



INVIVYD

INVIVYD CANOPY DATA UPDATE

August 27, 2024

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COVID-19 PROPHYLAXIS VIA MONOCLONAL ANTIBODY: A STEP FORWARD

- CANOPY exploratory clinical efficacy data demonstrated a substantial change - 84% Relative Risk Reduction (RRR) - in experiencing symptomatic COVID-19 disease with pemivibart prophylaxis versus placebo¹
- PEMGARDA^(TM) (pemivibart) Fact Sheet for Healthcare Providers updated to include exploratory clinical efficacy data²
- Safety profile of pemivibart consistent with previously reported CANOPY clinical trial data
- Today's CANOPY data represent the first look at the major medical role mAbs can play in an endemic SARS-CoV-2 environment and provide a striking contrast to estimated vaccine effectiveness (VE)³
- We hope to work with FDA to integrate clinical event findings from CANOPY into future mAb development work

¹180-day exploratory clinical event data assessment of immunocompetent participants in CANOPY clinical trial for pre-exposure prophylaxis (PrEP) of COVID-19

² Fact Sheet also updated to reflect certain risks related to variant susceptibility to PEMGARDA

³ FDA presentation to ACIP June 28, 2024

mAb = monoclonal antibody

CANOPY COVID-19 PREP RESULTS ARE THE FIRST REPORTED IN A CONTEMPORARY, "ENDEMIC VIRUS" POPULATION

<u>Study</u>	<u>Molecule(s)</u>	<u>Protocol Participation Criteria</u>
EVADE	adintrevimab	<u>Include:</u> Tests <u>negative</u> for prior SARS-CoV-2 infection via RT-PCR and serology <u>Exclude:</u> Has received a SARS-CoV-2 vaccine or convalescent plasma
PROVENT	tixagevimab + cilgavimab	<u>Include:</u> <u>Negative result</u> from point-of-care SARS-CoV-2 serology testing
CANOPY	pemivibart	<u>Exclude:</u> Cohort B: receipt of a vaccine boost within 120 days of randomization <u>Exclude:</u> Both Arms: prior known or suspected SARS-CoV-2 infection within 120 days of randomization
SUPERNOVA <i>(data pending)</i>	sipavibart	<u>Exclude:</u> Receipt of a Covid-19 vaccine within three months prior to Visit 1

Source: Clinicaltrials.gov

PrEP = Pre-Exposure Prophylaxis

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AGENDA

▶ CANOPY Clinical Trial Results

Q&A

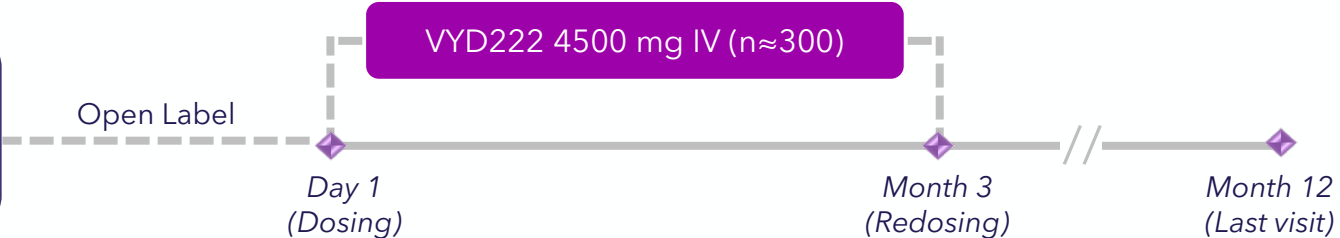
CANOPY: PHASE 3 CLINICAL TRIAL OF PEMIVIBART (VYD222)

CANOPY STUDY OVERVIEW

COHORT A
Moderate-to-severe immune compromise (N≈300)

Primary endpoints:

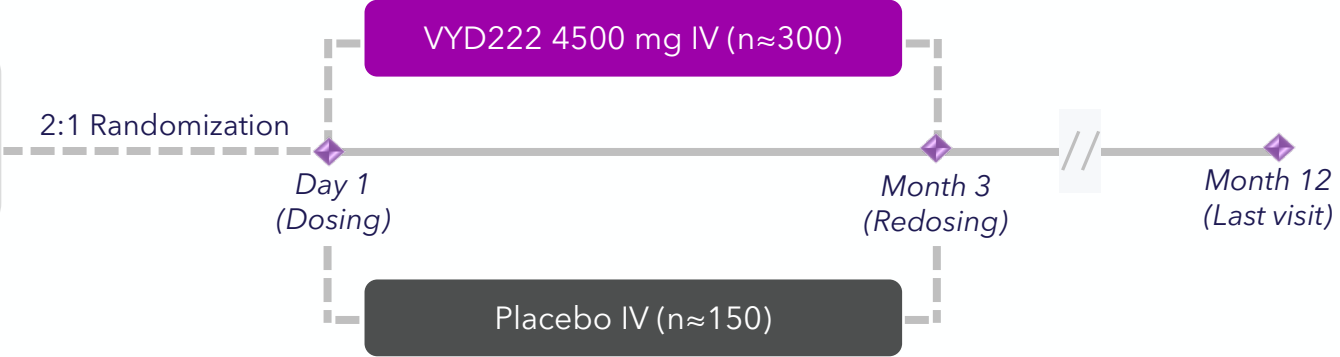
- Safety/tolerability
- Day 28 serum virus neutralizing antibody (sVNA) titers (calculated from the pharmacokinetic concentrations of VYD222 and the EC₅₀ value for VYD222 against relevant SARS-CoV-2 variants)



COHORT B
At risk of SARS-CoV-2 exposure due to regular unmasked indoor interactions (N≈450)

Primary endpoint:

- Safety/tolerability



BASELINE DEMOGRAPHICS

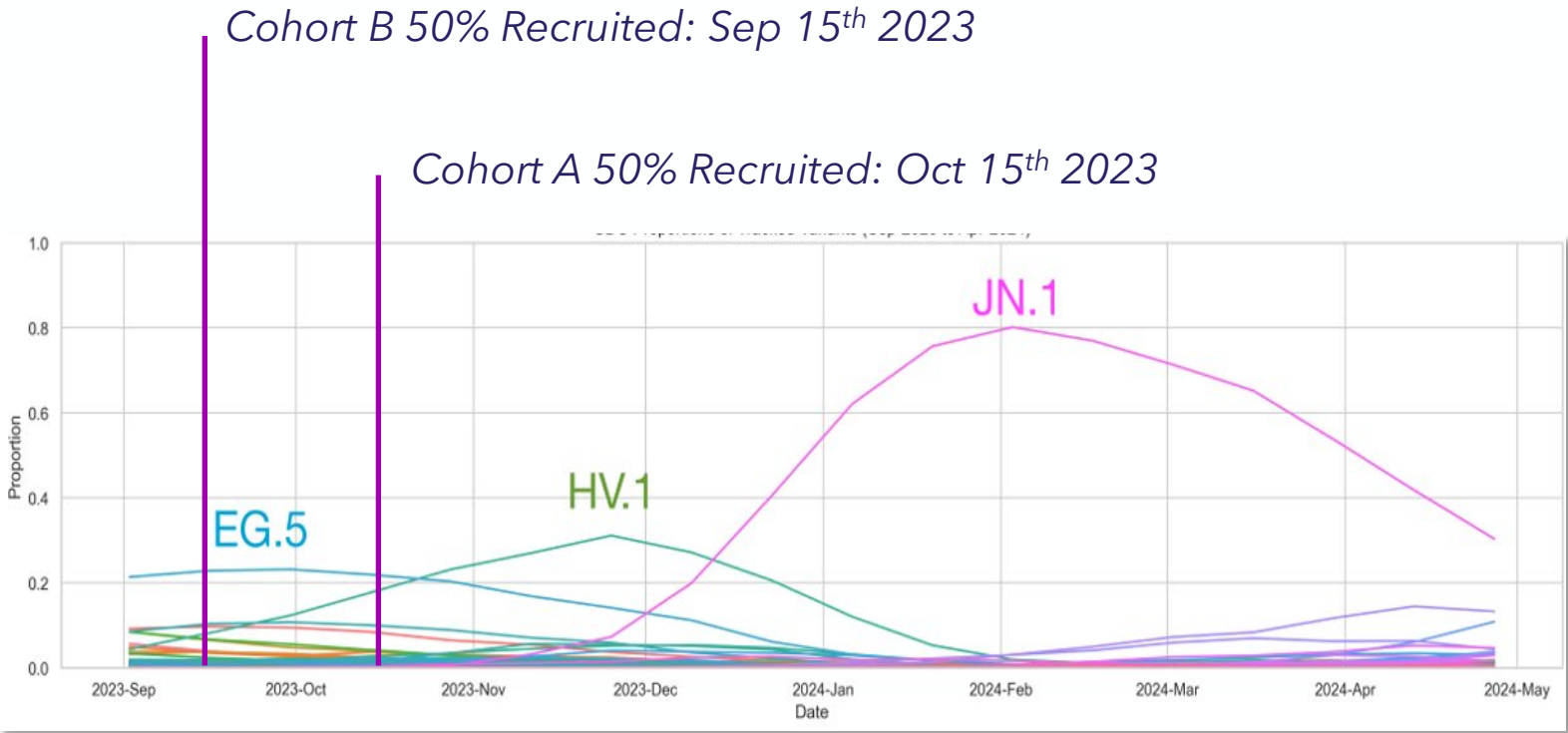
Parameter	Cohort A (N=306)	Cohort B VYD222 (N=322)	Cohort B Placebo (N=162)
Age (years) [1]			
n	306	322	162
Mean (SD)	56.3 (13.49)	48.3 (15.37)	47.6 (15.29)
Median	59.0	47.5	48.0
Q1, Q3	47.0, 66.0	37.0, 61.0	36.0, 61.0
Min, Max	22.0, 83.0	18.0, 84.0	19.0, 78.0
Age Group [n (%)]			
18 - <55 years	127 (41.5)	204 (63.4)	102 (63.0)
>=55 years	179 (58.5)	118 (36.6)	60 (37.0)
>=65 years	95 (31.0)	61 (18.9)	27 (16.7)
>=75 years	22 (7.2)	9 (2.8)	1 (0.6)
Sex [n (%)]			
Male	119 (38.9)	156 (48.4)	71 (43.8)
Female	187 (61.1)	166 (51.6)	91 (56.2)

Parameter	Cohort A (N=306)	Cohort B VYD222 (N=322)	Cohort B Placebo (N=162)
Race [n (%)] [2]			
American Indian or Alaska Native	4 (1.3)	3 (0.9)	1 (0.6)
Asian	6 (2.0)	15 (4.7)	7 (4.3)
Black or African American	37 (12.1)	94 (29.2)	48 (29.6)
Native Hawaiian or Other Pacific Islander	0	3 (0.9)	0
White	262 (85.6)	201 (62.4)	108 (66.7)
Other	2 (0.7)	1 (0.3)	0
Multiple	5 (1.6)	2 (0.6)	3 (1.9)
Not Reported	1 (0.3)	8 (2.5)	1 (0.6)
Ethnicity [n (%)]			
Hispanic or Latino	17 (5.6)	87 (27.0)	56 (34.6)
Not Hispanic or Latino	286 (93.5)	231 (71.7)	103 (63.6)
Not Reported	3 (1.0)	4 (1.2)	3 (1.9)

