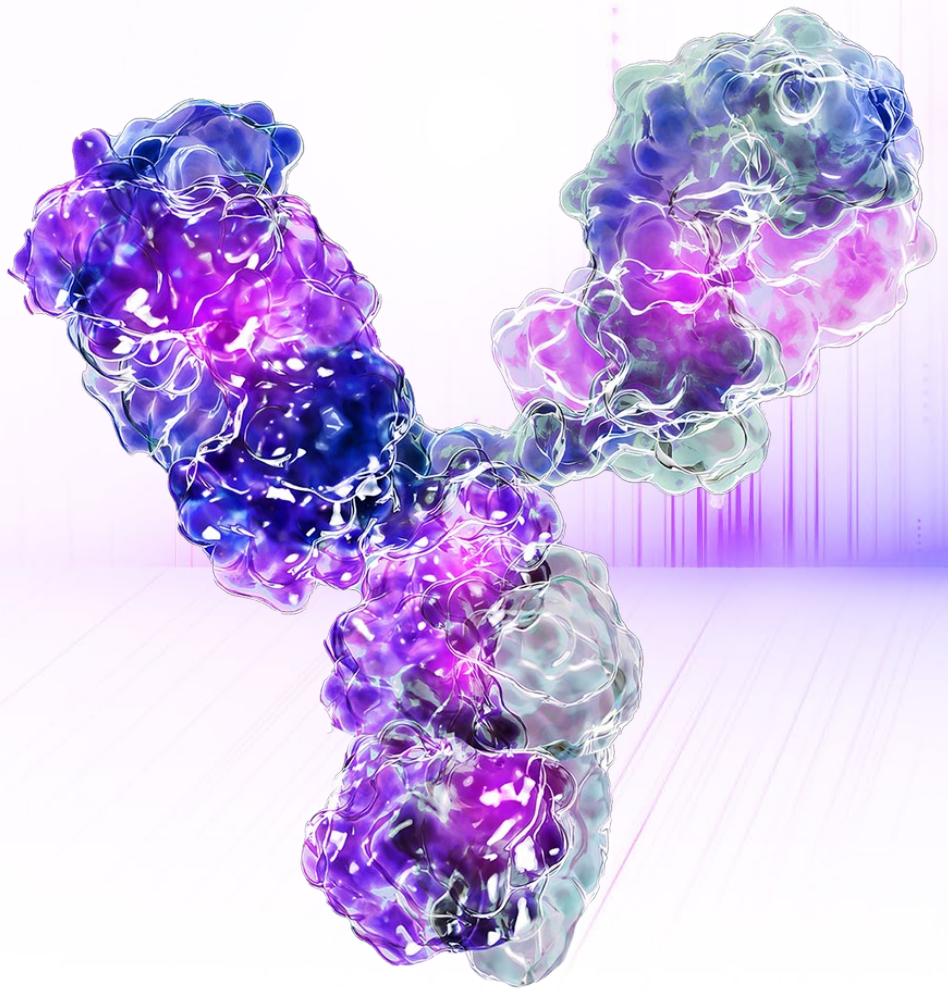


PEMGARDA™ FDA EMERGENCY USE AUTHORIZATION

March 22, 2024

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

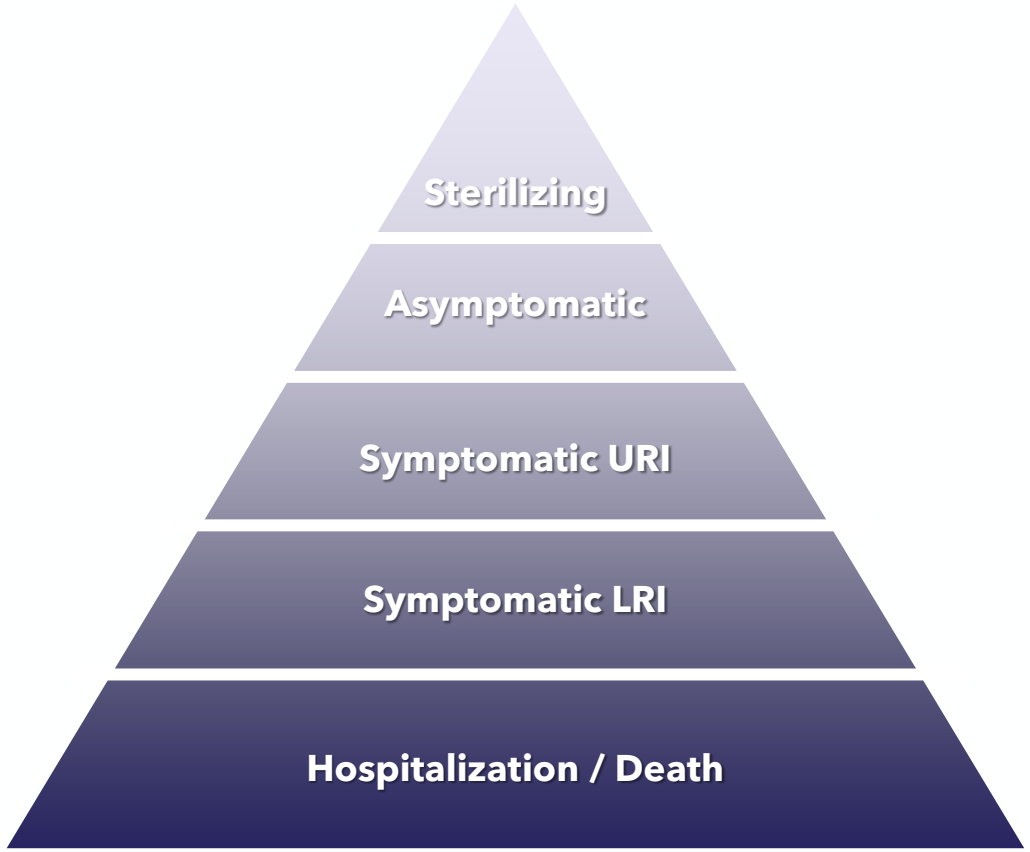
This presentation contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Statements in this presentation that are not statements of historical fact are forward-looking statements. Words such as "may," "will," "should," "expect," "plan," "anticipate," "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 PEMGARDA™ as a monoclonal antibody (mAb) for pre-exposure prophylaxis (prevention) of COVID-19 in adults and adolescents with moderate-to-severe immune compromise; our plans related to the launch and commercialization of PEMGARDA, including our expectations regarding availability and supply of PEMGARDA, our sales and marketing strategy, and our ability to secure third-party coverage and reimbursement for PEMGARDA, and the timing thereof; our plans to share launch metrics in coming quarters; our expectations about the size of target patient populations and the potential market opportunity for our product candidates, as well as our market position; the future of the COVID-19 landscape; the progress and timing of our ongoing research and clinical development activities and future plans; the potential repeatability of an immunobridging trial design for mAb candidates, and the potential for immunobridging to allow for serial, rapid development; the potential of our INVYMAB™ platform approach to enable the rapid, serial generation new mAbs, and our expectation that current Invivyd pipeline products are expected to improve on PEMGARDA profile; the potential for a scientific and regulatory framework designed to accommodate ongoing innovation that keeps pace with viral evolution; 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: 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; our ability to build and maintain sales, marketing and distribution capabilities to successfully commercialize PEMGARDA; whether we are able to provide sufficient commercial supply of PEMGARDA to meet market demand; whether we can timely obtain and maintain third-party coverage and adequate reimbursement for PEMGARDA or any other product candidate; whether PEMGARDA 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; changes in expected or existing competition; the timing and progress of our discovery, preclinical and clinical development activities; our ability to leverage our INVYMAB platform approach to enable the rapid, serial generation of new mAb candidates and improve future product profiles; the uncertainties and timing of the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval of our product candidates; changes in the regulatory environment; 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 PEMGARDA or any other product candidate following regulatory authorization or approval; whether we are able to successfully submit an EUA for any other product candidate in the future, and the outcome and timing of any such EUA submission; our ability to improve the profile of any future product candidates; the predictability of clinical success of our product candidates based on neutralizing activity in preclinical studies; the risk that results of preclinical 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; variability of results in models used to predict activity against SARS-CoV-2 variants; the complexities of manufacturing mAb therapies; our dependence on third parties to manufacture, label, package, store and distribute clinical and commercial supplies of our product candidates; any litigation and other proceedings or government 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 most recent Annual Report on Form 10-K for the year ended December 31, 2022 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.

