Pemivibart for Prevention of COVID-19: Subset Analysis of CANOPY Kidney Transplant Recipients

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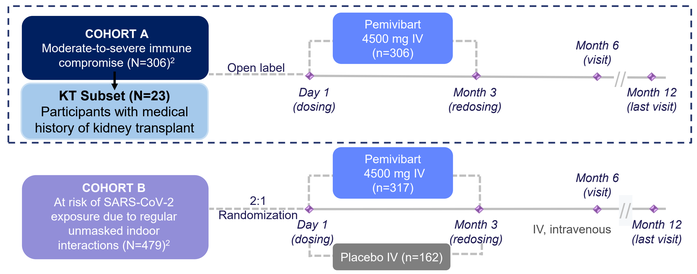
INTRODUCTION

- Kidney transplant (KT) patients experience reduced vaccine protection and remain at high risk of severe COVID-19 outcomes due to chronic immunosuppression[1]
- Pemivibart is a recombinant human monoclonal IgG1λ antibody that targets the SARS-CoV-2 spike protein receptor binding domain, thereby inhibiting virus attachment to host cells[2]
- Based on Phase 3 CANOPY data (NCT06039449), pemivibart was granted emergency use authorization (March 2024) for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise[3,4,5]

Objective: Here we describe a post hoc analysis of exclusively KT participants in the CANOPY open-label, single-arm immunocompromised Cohort A

METHODS

Figure 1. CANOPY, A Phase 3 Study To Evaluate Efficacy and Safety of Pemivibart for the Prevention Of COVID-19



Trial Design and Subset Analysis

- CANOPY was a Phase 3 study that evaluated the safety, tolerability, pharmacokinetics, and efficacy of pemivibart for pre-exposure prophylaxis of COVID-19 in adults aged ≥18 years (**Figure 1**)[3,4,5]
- CANOPY Cohort A: open-label, single-arm cohort that enrolled adults with significant immune compromise to receive pemivibart (**Figure 1 dashed box**)
- Primary and secondary objectives from CANOPY Cohort A included the following:
  - Primary
    - Evaluation of safety via study drug-related treatment emergent adverse events (TEAEs), serious adverse events (SAEs), and treatment interruption/discontinuation
    - Evaluation of protection against symptomatic COVID-19 based on calculated serum virus neutralizing antibody (csVNA) titers against SARS-CoV-2 after receiving pemivibart (immunobridging data reported previously[4])
  - Secondary
    - Evaluation of sVNA titers against SARS-CoV-2 after receiving pemivibart via csVNA and measured sVNA titers against relevant SARS-CoV-2 variants
    - Evaluation of pemivibart in the prevention of RT-PCR-confirmed symptomatic COVID-19 via RT-PCR-confirmed symptomatic COVID-19
    - Evaluation of the immunogenicity and PK of pemivibart
- Participants received a dose of study drug via intravenous infusion on Day 1 and then another equivalent dose at Month 3 over 30 minutes
  - Infusion time increased to 60 minutes with 31 participants in Cohort A that received 2nd dose
  - Participants were followed through Month 12; no additional doses were administered following the Month 3 dose
- The KT subset included Cohort A participants with a medical history of kidney transplant
- Data are presented for both Cohort A and Cohort A KT subset that were analyzed through Month 6

RESULTS

Participants

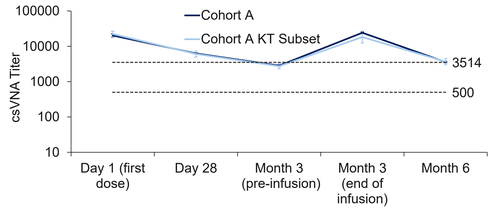
- CANOPY participants were enrolled from September 2023 – November 2023
- A total of 306 participants were enrolled in Cohort A
  - 23 (7.5%) were included in the KT subset (**Table 1**)
- Median time from transplant to first pemivibart dose was 4 years [IQR: 3-9.5]
- All 23 (100%) KT participants were concomitantly receiving immunosuppressants, including 15 (65.2%) receiving corticosteroids

Table 1. Baseline Characteristics in CANOPY Cohort A and CANOPY Kidney Transplant Subset

Parameter	Cohort A n=306[5]	Cohort A KT Subset n =23
Median age [range], years	59 [22-83]	64 [54-70]
Female, n (%)	187 (61.1)	12 (52.2)
BMI, mean (SD), kg/m^2	29.5 (7.8)	30.1 (9.2)
Participants with prior COVID-19 vaccinations, n (%)	269 (87.9)	22 (95.7)
Number of prior COVID-19 vaccinations, median (range)	5 (1-11)	6 (2-9)
≥1 Concomitant medication	305 (99.7)	23 (100)
Risk Factor for COVID-19[a] (%)		
Obesity (BMI > 30 kg/m^2)	37.9	39.1
Diabetes (T1 or T2)	17.6	26.1
Chronic kidney disease	10.1	52.2
Chronic lung disease	19.0	8.7
Cardiac disease	42.2	65.2
Sickle cell disease	0.3	0.0
Stroke or cerebrovascular disease	2.9	0.0
Substance use disorder	2.0	0.0
Baseline serology, (%)		
N-protein positive	49.0	26.1
N-protein negative	49.3	73.9
S-protein positive	97.7	95.7
S-protein negative	0.7	4.3
Baseline measured SARS-CoV-2 sVNA titers (%[b])		
msVNA titers against B.1.617.2	85.3	73.9
msVNA titers against BA.4/5	69.0	47.8
msVNA titers against XBB1.5	41.2	34.8