MEDICAL HISTORY

Parameter	Cohort A (N=306) n (%)	Cohort B VYD222 (N=322) n (%)	Cohort B Placebo (N=162) n (%)
Significant immune compromise (inclusion criteria #4a) [1]			
1. actively treated solid tumor or hematologic malignancies	20 (6.5)		
2. acute leukemia, chronic lymphocytic leukemia, non-Hodgkin lymphoma, or multiple myeloma	40 (13.1)		
3. solid organ transplant recipient taking immunosuppressive therapy	33 (10.8)		
4. CAR-T-cell therapy or hematopoietic stem cell transplant	0		
5. moderate or severe primary immunodeficiency	37 (12.1)		
6. advanced HIV infection	27 (8.8)		
7. taking immunosuppressive/immunomodulatory medications	202 (66.0)		
Risk Factor for COVID-19 Disease Progression (Adult)	306 (100)	213 (66.1)	100 (61.7)
Age >=55 Years	179 (58.5)	118 (36.6)	60 (37.0)
Obesity (Body Mass Index [BMI] > 30 kg/m2)	116 (37.9)	129 (40.1)	65 (40.1)
Diabetes (Type 1 or Type 2)	54 (17.6)	29 (9.0)	15 (9.3)
Chronic kidney disease	31 (10.1)	1 (0.3)	2 (1.2)
Chronic lung disease	58 (19.0)	8 (2.5)	7 (4.3)
Cardiac disease	58 (19.0)	68 (21.1)	41 (25.3)
Sickle cell disease	129 (42.2)	0	0
Solid organ transplant recipients	1 (0.3)	0	0
Other immunodeficiency due to underlying illness or immunosuppressant medication	33 (10.8)	4 (1.2)	1 (0.6)
Down Syndrome	306 (100)	0	0
Stroke or cerebrovascular disease	0	0	1 (0.6)
Substance use disorder	9 (2.9)	4 (1.2)	3 (1.9)
Pregnancy	6 (2.0)	0	0
	0	0	0

CANOPY CLINICAL EVENT 180-DAY TIME PERIOD COVERS A RANGE OF COVID-19 VIRUSES INCLUDING SUBSTANTIAL JN.1 IN THE SECOND HALF



Variant				
XBB.1.5	XBB.1.5.68	KS.1	EG.5	JN.1.16.1
XBB.1.42.2	BA.5.2.6	BA.5	JF.1	JN.1.16
XBB.1.16.6	BF.11	KP.4.1	KQ.1	JN.1.13.1
XBB.1.16.17	BF.7	JD.1.1	JG.3	JN.1.13
XBB.1.16.15	BN.1	HV.1	JN.1.11.1	JN.1
XBB.1.16.11	BQ.1	HK.3	KP.3.1.1	BA.4.6
XBB.1.16.1	BQ.1.1	HF.1	KP.3	KP.2.3
LP.1	CH.1.1	GK.2	KP.2	BA.2.86
XBB	XDV.1	GK.1.1	KP.1.2	B.1.1.529
Other	XDP	GE.1	KP.1.1.3	B.1.617.2
XBB.1.5.1	XBB.2.3.8	FL.1.5.1	KP.1.1	BA.1.1
LF.3.1	XBB.2.3	FE.1.1	JN.1.8.1	BA.4
LB.1	XBB.1.9.2	FD.2	JN.1.7	BA.2.12.1
XBB.1.16	XBB.1.9.1	FD.1.1	JN.1.4.3	BA.2.75.2
XBB.1.5.10	KV.2	EU.1.1	JN.1.32	BA.2
XBB.1.5.72	XBB.1.5.70	EG.6.1	JN.1.18	BA.2.75
	XBB.1.5.59	EG.5.1.8		

Sequence confirmation of CANOPY events underway; initial 1H analysis generally reflects U.S. CDC surveillance

DAY 180 SAFETY DATA ARE CONSISTENT WITH PRIOR DISCLOSURES AND INCLUDE NO NEW ADVERSE EVENTS (AEs) OF SPECIAL INTEREST (ANAPHYLAXIS)

COHORT A:

- The most common TEAEs were viral infection (7.8%), URTI (7.5%), influenza like illness (4.2%), infusion related reactions (3.6%), and urinary tract infection (3.6%)
- Anaphylaxis observed in 4 participants (0.6%) – 2 participants during the first infusion and 2 participants during the second infusion – two of which were life-threatening; all led to permanent discontinuation of pemivibart
 - Systemic infusion-related reactions and hypersensitivity reactions were observed within 24 hours of dosing pemivibart in 8.2% and 3.9% of participants after the initial dose and redose, respectively – generally mild to moderate in severity
 - No new anaphylaxis cases have been reported since EUA issued in March 2024