AGENDA

1. **Opening remarks & business updates**
   - **Dave Hering**, Chief Executive Officer
2. **Commercial launch plans**
   - **Jeremy Gowler**, Chief Operating & Commercial Officer
3. **Q&A**

IMMUNITY IS A GRADIENT

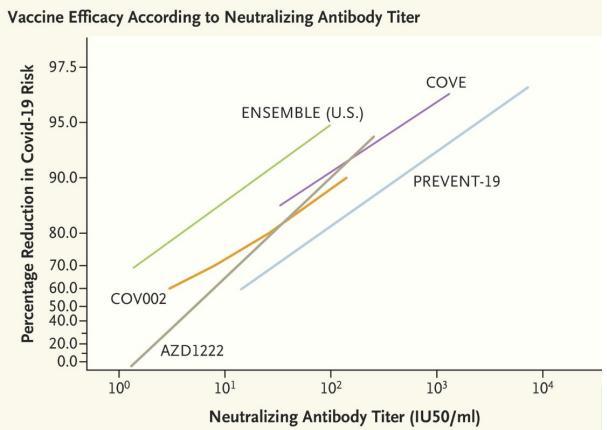
Immunity, titers, and correlates of efficacy



URI=Upper Respiratory Infection, LRI=Lower Respiratory Infection

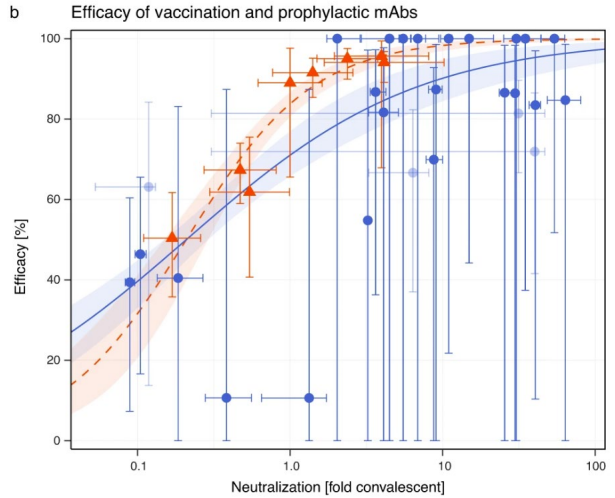
"A Covid-19 Milestone Attained – A Correlate of Protection for Vaccines"

The NEW ENGLAND JOURNAL of MEDICINE



"Monoclonal antibody levels and protection from COVID-19"

nature communications



References: Plotkin Clin Vaccine Immunol 2010; Gilbert N Engl J Med 2022; Stadler Nat Commun 2023;
Left-hand figure adapted from: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-09-22/03-COVID-Thornburg-508.pdf

IMMUNOBRIDGING ALLOWS FOR SERIAL, RAPID DEVELOPMENT

Jul 2022: Invivyd sets the goal of utilizing an immunobridging approach to accelerate development of its novel monoclonal antibody (mAb) candidates

Dec 2022: Presented rationale on immunobridging approach at joint FDA-EMA workshop

Mar 2023: VYD222 announced as the next candidate for clinical development

End of Mar 2023: First participants dosed in VYD222 Phase 1 clinical trial

Jun 2023: Announced general alignment with FDA on an immunobridging approach to a pivotal, EUA-directed clinical trial

Sept 2023: First participant dosed in VYD222 Phase 3 clinical trial (CANOPY)

