UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): August 27, 2024

Invivyd, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-40703**	**85-1403134**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1601 Trapelo Road, Suite 178 **Waltham, MA**	**02451**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 819-0080

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.0001 per share	IVVD	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

On August 27, 2024, Invivyd, Inc. (the "Company") issued a press release entitled "Invivyd Announces PEMGARDA(TM) (pemivibart) Demonstrated 84% Relative Risk Reduction in Symptomatic COVID-19 Compared to Placebo in an Exploratory Analysis from Ongoing CANOPY Phase 3 Clinical Trial." A copy of the press release is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

On August 27, 2024, the Company posted an updated corporate presentation on its website at www.invivyd.com. A copy of the presentation is filed herewith as Exhibit 99.2 and is incorporated by reference in this Item 8.01.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 27, 2024
99.2	Corporate Presentation, dated August 27, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INVIVYD, INC.

Date: August 27, 2024

By: /s/ Jill Andersen
Jill Andersen
Chief Legal Officer and Corporate Secretary

INVIVYD

Invivyd Announces PEMGARDA™ (pemivibart) Demonstrated 84% Relative Risk Reduction in Symptomatic COVID-19 Compared to Placebo in an Exploratory Analysis from Ongoing CANOPY Phase 3 Clinical Trial

- *In all-comer cohort of immunocompetent individuals at risk of contracting symptomatic COVID-19 in their everyday social interactions, participants receiving pemivibart experienced a 1.9% rate of confirmed symptomatic COVID-19 compared to an 11.9% rate for participants receiving placebo, an 84% relative risk reduction (nominal p= 0.000061)*
- *In immunocompromised participants, pemivibart demonstrated a rate of 3% of confirmed symptomatic COVID-19, an encouraging potential signal of protection during the assessed time period*
- *CANOPY data from planned exploratory clinical efficacy analyses during the 180-day period that included XBB* and JN.1* virus lineages*
- *Safety profile of pemivibart consistent with previously reported CANOPY clinical trial data*
- *PEMGARDA (pemivibart) Fact Sheet for Healthcare Providers updated by U.S. Food and Drug Administration (FDA) including exploratory clinical efficacy data*
- *Conference call today at 8:30AM EDT to discuss CANOPY data analyses*

WALTHAM, Mass., August 27, 2024 – Invivyd, Inc. (Nasdaq: IVVD), a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, today announced positive 180-day exploratory clinical efficacy data from the company's ongoing CANOPY Phase 3 clinical trial of pemivibart, a half-life extended investigational monoclonal antibody (mAb), for the pre-exposure prophylaxis (PrEP) of COVID-19.

The exploratory clinical efficacy data in Cohort B, a placebo-controlled cohort of all-comer immunocompetent individuals, showed a relative risk reduction of 84% with pemivibart compared to placebo in the likelihood of trial participants contracting confirmed symptomatic COVID-19, with no hospitalizations or deaths due to COVID-19 reported. Cohort B participants treated with pemivibart experienced a 1.9% rate of symptomatic COVID-19 across a 180-day time period, whereas Cohort B participants in the placebo arm experienced an 11.9% rate of symptomatic COVID-19, a robust attack rate for the trial. Cases of COVID-19 observed in the pemivibart arm were mild or moderate in severity.

Additionally, in Cohort A, the single-arm immunocompromised cohort of the trial, pemivibart demonstrated a 3% rate of confirmed symptomatic COVID-19 over the 180-day period. Cases of COVID-19 observed in this cohort were also mild or moderate in severity. These exploratory data support the concept of potential protection observed with pemivibart, aligned with expectations of a highly active prophylactic monoclonal antibody in this population.

The safety profile of pemivibart in the second half of the assessed 180-day time period remained consistent with previously disclosed CANOPY clinical trial data. In Cohort A, the most common treatment-emergent adverse events (TEAE) were viral infection (7.8%), upper respiratory tract infection (URTI) (7.5%), influenza like illness (4.2%), infusion related reactions (3.6%), and urinary tract infection (3.6%). Anaphylaxis was observed in 4 participants (0.6%) – 2 participants during the first infusion and 2

participants during the second infusion; two reactions were life-threatening, and 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, of this open-label single-arm cohort and were generally mild to moderate in severity. In 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.