COHORT B:

- The most common TEAEs in the pemivibart arm were URTI (8.2%), viral infection (7.3%), and influenza like illness (5.4%), with similar percentages in the placebo arm
- No participants developed anaphylaxis
 - Systemic infusion-related reactions and hypersensitivity reactions were observed within 24 hours of dosing pemivibart in 1.3% and 2.5% of participants after the initial dose and redose, respectively, and all were mild or moderate in severity

TEAEs - treatment emergent adverse reactions
URTI - upper respiratory tract infection

Source: Invivyd Data on File and CDC

EXPLORATORY CLINICAL EFFICACY ENDPOINTS

Key Exploratory Endpoint as Measured

Incidence of RT-PCR confirmed symptomatic COVID-19, COVID-19 related hospitalizations, and all-cause mortality through 3, 6 and 12 months

Post-hoc COVID-19-Related Analysis

Incidence of RT-PCR confirmed symptomatic COVID-19

COHORT B: EXPLORATORY EFFICACY ENDPOINT

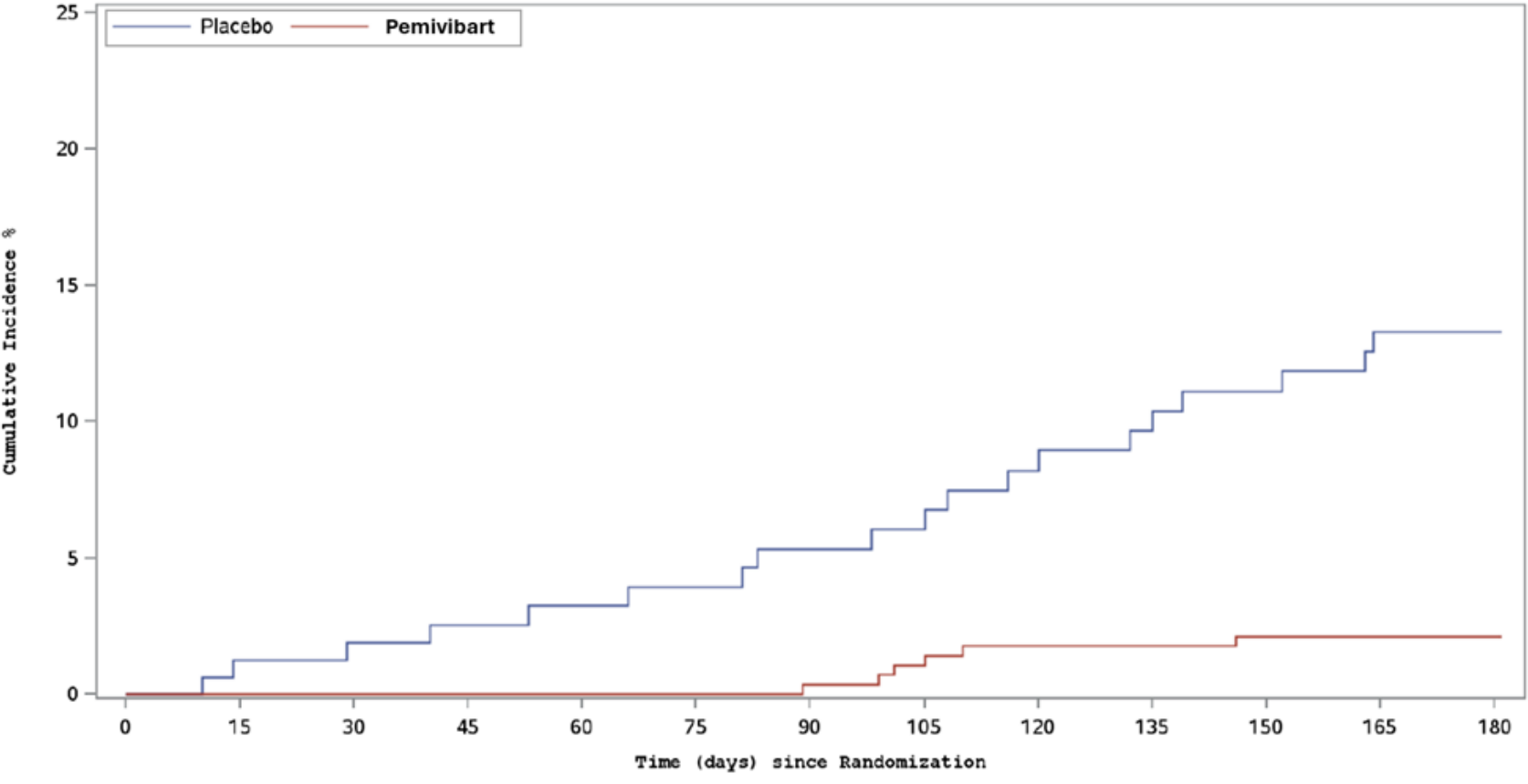
Cohort B: Randomized, placebo-controlled cohort *without* moderate-to-severe immune compromise, at risk of acquiring SARS-CoV-2 due to regular indoor, unmasked face-to-face interactions