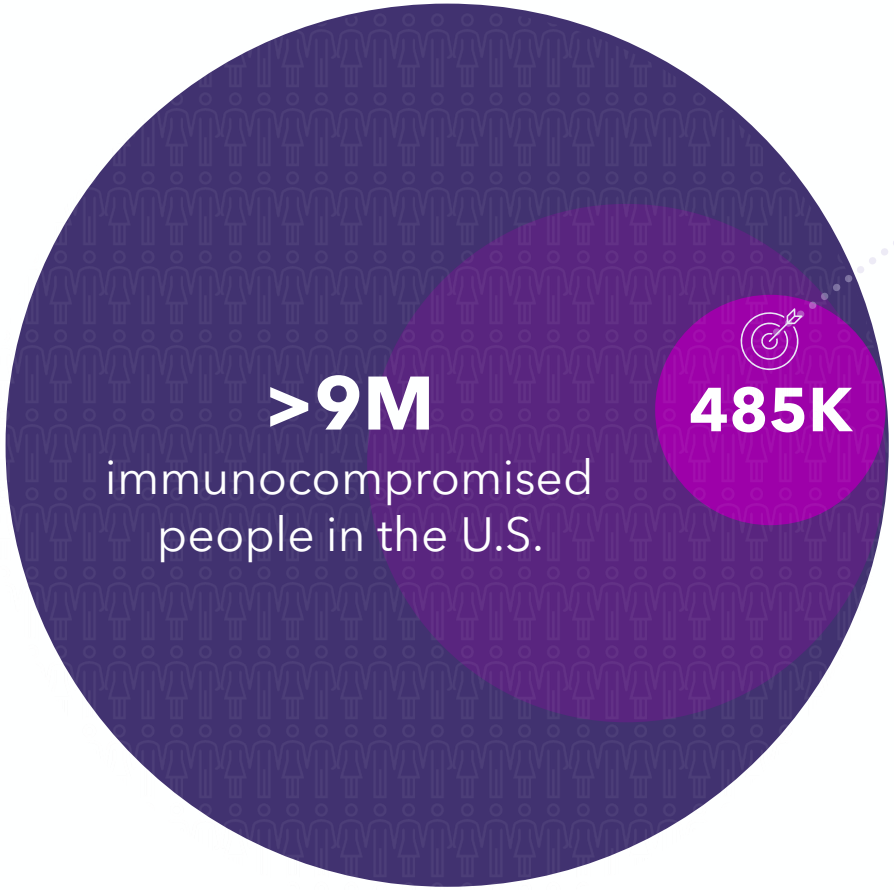
Dec 2023: Reported positive initial Phase 3 results

Mar 2024: PEMGARDA (formerly VYD222) is the first pre-exposure prophylaxis (PrEP) mAb to receive EUA from the U.S. FDA based on a novel, rapid, repeatable immunobridging trial design

NOW AUTHORIZED FOR EMERGENCY USE IN THE U.S.

The FDA Letter of Authorization and Fact Sheet for Healthcare Providers is available at PEMGARDA.com

INITIAL COMMERCIAL FOCUS ON HIGHEST RISK MODERATELY TO SEVERELY IMMUNOCOMPROMISED GROUPS



Lower → **Higher**

Risk of severe COVID-19 based on HCP surveys

Initial commercial focus:

- **~485K who are moderately to severely immunocompromised and at highest risk for severe COVID-19:**
  - 67K: stem cell transplants
  - 86K: solid organ transplants (liver/lung/kidney)
  - 332K: hematologic cancers
- Care for these populations is often associated with specialized centers
- These groups are often receiving other IV infusions as part of their care

Reference: Estimates based on Invivyd-sponsored market research and internal analysis.

ANTIBODY PROPHYLAXIS WAS GROWING PRIOR TO LOSS OF EVUSHELD ACTIVITY

EVUSHELD

----------EUA FOR EVUSHELD----------

The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

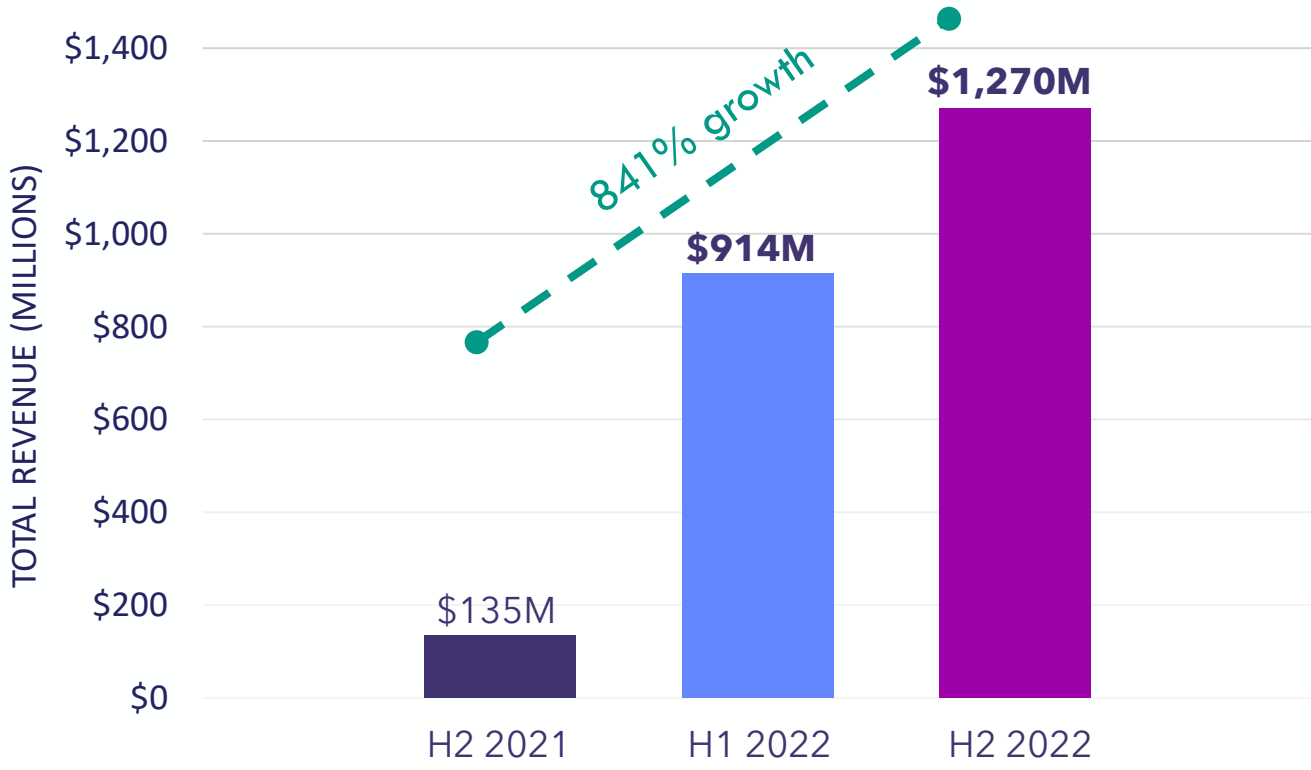
PEMGARDA

----------EUA FOR PEMGARDA----------

The U.S. FDA has issued an EUA for the emergency use of the unapproved product PEMGARDA (pemivibart), a SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents (12 years of age and older weighing at least 40 kg):

- who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**:
- who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** are unlikely to mount an adequate immune response to COVID-19 vaccination.