CANOPY clinical trial results provide data from mAb administration in a contemporary population that likely had acquired prior immune exposure from either vaccination or natural infection and overlapped with the height of the September 2023-March 2024 XBB* and JN.1* waves that saw a surge in COVID-19 cases nationwide in the United States. By contrast, ancestral studies of COVID-19 PrEP candidate mAbs were performed in populations naïve to vaccination or prior infection. CANOPY clinical trial participants received two doses of pemivibart (Cohort A and B) or placebo (Cohort B) administered via intravenous (IV) infusion three months apart; safety, serum virus neutralizing antibody (sVNA) titers and clinical endpoints were assessed at pre-specified timepoints over the 180-day period.

The 180-day clinical efficacy exploratory data announced today complements the initial clinical efficacy exploratory data demonstrating potential signals of clinical protection from symptomatic COVID-19 shared previously. The company expects the full data set to be provided in an upcoming scientific publication. The PEMGARDA (pemivibart) Fact Sheet for Healthcare Providers was updated by the U.S. Food and Drug Administration (FDA) including 180-day exploratory clinical efficacy data.

The following table elaborates the principal exploratory clinical efficacy findings based on the full 180-day analyses:

CANOPY Clinical Efficacy Results Over 180 Days

Cohort B	Pemivibart	Placebo	Standardized Relative Risk Reduction (95% CI)	Nominal p-value
Modified Full Analysis Set				
N	317	160		
Composite RT-PCR confirmed COVID-19, COVID-19-related Hospitalization, and All-cause Mortality	6 (1.9%)	19 (11.9%)	84.1% (60.9, 93.5)	0.000061
RT-PCR confirmed COVID-19	6	19		
COVID-19-related Hospitalization	0	0		
COVID-19-related Death	0	0		
All-cause Mortality	0	0		

Based on CANOPY 6-month data cutoff (21May2024). Cohort B Modified Full Analysis Set includes all randomized participants without current SARS-CoV-2 infection at baseline as measured by central lab RT-PCR.

Cohort A	Pemivibart
Full Analysis Set	
N	298
Composite RT-PCR confirmed COVID-19, COVID-19-related Hospitalization, and All-cause Mortality	11 (3.7%)*
RT-PCR confirmed COVID-19	9 (3.0%)
COVID-19-related Hospitalization	0
COVID-19-related Death	0
All-cause Mortality	2 (0.7%)* **One death is due to an unknown cause and one due to suicide*

Based on CANOPY 6-month data cutoff (21May2024). Cohort A Full Analysis Set includes all participants who received a full dose of study drug at the initial dosing.

“We are thrilled with the clinically meaningful protection shown by pemivibart in these exploratory analyses during a 180-day period with various SARS-CoV-2 circulating variants” commented Mark A. Wingertzahn, SVP of Clinical Development and Medical Affairs. “These CANOPY clinical efficacy data provide an important reminder that monoclonal antibodies can provide meaningful protection against COVID-19 when people encounter the virus in indoor settings and unmasked during their everyday lives. Importantly, given the timeframe in which this study was conducted, these CANOPY data suggest that even with a substantial population-level backdrop of immunologic experience with SARS-CoV-2 from either infection or vaccination, additional protection against symptomatic COVID-19 may be available with monoclonal antibodies, including for certain individuals with moderate-to-severe immunocompromise.”

“Invivyd is devoted to delivering protection from serious viral infectious diseases such as SARS-CoV-2. Today’s data align with and fuel our broader goals of innovating new molecules and educating the clinical community on the possibility of strong protection from monoclonal antibodies so that we can scale and democratize access to such medicines,” noted Marc Elia, Chairperson of the Board. “COVID-19 remains an unacceptable medical burden in the U.S. and around the world, and the incremental protection demonstrated by pemivibart in the CANOPY study points the way to the potential for a radically diminished risk of symptomatic disease via antibody prophylaxis. Our mission remains to innovate so that the immunocompromised community and ultimately much broader populations can experience high rates of protection from symptomatic COVID-19.”

