# Pemivibart for Prevention of COVID-19: Subset Analysis of CANOPY Participants with Solid Tumor or Hematologic Malignancies

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## INTRODUCTION

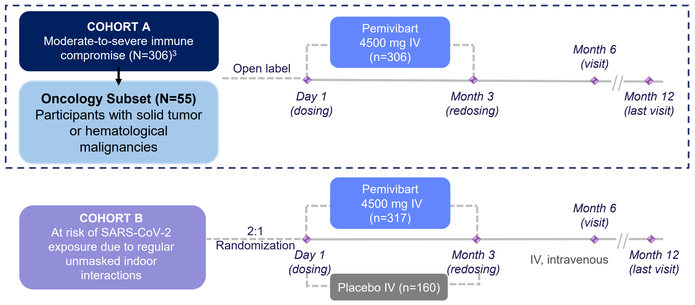
- Due to the chronic immunosuppression associated with both their condition and treatment regimens, patients with solid tumors or hematologic malignancies experience reduced vaccine protection and are at high risk of infections, including COVID-19[1,2]
- Pemivibart is a recombinant human monoclonal IgG1λ antibody that targets the SARS-CoV-2 spike protein receptor binding domain, thereby inhibiting virus attachment to host cells[3]
- Based on Phase 3 CANOPY data (NCT06039449), pemivibart was granted emergency use authorization (Mar 2024) for pre-exposure prophylaxis of COVID-19 in certain adults and adolescents with moderate-to-severe immune compromise[4-6]
  - Pemivibart has continued to demonstrate neutralization of contemporary dominant circulating variants[3]

**Here we describe a post hoc analysis of participants in the joint oncology subset (including participants with solid tumor or hematological malignancies) 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**

CANOPY STUDY OVERVIEW




### 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: 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 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 oncology subset included Cohort A participants receiving active treatment (agnostic to duration/choice of therapy) for solid tumor or hematologic malignancies or those with acute leukemia, chronic lymphocytic leukemia, non-Hodgkin lymphoma, or multiple myeloma
- Data are presented for both Cohort A and Cohort A oncology subset that were analyzed through Month 6

## RESULTS

### Participants

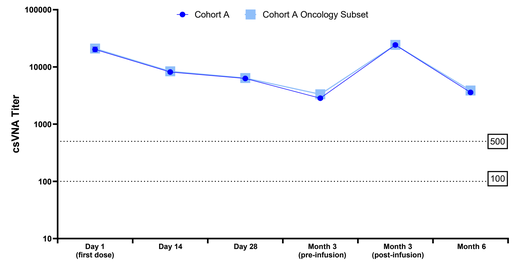
- CANOPY participants were enrolled from September 2023 – November 2023
- A total of 306 participants were enrolled in Cohort A
  - 55 (18.0%) were included in the Cohort A oncology subset (**Table 1**)
- Eight participants (14.5%) were receiving immunosuppressants, including 6 (10.9%) receiving corticosteroids
- Prior to enrollment, 89.1% of participants in the Cohort A oncology subset received ≥ 1 COVID-19 vaccine; the majority were seropositive to S antigen (98.2%) but less than half were seropositive to N (43.6%). Most had measurable sVNA titers against historical variants (B.1.617.2 [92.7%] and BA.4/5 [80.0%]) but fewer against concurrent XBB.1.5 [45.5%];**Table 1**)