$2.2B in global revenue of Evusheld® in 2022, a mAb previously authorized to protect vulnerable populations from COVID-19

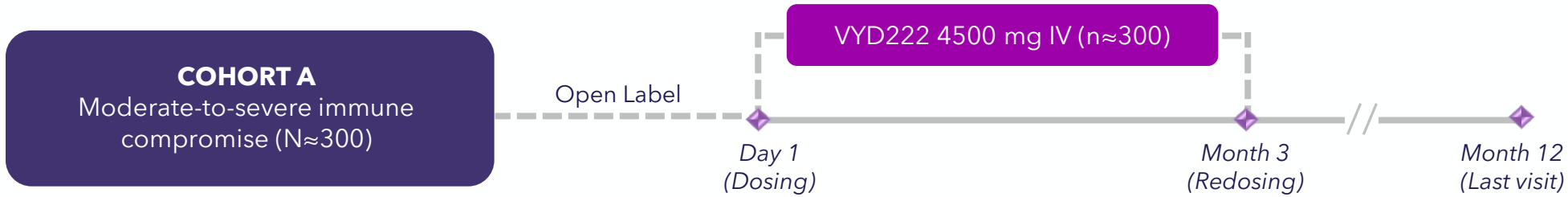


Source: Results publicly reported by AstraZeneca; EVUSHELD Fact Sheet for Healthcare Providers (01/2023) ; EVUSHELD™ is a registered trademark of AstraZeneca UK Limited. EVUSHELD™ is not currently authorized for emergency use in the U.S.

CANOPY Interim Data Update

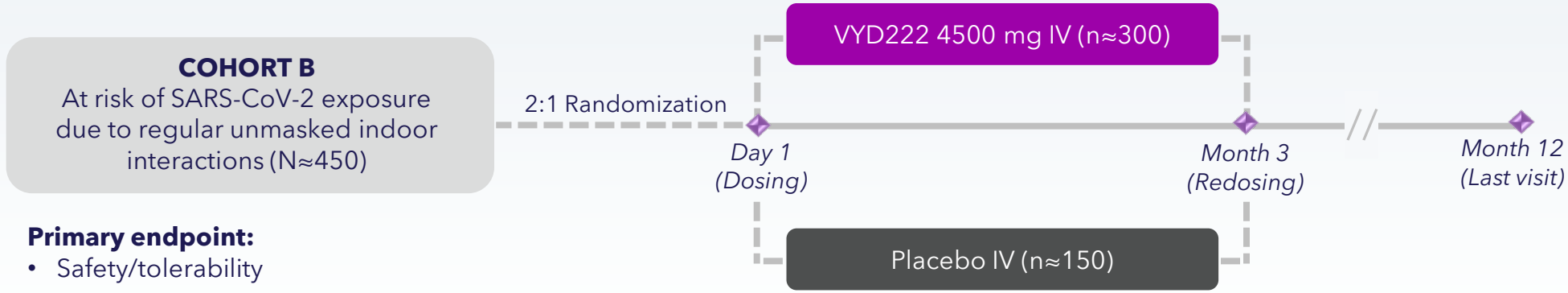
THE PEMGARDA EUA IS BASED ON THE ONGOING CANOPY TRIAL

CANOPY CLINICAL TRIAL 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

Source: F: NCT06039449; IV, intravenous; SAEs, serious adverse events; AEs, adverse events

CANOPY COHORT A, SINGLE ARM AND OPEN LABEL, COMPRISES OLDER MEDICALLY COMPLEX SUBJECTS

Parameter	Cohort A (N=306)	Cohort B (N=479)
Gender	61% female; 39% male	53% female; 47% male
Age	59 years, median (31% aged 65 years or older)	48 years, median (18% aged 65 years or older)
Moderate-to-severe immune compromise	**100%**	**0%**
Taking high-dose corticosteroids/other immunosuppressive medications	65%	0%
Acute leukemia, chronic lymphocytic leukemia, non-Hodgkin, lymphoma, or multiple myeloma (regardless of treatment)	13%	0%
Primary immunodeficiency	12%	0%
Solid organ transplant recipient	11%	0%
Advanced HIV infection	9%	0%
Actively treated for solid tumor or hematologic malignancies	7%	0%
Risk factor for COVID-19 disease progression	**100%**	**65%**
Age >=55 Years	59%	37%
Obesity (Body Mass Index [BMI] > 30 kg/m2)	38%	40%
Diabetes (Type 1 or Type 2)	18%	9%
Chronic kidney disease	10%	1%
Chronic lung disease	18%	3%
Cardiac disease	42%	23%
Stroke or cerebrovascular disease	3%	.2%
Other immunodeficiency due to underlying illness or immunosuppressant medication	99%	1%

Cohort A included significant numbers of participants from the highest risk groups that Invivyd plans to initially focus on at launch

OVERVIEW OF INTERIM CANOPY COHORT A CLINICAL TRIAL SAFETY DATA

- The safety of VYD222 (PEMGARDA) is based on exposure of 623 participants who received at least one dose of VYD222 4500 mg IV in one of two cohorts in the ongoing CANOPY trial.

- Interim safety data presented today include:
  - In Cohort A, 296 participants who received a second dose of VYD222 three months after the initial dose.
  - In Cohort B, 450 participants received a second dose of VYD222 or placebo three months after the initial dose, but cumulative safety with the first two doses of VYD222 is assessed only in Cohort A because unblinded safety data in Cohort B were not available after Day 28.