Exploratory Efficacy Endpoint: Incidence of RT-PCR confirmed symptomatic COVID-19, COVID-19 related hospitalizations, and all-cause mortality

	Through Day 180	RRR	Nominal p value
PLACEBO	11.9% (19/160)		
PEMIVIBART (VYD222)	1.9% (6/317)	84.1%	0.000061

CLINICAL PROTECTION SHOWN THROUGH THE SUBSTANTIAL JN.1 WAVE IN THE U.S. IN EARLY 2024

Cohort B: Kaplan Meier on Exploratory Clinical Efficacy Endpoint



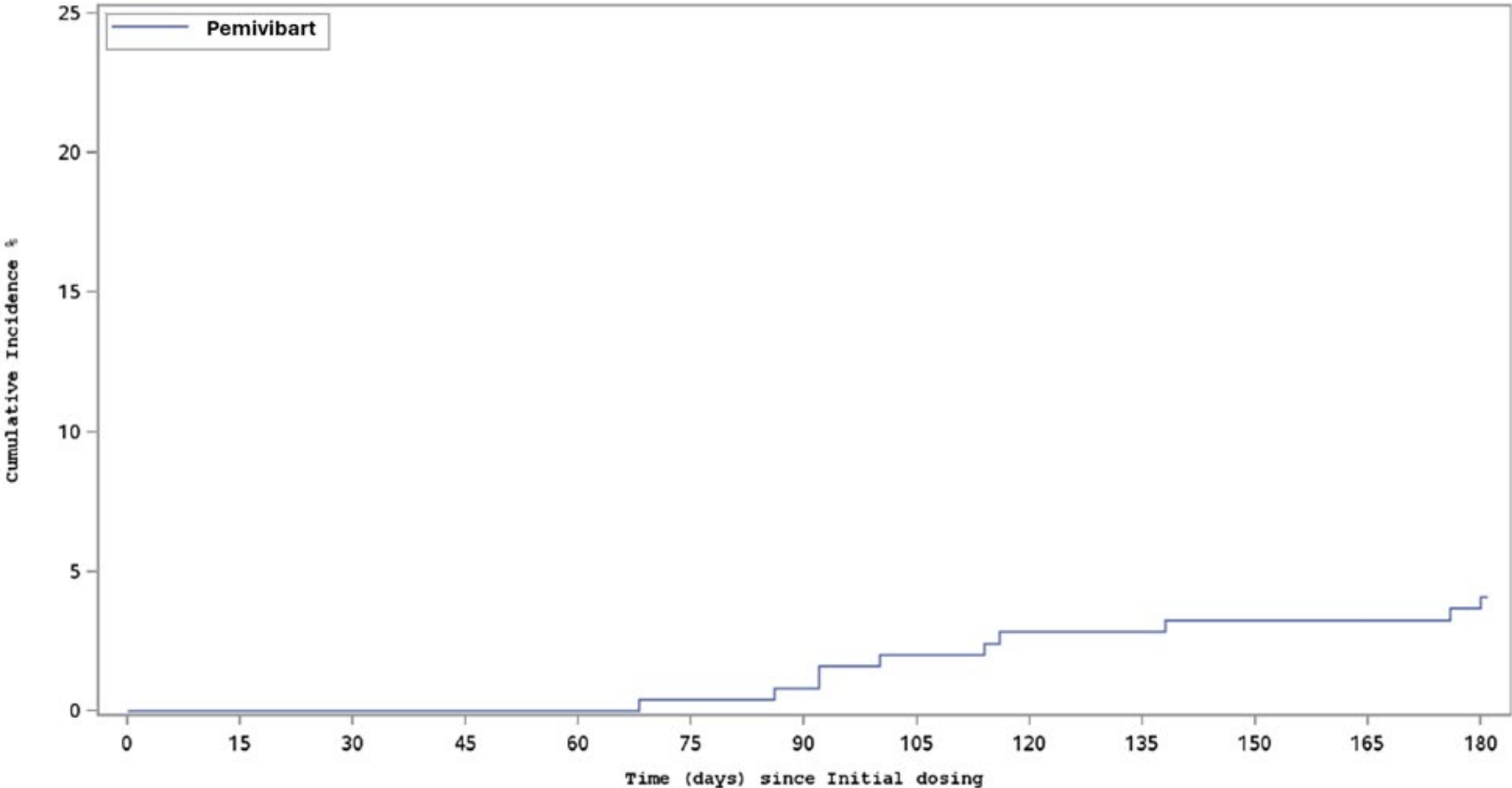
COHORT A: EXPLORATORY EFFICACY ENDPOINT

Cohort A: Single-arm, open-label cohort in adults *with* moderate-to-severe immune compromise

Exploratory Efficacy Endpoint Through Day 180		
Pemivibart (VYD222)	3.0% (9/298)	Rate of symptomatic, RT-PCR confirmed COVID-19 disease
	3.7% (11/298)	Rate of symptomatic, RT-PCR confirmed COVID-19 disease, COVID-19 related hospitalizations (0 in dataset), and all-cause mortality (2 in dataset: 1 suicide, 1 of unknown causes)

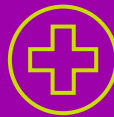

CLINICAL PROTECTION SHOWN THROUGH THE SUBSTANTIAL JN.1 WAVE IN THE U.S. IN EARLY 2024

Cohort A: Kaplan Meier on Exploratory Clinical Efficacy Endpoint



COVID-19 IS THE MOST DAMAGING AND DEADLY OF PREVALENT RESPIRATORY VIRUSES

