivibart as a preventive option against COVID-19 for individuals with or without immune compromise