**Table 1: Baseline Characteristics in CANOPY Cohort A and Cohort A Oncology Subset**

| Parameter | Cohort A n=306[6] | Cohort A Oncology Subset n =55 |
|---|---|---|
| Median age [range], years | 59 [22-83] | 64 [35-83] |
| Female, n (%) | 187 (61.1) | 25 (45.5) |
| BMI, mean (SD), kg/m$^2$ | 29.5 (7.8) | 28.1 (6.2) |
| Participants with prior COVID-19 vaccinations, n (%) | 269 (87.9) | 49 (89.1) |
| Number of prior COVID-19 vaccinations, median (range) | 5 (1-11) | 6 (2-8) |
| ≥1 Concomitant medication | 305 (99.7) | 49 (89.1) |
| Risk Factor for COVID-19[a] (%) | | |
| Age (≥55 years) | 58.5 | 80.0 |
| Obesity (BMI > 30 kg/m$^2$) | 37.9 | 36.4 |
| Diabetes (T1 or T2) | 17.6 | 16.4 |
| Chronic kidney disease | 10.1 | 5.5 |
| Chronic lung disease | 19.0 | 20.0 |
| Cardiac disease | 42.2 | 49.1 |
| Sickle cell disease | 0.3 | 0.0 |
| Solid organ transplant recipient | 10.8 | 5.5 |
| Stroke or cerebrovascular disease | 2.9 | 7.3 |
| Substance use disorder | 2.0 | 0 |
| Baseline serology, (%) | | |
| N-protein positive | 49.0 | 43.6 |
| N-protein negative | 49.3 | 54.5 |
| S-protein positive | 97.7 | 98.2 |
| S-protein negative | 0.7 | 0 |
| Baseline measured SARS-CoV-2 sVNA titers (%[b]) | | |
| msVNA titers against B.1.617.2 | 85.3 | 92.7 |
| msVNA titers against BA.4/5 | 69.0 | 80.0 |
| msVNA titers against XBB1.5 | 41.2 | 45.5 |

*[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; msVNA, measured serum virus neutralizing antibody*

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




*[a]JN.1 variant was a 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 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, 58.2% of Cohort A oncology subset participants reported a TEAE (**Table 2**)
  - 5 (9.1%) were SAEs, none were considered drug-related
  - 5 (9.1%) were study drug-related, 1 (3.7%) of which required treatment interruption due to infusion site extravasation and tachycardia
- In the Cohort A oncology subset, one all-cause mortality was reported (**Table 3**)
- There were no instances of anaphylaxis in the Cohort A oncology subset; 4 cases of anaphylaxis were reported in the overall Cohort A

### Assessment of COVID-19 for Cohort A and Cohort A Oncology Subset

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

**Table 2: Safety for CANOPY Cohort A and Cohort A Oncology Subset Through Month 6[a]**

| Parameter | Overall Cohort A n=306 | Cohort A Oncology Subset n=55 |
|---|---|---|
| TEAE, n (%) | 204 (66.7) | 32 (58.2) |
| SAE, n (%) | 35 (11.4) | 5 (9.1) |
| Study drug related TEAEs, n (%) | 34 (11.1) | 5 (9.1) |
| -leading to death | 0 (0.0) | 0 (0.0) |
| -leading to interruption | 14 (4.6) | 1 (3.7)[c] |
| -leading to discontinuation | 7 (2.3)[b] | 0 (0.0) |

*[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 oncology subset pemivibart-related cause of study interruption included: infusion site extravasation and tachycardia (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 Oncology Subset Through Month 6[a]**

| Parameter | Overall Cohort A n=298 | Cohort A Oncology Subset n=55 |
|---|---|---|
| COVID-19 composite event, n (%)[b] | 11 (3.7) | 1 (1.8) |
| PCR-confirmed case, n (%) | 9 (3.0) | 0 (0.0) |
| All-cause mortality | 2 (0.7)[c] | 1 (1.8)[d] |

*[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)*
*[d]Unknown (n=1)*

## KEY FINDINGS

for Cohort A Oncology Subset

**CANOPY enrolled participants with significant immune compromise (Cohort A); among these, 55 (18.0%) participants in Cohort A were in the oncology subset**

**Pemivibart was well-tolerated in the Cohort A oncology subset as measured by study drug-related TEAEs**

**csVNA titers were elevated to protective levels from symptomatic COVID-19 in the Cohort A oncology subset**

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

## CONCLUSIONS

for Cohort A Oncology 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 not powered for these endpoints therefore findings are exploratory.**

## REFERENCES

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## DISCLOSURES

ML, KN, and IY are employees of Invivyd, Inc. and may own stock. JW: Stock and Other Ownership Interests: HemeOnc.org. Honoraria: Henry Ford Health System, Prime Healthcare Services. Consulting or Advisory Role: Invivyd, Westat, Lewin Group, University of Texas Medical Branch, Nemesis Health. DW is a paid consultant of Invivyd, Inc.

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