COVID-19 is the leading cause of hospitalizations and death from respiratory viruses in the U.S. (2023-2024 data)*

	 Hospitalizations ^{1*}	 Deaths*
COVID-19	460,000	45,200²
INFLUENZA	272,000	9,900 ³
RSV	179,000	~6,000-10,000 ^{4†}

COVID-19=coronavirus disease 2019; RSV=respiratory syncytial virus.
 *From Oct 1, 2023, through June 15, 2024; hospitalizations for all 3 viruses calculated based on 334.9 million US Census Bureau estimate of US population size and CDC reported rates of hospitalizations. RSV death data are an estimate from the CDC prior to the COVID-19 pandemic.
 †Estimate in adults aged ≥65 years prior to the COVID-19 pandemic. Mortality data for the 2023-2024 season are not currently available.
References: **1.** CDC. RESP-NET. Accessed July 8, 2024. <https://www.cdc.gov/resp-net/dashboard/?CDC> **2.** CDC. COVID Data Tracker. Accessed July 8, 2024. https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00 **3.** CDC. FluView. Accessed July 8, 2024. <https://gis.cdc.gov/grasp/fluview/mortality.html> **4.** CDC. Readout of Advisory Committee on Immunization Practices Meeting Held June 26 - 28, 2024. Accessed July 8, 2024. <https://www.cdc.gov/media/releases/2024/s-0627-immunization-practices-meeting.html>

AGENDA

CANOPY Results

▶ Q&A