“The positive CANOPY clinical efficacy data through 6 months is encouraging and will be helpful to clinicians in making an informed decision about PEMGARDA use in their immunocompromised, at-risk patients, “ said Cameron R. Wolfe, M.B.B.S., M.P.H., Professor of Medicine, Transplant Infectious Disease at Duke University School of Medicine. “The risk of COVID-19 for immunocompromised people remains disproportionate and having a mAb in the toolbox for pre-exposure prophylaxis is extremely beneficial.”

About PEMGARDA

PEMGARDA™ (pemivibart) is a half-life extended investigational monoclonal antibody (mAb). PEMGARDA was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in a global Phase 2/3 clinical trial for the prevention and treatment of COVID-19. PEMGARDA has demonstrated in vitro neutralizing activity against major SARS-CoV-2 variants, including JN.1. PEMGARDA targets the SARS-CoV-2 spike protein receptor binding domain (RBD), thereby inhibiting virus attachment to the human ACE2 receptor on host cells.

PEMGARDA (pemivibart) injection (4500 mg), for intravenous use is an investigational mAb that has not been approved, but has been authorized for emergency use by the U.S. FDA under an EUA for the pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg) who have moderate-to-severe immune compromise due to certain medical conditions or receipt of certain immunosuppressive medications or treatments and are unlikely to mount an adequate immune response to COVID-19 vaccination. Recipients should not be currently infected with or have had a known recent exposure to an individual infected with SARS-CoV-2.

PEMGARDA is not authorized for use for treatment of COVID-19 or post-exposure prophylaxis of COVID-19. Anaphylaxis has been observed with PEMGARDA and the PEMGARDA Fact Sheet for Healthcare Providers includes a boxed warning for anaphylaxis. The most common adverse events (all grades, incidence ≥2%) observed in participants who have moderate-to-severe immune compromise treated with PEMGARDA included systemic and local infusion-related or hypersensitivity reactions, upper respiratory tract infection, viral infection, influenza-like illness, fatigue, headache, and nausea. For additional information, please see the PEMGARDA full product Fact Sheet for Healthcare Providers, including important safety information and boxed warning.

To support the EUA for PEMGARDA, an immunobridging approach was used to determine if PEMGARDA may be effective for pre-exposure prophylaxis of COVID-19. Immunobridging is based on the serum virus neutralizing titer-efficacy relationships identified with other neutralizing human mAbs against SARS-CoV-2. This includes adintrevimab, the parent mAb of pemivibart, and other mAbs that were previously authorized for EUA. There are limitations of the data supporting the benefits of PEMGARDA. Evidence of clinical efficacy for other neutralizing human mAbs against SARS-CoV-2 was based on different populations and SARS-CoV-2 variants that are no longer circulating. Further, the variability associated with cell-based EC50 value determinations, along with limitations related to pharmacokinetic data and efficacy estimates for the mAbs in prior clinical trials, impact the ability to precisely estimate protective titer ranges. Additionally, certain SARS-CoV-2 viral variants may have substantially reduced susceptibility to PEMGARDA, and PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants.

The emergency use of PEMGARDA is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biological products during the COVID-19 pandemic under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization revoked sooner. PEMGARDA is authorized for use only when the combined national frequency of variants with substantially reduced susceptibility to PEMGARDA is less than or equal to 90%, based on available information including variant susceptibility to PEMGARDA and national variant frequencies.

About CANOPY

The ongoing CANOPY Phase 3 clinical trial is designed to evaluate the safety and tolerability of pemivibart and to assess immunobridging from pemivibart to certain historical data from the company's previous Phase 2/3 clinical trial of adintrevimab (ADG20) for the prevention of symptomatic COVID-19 (EVADE). Additionally, there are pre-specified exploratory endpoints through three, six and twelve months to evaluate clinical efficacy of pemivibart compared to placebo in the prevention of RT-PCR-confirmed symptomatic COVID-19. The latest analysis from the Phase 3 CANOPY clinical trial includes 180-day data. The CANOPY clinical trial enrolled participants in two cohorts: Cohort A is a single-arm, open-label trial in adults who have moderate-to-severe immune compromise including complex underlying medical conditions. Cohort B is a randomized, placebo-controlled cohort that enrolled adults without moderate-to-severe immune compromise who are at risk of acquiring COVID-19 due to regular unmasked face-to-face interactions in indoor settings.

