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

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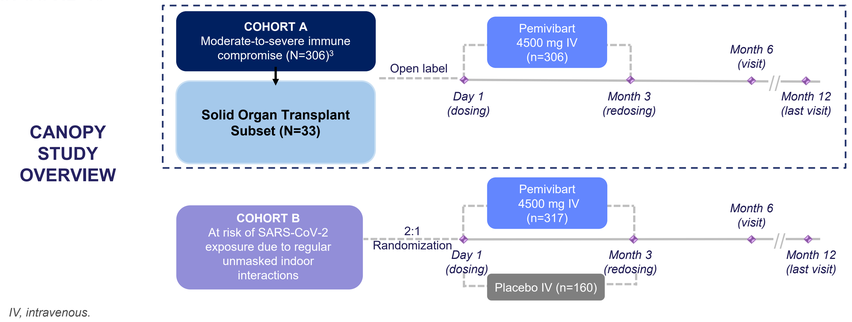
INTRODUCTION

- Solid organ transplant recipients can experience reduced vaccine protection and remain at high risk for severe COVID-19 due to chronic immunosuppression[1,2]
- 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[3]
- Pemivibart has continued to demonstrate *in vitro* neutralization of contemporary dominant circulating variants[3]
- 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[3-6]

Here we describe a post hoc analysis of participants in the solid organ transplant subset of 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



IV, intravenous.

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**)[4-6]
- CANOPY Cohort A was an open-label, single-arm cohort receiving pemivibart that enrolled adults with significant immune compromise (**Figure 1 dashed box**)
- Primary and secondary objectives from CANOPY Cohort A included the following:
  - Primary
    - Evaluation of safety and tolerability of pemivibart in all treated participants
    - 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[5])
  - Secondary
    - 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)
    - Evaluation of pemivibart in the prevention of reverse transcriptase polymerase chain reaction (RT-PCR)-confirmed symptomatic COVID-19
- 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
- The solid organ transplant subset included Cohort A participants who were solid organ transplant recipients receiving active immunosuppressive therapy (agnostic to duration/choice of therapy)
- Data are presented for both Cohort A and Cohort A solid organ transplant subset that were analyzed through Month 6

RESULTS

Participants

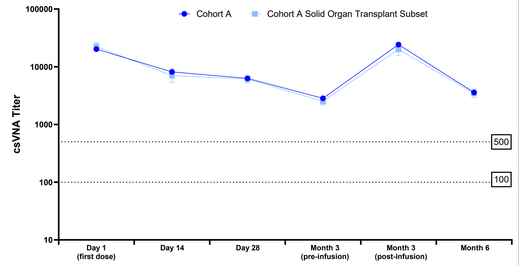
- All CANOPY participants were enrolled from September 2023 – November 2023
- A total of 306 participants were enrolled in Cohort A
  - 33 (10.8%) were included in the Cohort A solid organ transplant subset (**Table 1**)
    - Among these 33 participants: 23 (69.7%) had kidney transplants, 4 (12.1%) had liver transplants, 2 (6.1%) had heart transplants, 2 (6.1%) had lung transplants, and 2 (6.1%) had multi-organ transplants (kidney and pancreas transplant [n=2])
- Participants had a median [Q1-Q3] of 5 [3-10] years since transplant to their first dose of study drug
- All 33 (100%) and 18 (54.5%) solid organ transplant participants were concomitantly receiving immunosuppressants and corticosteroids, respectively
- Prior to enrollment, 89.1% of participants in the Cohort A solid organ transplant subset received ≥ 1 COVID-19 vaccinations; the majority were seropositive to S antigen (97.0%) and 30.3% were seropositive to N antigen
- At baseline, most participants had measurable sVNA titers against historical variants (B.1.617.2 [75.8%] and BA.4/5 [54.5%]) but fewer against the concurrent variant XBB.1.5 [33.3%];**Table 1**)

Table 1: Baseline Characteristics in CANOPY Cohort A and Cohort A Solid Organ Transplant Subset

Parameter	Cohort A n=306[6]	Cohort A Solid Organ Transplant Subset n =33
Median age [range], years	59 [22-83]	64 [24-75]
Female, n (%)	187 (61.1)	16 (48.5)
BMI, mean (SD), kg/m²	29.5 (7.8)	29.96 (9.94)
Participants with prior COVID-19 vaccinations, n (%)	269 (87.9)	32 (97.0)
Number of prior COVID-19 vaccinations, median (range)	5 (1-11)	5.5 (1-9)
Concomitant Medications, n (%)		
Immunosuppressants	190 (62.1)	33 (100)
Corticosteroids for systemic use	94 (30.7)	18 (54.5)
Risk Factor for COVID-19[a] (%)		
Age (≥55 years)	58.5	72.7
Obesity (BMI > 30 kg/m²)	37.9	36.4
Diabetes (T1 or T2)	17.6	39.4
Chronic kidney disease	10.1	45.5
Chronic lung disease	19.0	15.2
Cardiac disease	42.2	60.6
Sickle cell disease	0.3	0
Stroke or cerebrovascular disease	2.9	0
Substance use disorder	2.0	0
Baseline serology, (%)		
N-protein positive	49.0	30.3
N-protein negative	49.3	69.7
S-protein positive	97.7	97.0
S-protein negative	0.7	3.0
Baseline measured SARS-CoV-2 sVNA titers (%[b])		
msVNA titers against B.1.617.2	85.3	75.8
msVNA titers against BA.4/5	69.0	54.5
msVNA titers against XBB1.5	41.2	33.3