[a]Participants may be in more than one category;
[b]Baseline msVNA titer above detectable threshold
BMI, body mass index; N-protein, nucleocapsid protein, S-protein, spike protein; KT, kidney transplant, msVNA, measured serum virus neutralizing antibody

Figure 2: csVNA Titer Against JN.1[a] in CANOPY Cohort A and Kidney Transplant Subset Through Month 6



[a]JN.1 variant was the predominant variant in the United States at the time of analysis; The plot displays 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). The dotted lines represent protection titer thresholds. A threshold of 3514 is based on historical data from the EVADE study (NCT04859517), which demonstrated clinical efficacy (71% relative risk reduction vs. placebo) of adintrevimab for pre-exposure prophylaxis against the Delta variant through 3 months.[6,7] A time-varying Cox proportional hazards model developed using total CANOPY efficacy and csVNA titer data demonstrated a threshold of 500 was associated with an estimated efficacy of 50% (immunocompromised) and 70% (non-immunocompromised) for the protection against symptomatic COVID-19.[8]

Safety and Tolerability

- Through Month 6, 60.9% of Cohort A KT participants reported a TEAE (**Table 2**)
  - 2 (8.7%) were SAEs
  - 2 (8.7%) were study-drug related and were not considered SAEs
  - Treatment interruption was warranted in 2 instances (8.7%), 1 of which resulted in treatment discontinuation
- There were no instances of anaphylaxis in the KT subset; 4 cases of anaphylaxis were reported in the overall Cohort A through Month 6

Assessment of COVID-19 for Cohort A and the Kidney Transplant Subset

- KT subset csVNA titers were elevated to levels associated with protection against COVID-19 and were comparable with the overall Cohort A (**Figure 2**)
- No cases of RT-PCR–confirmed symptomatic COVID-19 were reported in the Cohort A KT subset through Month 6 (**Table 3**)

Table 2. Safety for CANOPY Cohort A and Kidney Transplant Subset Through Month 6[a]

Parameter	Overall Cohort A n=306	Cohort A KT Subset n=23
TEAE, n (%)	204 (66.7)	14 (60.9)
SAE, n (%)	35 (11.4)	2 (8.7)
Study drug related TEAEs, n (%)	34 (11.1)	2 (8.7)
-leading to death	0 (0.0)	0 (0.0)
-leading to interruption	14 (4.6)	2 (8.7)[c]
-leading to discontinuation	7 (2.3)[b]	1 (4.3)[d]

[a]Safety analysis set includes all participants who received any amount of study drug during the study
[b]Cohort A pemivibart-related causes of study discontinuation included: Hypersensitivity (n = 2), anaphylaxis (n = 2), infusion related reaction (n = 2), tachycardia (n = 1), tremor (n = 1).
[c]Cohort A KT subset pemivibart-related causes of study interruption included: infusion related reaction (n = 1), tachycardia and tremor (n = 1)
[d]Cohort A KT subset pemivibart-related causes of study discontinuation included: tachycardia and tremor (n = 1)

Table 3. Incidence of RT-PCR–confirmed symptomatic COVID-19, COVID-19–related hospitalizations, and all-cause mortality among CANOPY Cohort A and Kidney Transplant Subset Through Month 6[a]

Parameter	Overall Cohort A n=298	Cohort A KT Subset n=20
COVID-19 composite event, n (%)[b]	11 (3.7)	0 (0.0)
PCR-confirmed case, n (%)	9 (3.0)	0 (0.0)
All-cause mortality	2 (0.7)[c]	0 (0.0)

[a]Full analysis set includes all participants who received a full dose of study drug at the initial dosing
[b]Assessment of COVID-19: A participant was considered to have COVID-19 if they had RT-PCR–confirmed SARS-CoV-2 with onset of symptoms ≤14 days from the date of the positive sample collection or had a COVID-19–related hospitalization or all-cause death
[c]Cause: Suicide (n=1), Unknown (n=1)

KEY FINDINGS

for Subset of Kidney Transplant Recipients

CANOPY enrolled participants with immune compromise (Cohort A); among these, 23 participants (7.5%) were in the KT subset

Pemivibart was well-tolerated in the KT subset

csVNA titers were elevated to levels associated with protection by pemivibart in the KT subset

No KT participants had RT-PCR-confirmed symptomatic COVID-19 through Month 6

CONCLUSIONS

for Subset of Kidney Transplant Recipients

These data support pemivibart as a preventative option against COVID-19 in this high-risk clinical group

REFERENCES

1. Reischig T, et al. Am J Transplant. 2022;22 (3), 801-812.
2. Fact Sheet for Healthcare Providers: Emergency Use Authorization for Pemivibart. Last updated September 2025.
3. ClinicalTrials.gov. https://clinicaltrials.gov/study/NCT06039449.
4. Schmidt, P, et al. NEJM. 2024,391:1860-1862.
5. Wolfe C, et al, CID. 2025;81(3):439-450.
6. Stadler E, et al. Nat Commun. 2023; 14-4545.
7. Ison MG, et al. Open Forum Infect Dis. 2023;10:ofad314.
8. Yalcin I, et al. *medRxiv.* 2025.07.24.25332145

DISCLOSURES

ML, KN, IY, MW are employees of Invivyd, Inc, and may own stock. DW is a paid consultant of Invivyd, Inc.

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