About Pemivibart (VYD222)

Pemivibart is a half-life extended monoclonal antibody (mAb) candidate being investigated for the pre-exposure prophylaxis (prevention) of COVID-19 and the treatment of mild to moderate symptomatic COVID-19 in certain immunocompromised adults and adolescents. Pemivibart has demonstrated in vitro neutralizing activity in pseudotyped virus-like particle and authentic virus neutralization assays against various pre-Omicron and Omicron variants. Pemivibart was engineered from adintrevimab, Invivyd's investigational mAb that has a robust safety data package and provided evidence of clinical efficacy in global Phase 2/3 clinical trials for both the prevention and treatment of COVID-19. Pemivibart has not been approved by the U.S. FDA or any other regulatory authority.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. The company's proprietary INVYMAB™ platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody engineering. INVYMAB is designed to facilitate the rapid, serial generation of new monoclonal antibodies (mAbs) to address evolving viral threats. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for its first mAb in a planned series of innovative antibody candidates. Visit https://invivyd.com/ to learn more.

Cautionary Note Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "believes," "could," "expects," "estimates," "intends," "potential," "projects," and "future" or similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements include statements concerning, among other things, the company's ongoing research and clinical development activities, as well as future potential research and clinical development efforts; the potential of pemivibart for clinical protection from symptomatic COVID-19 based on the 180-day exploratory clinical efficacy data from the CANOPY clinical trial; the potential for mAbs to provide meaningful protection against COVID-19; the company's goal to scale and democratize access to mAbs; the potential for mAbs to provide additional protection against COVID-19; the company's goals of innovating new molecules and educating the clinical community on the

possibility of strong protection from mAbs; the company's devotion to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2; the design of the company's INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; the company's plans for a series of innovative antibody candidates; the company's expectation to provide full CANOPY clinical trial data in an upcoming scientific publication; the potential of PEMGARDA as a mAb for pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents who have moderate-to-severe immune compromise; the ongoing *in vitro* neutralizing activity of PEMGARDA against major SARS-CoV-2 variants; and other statements that are not historical fact. The company may not actually achieve the plans, intentions or expectations disclosed in the company's forward-looking statements and you should not place undue reliance on the company's forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause the company's actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: the timing and progress of the company's discovery, preclinical and clinical development activities; the risk that results of nonclinical studies or clinical trials may not be predictive of future results, and interim data are subject to further analysis; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of the company's product candidates based on neutralizing activity in nonclinical studies; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; the company's reliance on third parties with respect to virus assay creation and product candidate testing and with respect to its clinical trials; variability of results in models used to predict activity against SARS-CoV-2 variants; whether pemivibart or any other product candidate is able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants, particularly in the face of viral evolution; how long the EUA granted by the FDA for PEMGARDA will remain in effect and whether the EUA is revoked or revised by the FDA; the company's ability to build and maintain sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of the company's product candidates; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; changes in the regulatory environment; changes in expected or existing competition; the complexities of manufacturing mAb therapies; the company's ability to leverage its INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; any legal proceedings or investigations relating to the company; the company's ability to continue as a going concern; and whether the company has adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause the company's actual results to differ materially from those expressed or implied in the forward-looking statements in this press release are described under the heading "Risk Factors" in the company's Annual Report on Form 10-K for the year ended December 31, 2023 and the company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, each filed with the Securities and Exchange Commission (SEC), and in the company's other filings with the SEC, and in its future reports to be filed with the SEC and available at www.sec.gov. Forward-looking statements contained in this press release are made as of this date, and Invivyd undertakes no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

This press release contains hyperlinks to information that is not deemed to be incorporated by reference in this press release.