Anaphylaxis has been observed with VYD222 in 0.6% (4/623) of participants in the CANOPY clinical trial*

Cohort A - First & second VYD222 dose, cumulatively (interim data)
Most common (≥2%) treatment-emergent adverse events

Adverse events	
Systemic infusion-related reactions and hypersensitivity reactions	9%
Upper respiratory tract infection	6%
Infusion site infiltration/extravasation/vein rupture	5%
Viral infection	4%
Influenza-like illness	3%
Fatigue	3%
Headache	2%
Nausea	2%
Local infusion site reactions	2%

* PEMGARDA (pemivibart) Fact Sheet includes a boxed warning for anaphylaxis

HIGHER RATE OF HYPERSENSITIVITY OBSERVED IN OPEN-LABEL UNCONTROLLED COHORT A

Anaphylaxis and Systemic Infusion-related Reactions and Hypersensitivity Reactions

In Cohort A, the reactions were generally mild (17/27) or moderate (8/27); two anaphylaxis reactions were life threatening

PEMGARDA Fact Sheet includes a boxed warning for anaphylaxis

Cohort A (Cohort with moderate-to-severe immune compromise)

Cohort A (n=306)	VYD222 First Dose	VYD222 First & Second Dose, Cumulatively
Systemic infusion-related and hypersensitivity reactions	20 total (20/306 = **7%**) (20 mild or moderate, including 2 anaphylaxis*)	27 total (27/306 = 9%) (17 mild and 8 moderate, including 2 anaphylaxis*; plus 2 life-threatening anaphylaxis)

*These two events were initially classified as mild or moderate hypersensitivity adverse reactions. Subsequently, during the review of the EUA application, the FDA reclassified these hypersensitivity adverse reactions as anaphylaxis adverse reactions.

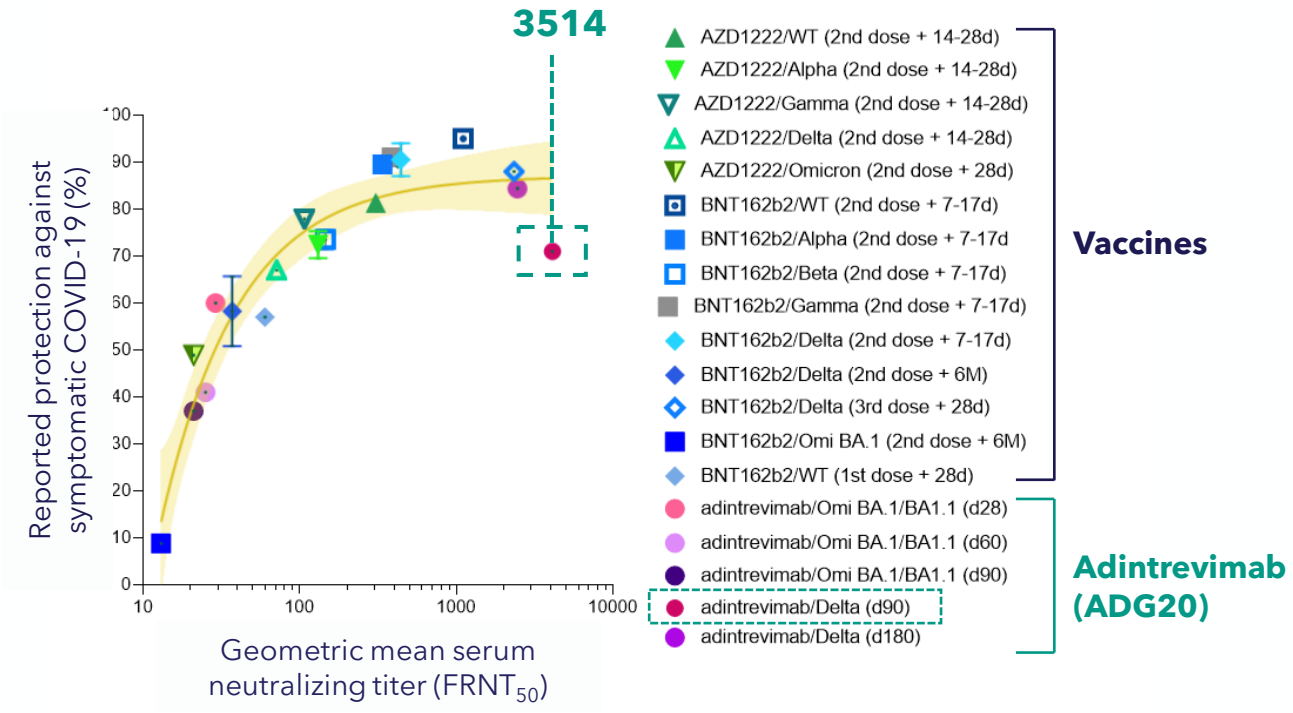
In Cohort B, there were no observations of anaphylaxis in the VYD222 arm as of Day 28 (post first-dose only); unblinded safety data in Cohort B were not available yet after Day 28

Cohort B (Cohort without moderate-to-severe immunocompromise at risk of acquiring SARS-CoV-2 due to regular unmasked face-to-face interactions)

Cohort B (n=479)	VYD222 First Dose (n=317)	Placebo First Dose (n=162)
Systemic infusion-related and hypersensitivity reactions	4 total (4/317 =**1%**) (3 mild and 1 moderate)	0 total