[a]Participants may be in more than one category
[b]Percent of participants with specific and detectable baseline msVNA titer above detectable threshold
BMI, body mass index; N-protein, nucleocapsid protein, S-protein, spike protein; msVNA, measured serum virus neutralizing antibody

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



[a]JN.1 variant was a dominant variant in the United States during the conduct of CANOPY; 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 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]

Safety and Tolerability

- Through Month 6, 60.6% of Cohort A solid organ transplant subset participants reported a TEAE (**Table 2**)
  - 5 (15.2%) were SAEs, none were considered drug-related; there were no deaths among the Cohort A solid organ transplant subset participants
  - 3 (9.1%) were study drug-related and required treatment interruption; 1 participant had study drug discontinuation due to study drug-related TEAEs
- There were no instances of anaphylaxis in the Cohort A solid organ transplant subset; 4 cases of anaphylaxis were reported in the overall Cohort A

Assessment of COVID-19 for Cohort A and Cohort A Solid Organ Transplant Subset

- Following pemivibart dosing, csVNA titers in the Cohort A solid organ transplant subset were elevated to levels historically associated with protection against COVID-19 and were comparable with the overall Cohort A[7] (**Figure 2**)
- No cases of RT-PCR-confirmed symptomatic COVID-19 were reported in the Cohort A solid organ transplant subset through Month 6 (**Table 3**)

Table 2: Safety for CANOPY Cohort A and Cohort A Solid Organ Transplant Subset Through Month 6[a]

Parameter	Overall Cohort A n=306	Cohort A Solid Organ Transplant Subset n =33
TEAE, n (%)	204 (66.7)	20 (60.6)
SAE, n (%)	35 (11.4)	5 (15.2)
Study drug related TEAEs, n (%)	34 (11.1)	3 (9.1)
-leading to death	0	0
-leading to interruption	14 (4.6)	3 (9.1)[c]
-leading to discontinuation	7 (2.3)[b]	1 (3.0)[d]

[a]Safety analysis set includes all participants who received any amount of study drug during the study. Participants could cite multiple reasons for treatment interruption or discontinuation.
[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 solid organ transplant subset pemivibart-related cause of study interruption included: infusion site extravasation (n = 1), tachycardia (n = 1), and other (n = 1).
[d]Cohort A solid organ transplant subset pemivibart-related causes of study discontinuation was 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 Cohort A Solid Organ Transplant Subset Through Month 6[a]

Parameter	Overall Cohort A n=298	Cohort A Solid Organ Transplant Subset n =33
COVID-19 composite event, n (%)[b]	11 (3.7)	0
PCR-confirmed case, n (%)	9 (3.0)	0
All-cause mortality, n (%)	2 (0.7)[c]	0

[a]Full analysis set includes all participants who received a full dose of study drug at the initial dosing
[b]Included RT-PCR–confirmed SARS-CoV-2 with an onset of symptoms occurring no more than 14 days from the date of the positive SARS-CoV-2 test sample collection (nasopharyngeal or saliva for RT-PCR or nasopharyngeal for respiratory pathogen panel), COVID-19–related hospitalization, or all-cause death.
[c]Cause: Suicide (n=1), Unknown (n=1).

KEY FINDINGS

For Cohort A Solid Organ Transplant Subset

CANOPY enrolled participants with significant immune compromise (Cohort A); among these, 33 (10.8%) participants in Cohort A were in the solid organ transplant subset

Pemivibart was well-tolerated in the Cohort A solid organ transplant subset as measured by study drug-related TEAEs

csVNA titers were elevated to protective levels from symptomatic COVID-19 in the Cohort A solid organ transplant subset

- **Notably, csVNA titer levels within the Cohort A solid organ transplant subset were comparable to those observed in the overall parent cohort**

There were no cases of RT-PCR-confirmed symptomatic COVID-19 reported through Month 6 in the Cohort A solid organ transplant subset

CONCLUSIONS

For Cohort A Solid Organ Transplant Subset

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

LIMITATIONS

This was a post-hoc, non-prespecified subset analysis; findings should therefore be interpreted as exploratory.

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DISCLOSURES

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

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