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Exhibit 99.2

INVIVYD CANOPY DATA UPDATE

August 27, 2024

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this presentation that are not statements of historical fact are forward-looking statements. Words such as "may," "will," "should," "expect," "plan," "anticipate," "seek," "could," "intend," "target," "aim," "project," "designed to," "estimate," "believe," "predict," "potential" or "continue" or the negative of these terms or other similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. Forward-looking statements include statements concerning, among other things, the potential of pemivibart for clinical protection from symptomatic COVID-19 based on the 180-day clinical event exploratory efficacy analysis from the CANOPY clinical trial; our plans to work with the FDA to integrate clinical event findings from the CANOPY clinical trial into future mAb development work; our expectations regarding the safety profile of pemivibart; our expectations regarding the evolution of the PEMGARDA fact sheet; our belief that mAbs may be critical for managing endemic virus over the long term; our business strategies and objectives, and ability to execute on them; our future prospects; and other statements that are not historical fact. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: the timing, progress and results of our discovery, preclinical and clinical development activities; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; the predictability of clinical success of our product candidates based on neutralizing activity in nonclinical studies; the risk that results of nonclinical studies or clinical trials may not be predictive of future results, and interim data are subject to further analysis; our reliance on third parties with respect to virus assay creation and product candidate testing and with respect to our clinical trials; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; variability of results in models used to predict activity against SARS-CoV-2 variants; whether pemivibart or any other product candidate is able to demonstrate and sustain neutralizing activity against major SARS-CoV-2 variants, particularly in the face of viral evolution; the complexities of manufacturing mAb therapies; our ability to leverage our INVYMAB platform approach to facilitate the rapid, serial generation of new mAbs to address evolving viral threats; our dependence on third parties to manufacture, label, package, store and distribute clinical and commercial supplies of our product candidates; whether we can obtain and maintain third-party coverage and adequate reimbursement for pemivibart or any other product candidate; whether we are able to achieve improved clinical and commercial profiles with our product pipeline; any legal proceedings or investigations relating to the company; our ability to continue as a going concern; and whether we have adequate funding to meet future operating expenses and capital expenditure requirements. Other factors that may cause our actual results to differ materially from those expressed or implied in the forward-looking statements in this presentation are described under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, each filed with the Securities and Exchange Commission (SEC), and in our other filings with the SEC, and in our future reports to be filed with the SEC and available at www.sec.gov. Forward-looking statements contained in this presentation are made as of this date, and we undertake no duty to update such information whether as a result of new information, future events or otherwise, except as required under applicable law.

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 placebo[1]
- PEMGARDA(TM) (pemivibart) Fact Sheet for Healthcare Providers updated to include exploratory clinical efficacy data[2]
- 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

[1]180-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

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

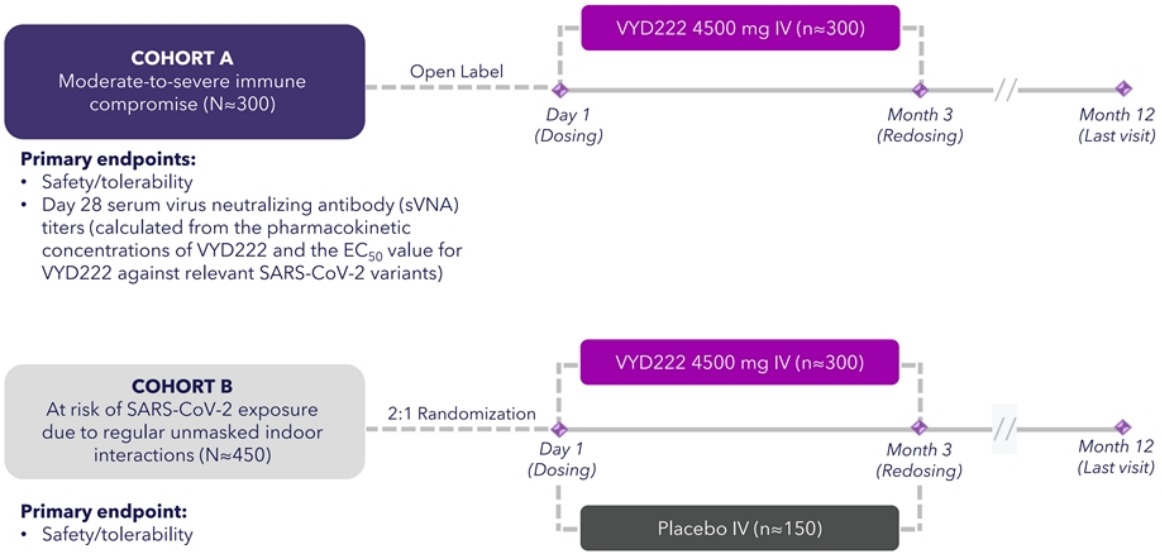
Source: Clinicaltrials.gov
PrEP = Pre-Exposure Prophylaxis