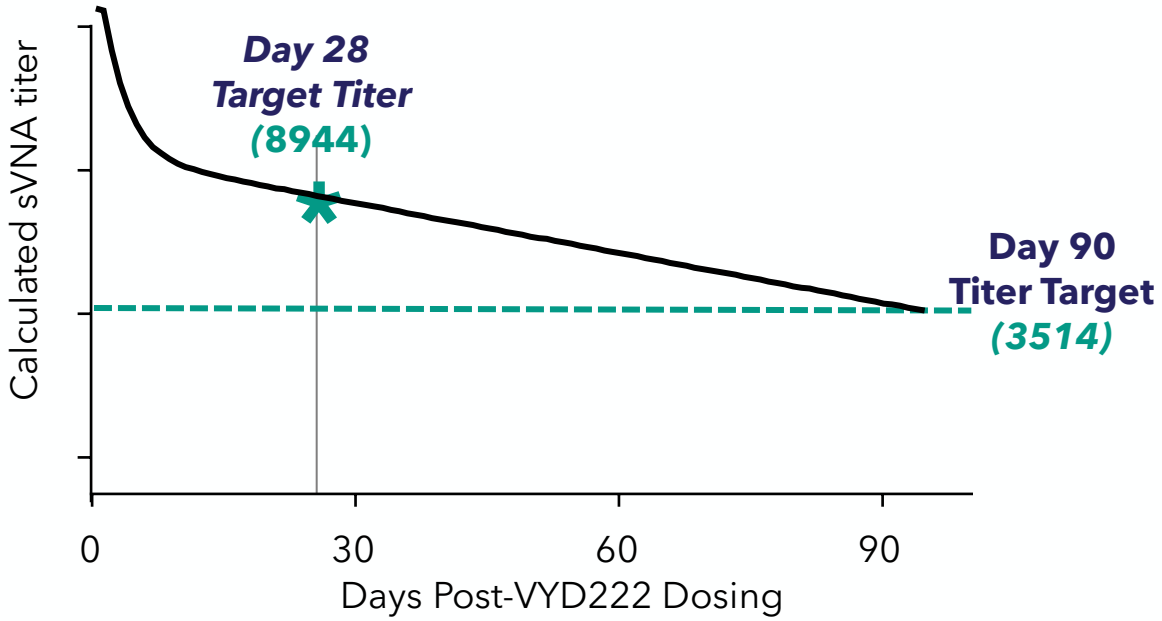
CANOPY COHORT A BRIDGES SVNA TITERS FROM ADINTREVIMAB TO PEMGARDA

From the EVADE clinical trial studying adintrevimab, a titer of 3514 at Day 90 was conservatively selected as the reference titer for the CANOPY clinical trial



The Day 90 reference titer from EVADE was used to extrapolate a Day 28 reference (target) titer for the CANOPY clinical trial of 8944

Illustrative figure



Reference: Schmidt Sci Transl Med 2023; FRNT, focus reduction neutralization test

IMMUNOBRIDGING RESULTS INCLUDE VERY HIGH CALCULATED TITERS ACROSS THE CANOPY CLINICAL TRIAL 90-DAY DOSING INTERVAL

Cohort A – Calculated VYD222 sVNA Titer Results Against JN.1

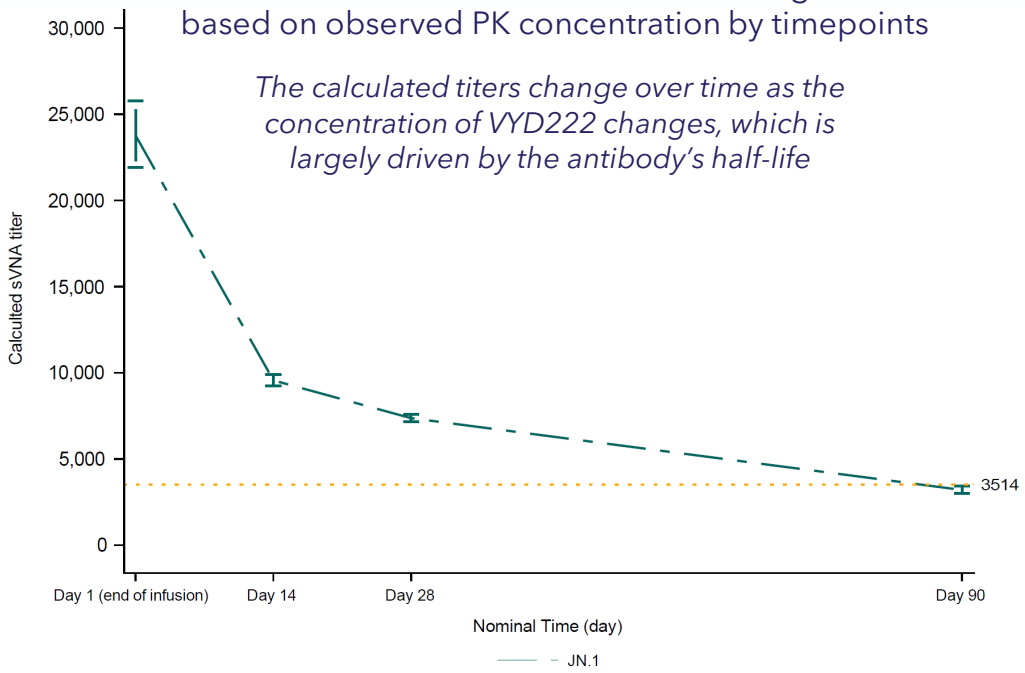
Parameter	Result GMT (90% CI)
Day 28 VYD222 calculated sVNA titer (Concentration of VYD222/authentic virus EC_{50})	7365 (7148, 7589)
Day 28 VYD222 titer/Day 28 reference (target) titer of 8944[a]	0.82 (0.80, 0.85)
Day 90 VYD222 calculated sVNA titer, prior to redosing (Concentration of VYD222/authentic virus EC_{50})	3199 (2995, 3418)
Duration titers are projected to stay above a reference titer of 3514[b]	≈77 days (median)

a. Immunobridging is demonstrated if the lower limit of the 2-sided 90% CI of the GMT ratio at Day 28 to the extrapolated Day 28 titer target (8944) for 3 months of protection is greater than 0.8.

b. Duration is defined as the period of time for which 50% of participants are projected to have sVNA titers sustained above the reference titer threshold (3514) following a single dose of 4500 mg VYD222 based on the VYD222 popPK model.

Cohort A - Calculated VYD222 sVNA titers against JN.1 based on observed PK concentration by timepoints

The calculated titers change over time as the concentration of VYD222 changes, which is largely driven by the antibody's half-life



Furthermore, when compared to published literature, VYD222 titers against JN.1 were consistent with titer levels associated with efficacy of other SARS-CoV-2 mAbs in prior clinical trials[1-2]

1. Schmidt Sci Transl Med 2023; 2. Stadler Nat Commun 2023; Definitions: CI=confidence interval; GMT=geometric mean titer; sVNA=serum virus neutralizing antibody.

PEMGARDA DESIGNED TO RE-START AN IMPORTANT CATEGORY OF MEDICINES THAT ADDRESSES VIRAL EVOLUTION

INVYMAB™ PLATFORM APPROACH

CANOPY clinical trial designed in collaboration with FDA to address critical needs in the COVID-19 prophylaxis category

PEMGARDA is the first product from a repeatable process; our goal will be continuous enhancement of future product candidates (dose, safety observations, ROA, etc.)

Scientific and regulatory framework anticipated to accommodate ongoing innovation that keeps pace with viral evolution

Current Invivyd pipeline products are expected to improve on PEMGARDA profile

Commercial Launch Plans

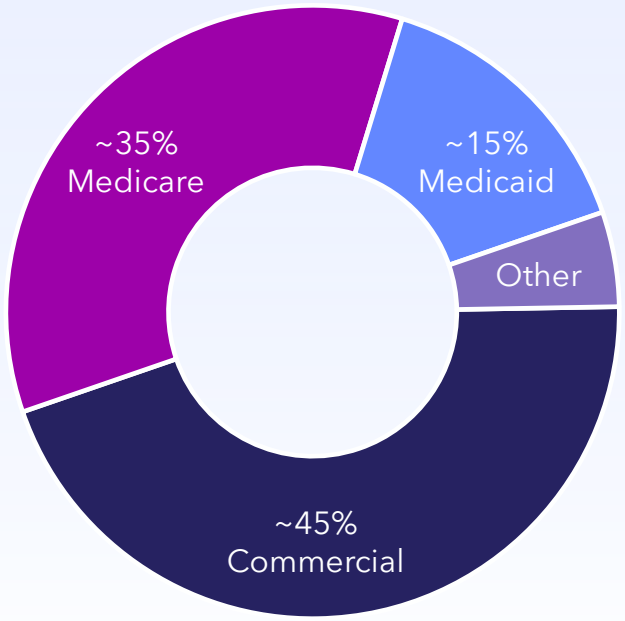
Jeremy Gowler
Chief Operating & Commercial Officer

EXPERIENCED COMMERCIAL TEAM WELL-POSITIONED TO LAUNCH PEMGARDA

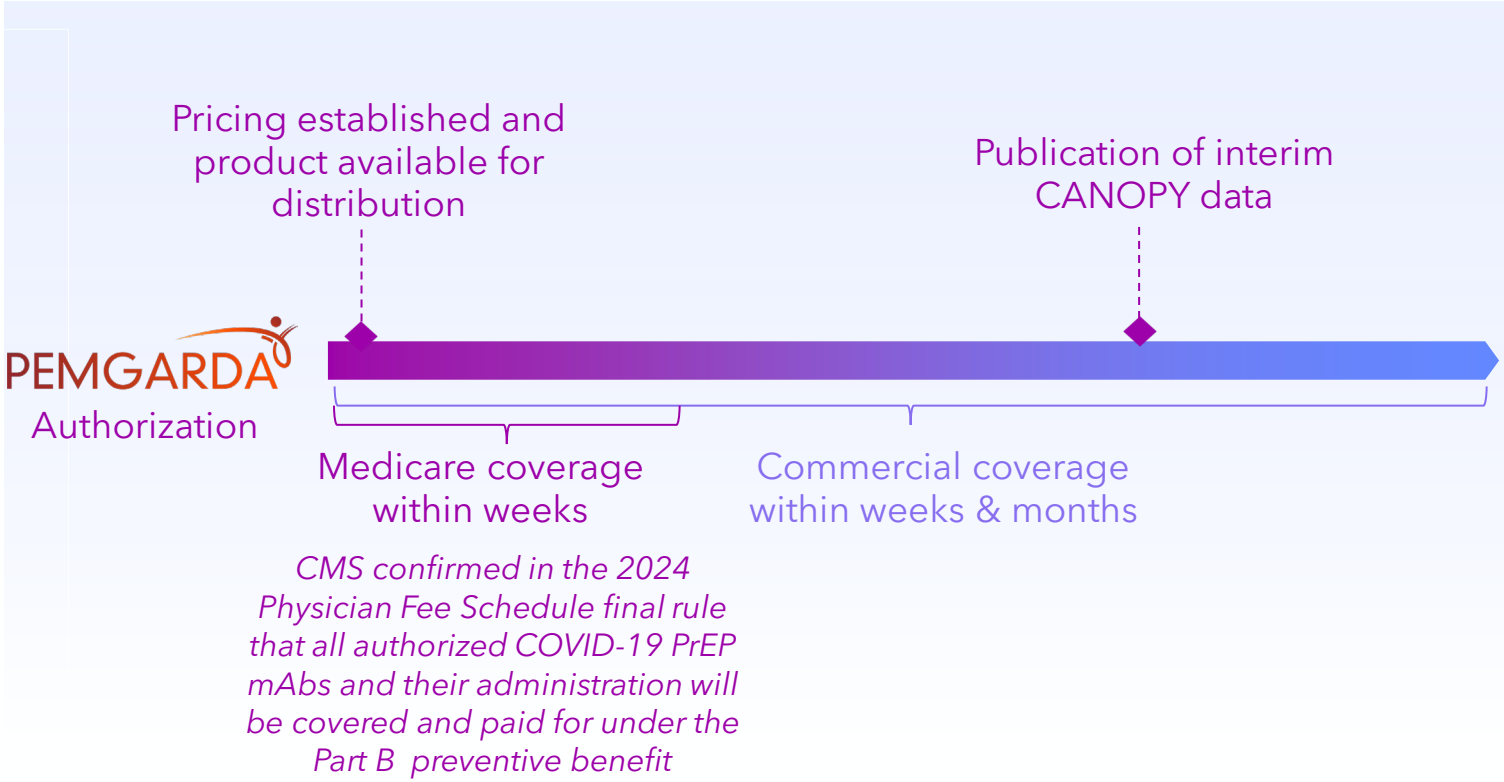
- Poised to offer an important product to an established, yet open market that has been without a PrEP mAb for >1 year
- Initial PEMGARDA inventory manufactured & expected to be ready for purchase through major distributors imminently
- Invivyd sales & marketing leadership team hired, e.g., VP of Sales and Regional Sales Managers
  - 20-25 contracted Key Account Managers (KAMs) are in the process of being engaged & trained
  - KAMs will target the estimated 1,150 U.S. institutions that care for ~70% of the 485K moderately to severely immunocompromised individuals we are initially focused on