AGENDA

- **CANOPY Clinical Trial Results**
- **Q&A**

CANOPY: PHASE 3 CLINICAL TRIAL OF PEMIVIBART (VYD222)

CANOPY STUDY OVERVIEW



Primary endpoints:
- Safety/tolerability
- Day 28 serum virus neutralizing antibody (sVNA) titers (calculated from the pharmacokinetic concentrations of VYD222 and the EC_{50} value for VYD222 against relevant SARS-CoV-2 variants)

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)

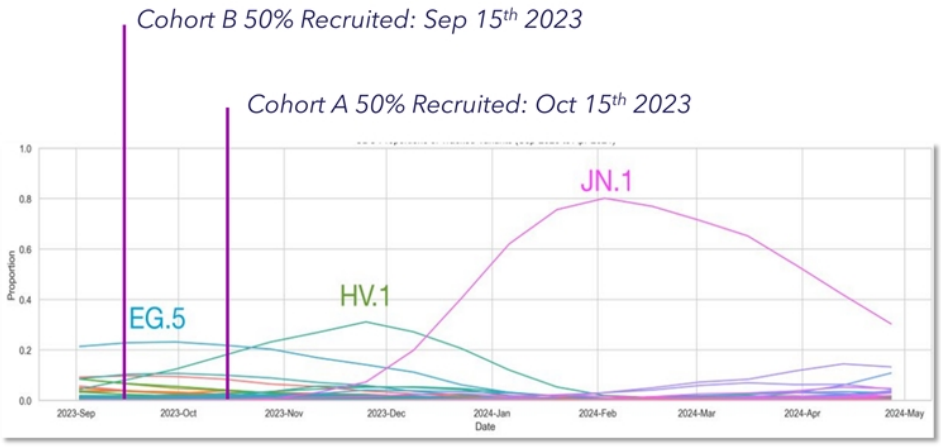
Source: Invivyd Data on File

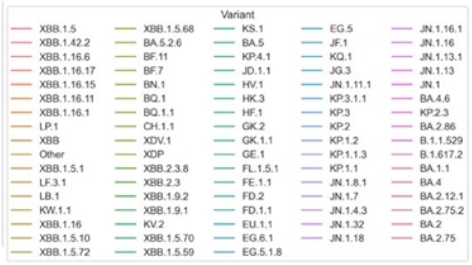
MEDICAL HISTORY

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	129 (42.2)	68 (21.1)	41 (25.3)
Sickle cell disease	1 (0.3)	0	0
Solid organ transplant recipients	33 (10.8)	0	0
Other immunodeficiency due to underlying illness or immunosuppressant medication	306 (100)	4 (1.2)	1 (0.6)
Down Syndrome	0	0	0
Stroke or cerebrovascular disease	9 (2.9)	0	1 (0.6)
Substance use disorder	6 (2.0)	4 (1.2)	3 (1.9)
Pregnancy	0	0	0