ENGAGING WITH KEY PAYORS TO SECURE BROAD COVERAGE

ANTICIPATED PAYOR MIX



ANTICIPATED U.S. TIMELINES



References: 1. Komodo Health claims & internal analysis; 2. Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program, November 16, 2023. https://www.federalregister.gov/documents/2023/11/16/2023-24184/
PrEP, Pre-exposure prophylaxis

WE PLAN TO SHARE A VARIETY OF LAUNCH METRICS IN COMING QUARTERS TO PROVIDE VISIBILITY INTO OUR PROGRESS

PEMGARDA
(pemivibart) injection

Example metrics:

- Patient lives covered via CMS & commercial payors
- Progress reaching/calling on targeted institutions
- Number of target accounts that have ordered product
- Number of targeted accounts placing reorders

INVIVYD

Q&A

IMPORTANT SAFETY INFORMATION

WARNING: ANAPHYLAXIS

- **Anaphylaxis has been observed with PEMGARDA in 0.6% (4/623) of participants in a clinical trial.**
- **Anaphylaxis was reported during the first and second infusion of PEMGARDA.**
- **Anaphylaxis can be life-threatening.**
- **Prior to administering PEMGARDA, consider the potential benefit of COVID-19 prevention along with the risk of anaphylaxis.**
- **Administer PEMGARDA only in settings in which healthcare providers have immediate access to medications to treat anaphylaxis and the ability to activate the emergency medical system (EMS), as necessary.**
- **Clinically monitor individuals during the infusion and for at least two hours after completion of the infusion.**
- **Discontinue PEMGARDA immediately if signs or symptoms of anaphylaxis or any severe systemic reaction are observed and initiate appropriate medications and/or supportive therapy.**

CONTRAINDICATIONS

PEMGARDA is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of PEMGARDA.

WARNINGS AND PRECAUTIONS

Hypersensitivity Including Anaphylaxis and Infusion-Related Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been observed with PEMGARDA. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration, and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals during infusion and observe for at least two hours after infusion is complete.

Risk of Cross-Hypersensitivity With COVID-19 Vaccines

PEMGARDA contains polysorbate 80, which is in some COVID-19 vaccines and is structurally similar to polyethylene glycol (PEG), an ingredient in other COVID-19 vaccines. For individuals with a history of severe hypersensitivity reaction to a COVID-19 vaccine, consider consultation with an allergist-immunologist prior to PEMGARDA administration.

Risk for COVID-19 Due to SARS-CoV-2 Viral Variants Not Neutralized by PEMGARDA

Certain SARS-CoV-2 viral variants may emerge that are not neutralized by monoclonal antibodies such as PEMGARDA. PEMGARDA may not be effective at preventing COVID-19 caused by these SARS-CoV-2 viral variants. Inform individuals of the increased risk, compared to other variants, for COVID-19 due to emergent SARS-CoV-2 viral variants not neutralized by PEMGARDA. If signs and symptoms of COVID-19 occur, advise individuals to test for COVID-19 and seek medical attention, including starting treatment for COVID-19 as appropriate.

ADVERSE REACTIONS

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.

USE IN SPECIFIC POPULATIONS

Pregnancy

There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. PEMGARDA should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Lactation

There are no available data on the presence of PEMGARDA in human or animal milk, the effects on the breastfed infant, or the effects on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for PEMGARDA and any potential adverse effects on the breastfed infant from PEMGARDA.

Pediatric Use

PEMGARDA is not authorized for use in pediatric patients less than 12 years of age or weighing less than 40 kg. The safety and effectiveness of PEMGARDA has not been established in pediatrics.

EMERGENCY USE AUTHORIZATION (EUA) FOR PEMGARDA

The U.S. Food and Drug Administration (FDA) has issued an EUA for the emergency use of the unapproved product PEMGARDA for the pre-exposure prophylaxis of COVID-19 in adults and adolescents (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
- Who have moderate-to-severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** are unlikely to mount an adequate response to COVID-19 vaccination.

LIMITATIONS OF AUTHORIZED USE

- PEMGARDA is not authorized for use:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

- Pre-exposure prophylaxis with PEMGARDA is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate-to-severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.

- In individuals who have recently received a COVID-19 vaccine, PEMGARDA should be administered at least 2 weeks after vaccination.

PEMGARDA may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs.

PEMGARDA has been authorized by FDA for the emergency use described above.

PEMGARDA is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

PEMGARDA is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of PEMGARDA under Section 564(b)(1) of the Federal Food Drug, and Cosmetic Act, 21 U.S.C. § 360bbb 3(b)(1), unless the authorization is terminated or revoked sooner.

See full **Fact Sheet for Healthcare Providers** and **Fact Sheet for Patients, Parents, and Caregivers** for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. The **FDA Letter of Authorization** is also available for reference.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events* and medication errors potentially related to PEMGARDA within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500 (for information on how to access this form, see below). The FDA requires that such reports, using FDA Form 3500, include the following:

- Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, sex, weight, ethnicity, and race).
- A statement "PEMGARDA use for the pre-exposure prophylaxis of COVID-19 under Emergency Use Authorization (EUA)" under the **"Describe Event, Problem, or Product Use/Medication Error"** heading.
- Information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatment required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes).
- Patient's preexisting medical conditions and use of concomitant products.
- Information about the product (e.g., dosage, route of administration, NDC #).

Submit serious adverse event and medication error reports using FDA Form 3500 to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm.
- Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
  - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
  - Fax to 1-800-FDA (332)-0178, or
- Call 1-800-FDA (332)-1088 to request a reporting form.

In addition, please provide a copy of all FDA MedWatch forms to:

Invivyd, Inc.
Email: pv@invivyd.com
Or call Invivyd, Inc. at 1-800-890-3385 to report serious adverse events.

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory responses to requests from FDA for information about serious adverse events and medication errors following receipt of PEMGARDA.

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- Other important medical events, which may require a medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly

You may report side effects related to Invivyd, Inc. products by sending an email to medinfo@invivyd.com.

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THANK YOU!