Table 14.1.2.2a/b Source: Invivyd Data on File

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





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

Source: Invivyd Data on File and CDC

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

Source: Invivyd Data on File

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

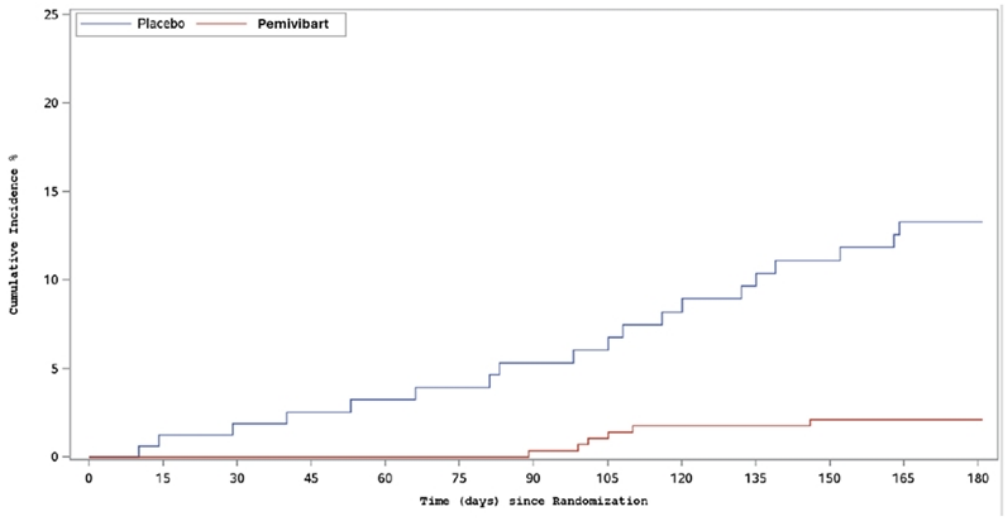
Exploratory Efficacy Endpoint: Incidence of RT-PCR confirmed symptomatic COVID-19, COVID-19 related hospitalizations, and all-cause mortality

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

Source: ClinicalTrials.gov Identifier: NCT06039449; IV = intravenous; SAEs = serious adverse events; AEs = adverse events; RRR = relative risk reduction

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



Source: Invivyd Data on File

COHORT A: EXPLORATORY EFFICACY ENDPOINT

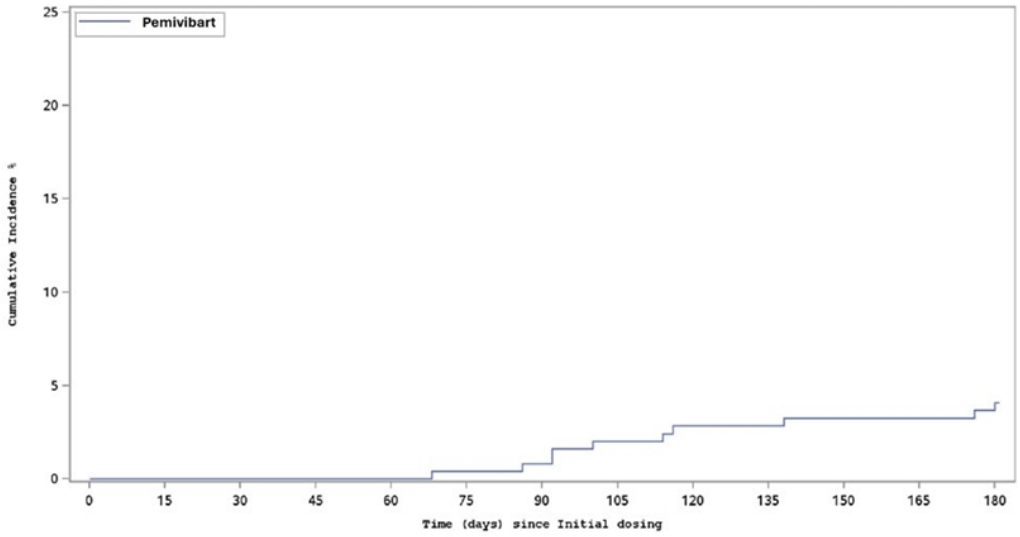
Cohort A: Single-arm, open-label cohort in adults *with* moderate-to-severe immune compromise

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)

Source: Invivyd Data on File

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



Source: Invivyd Data on File

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**	**45,200[2]**
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