# 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): January 8, 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<br>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 January 8, 2024, Invivyd, Inc. posted an updated corporate presentation on its website at www.invivyd.com. A copy of the presentation is filed herewith as Exhibit 99.1 and is incorporated by reference in this Item 8.01.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

| Exhibit No. | Description |
|---|---|
| 99.1 | Corporate Presentation, dated January 8, 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: January 8, 2024

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

Exhibit 99.1

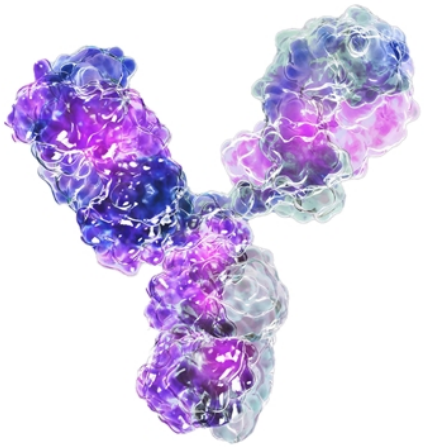
# CORPORATE OVERVIEW

January 8, 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, our belief that Invivyd is poised to enter a transformational period, and our preparations for potential commercial launch of VYD222 if our request for Emergency Use Authorization (EUA) is granted; the potential scope of an EUA for VYD222, if granted, including disease state and patient population; our mission to rapidly deliver antibodies that protect vulnerable populations from viral threats; the future of the COVID-19 landscape; our expectations regarding the size of target patient populations and the potential market opportunity for our product candidates, as well as our market position; our beliefs regarding the clinical utility of anti-SARS-CoV-2 monoclonal antibodies (mAbs); the potential of the company's INVYMAB™ platform approach to rapidly, serially generate new antibodies to address viral threats; the anticipated broad activity and prolonged utility of VYD222; the progress and timing of our ongoing research and clinical development activities, including with respect to VYD222; the CANOPY clinical trial design, including our plans to use an immunobridging approach comparing data obtained in the CANOPY clinical trial to certain historical adintrevimab data; our expectation that historical adintrevimab data from the company's EVADE clinical trial may accelerate VYD222 development; the potential of VYD222 for strong clinical protection from symptomatic COVID-19 based on early signals observed in the CANOPY clinical trial; the ability to have VYD222 commercially available in the U.S. rapidly, if EUA is granted; the potential of our pipeline of product candidates which, if authorized or approved, could be used in prevention or treatment of serious viral diseases, starting with COVID-19 and expanding into influenza and other high-need indications; 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 and progress of our discovery, preclinical and clinical development activities; our ability to generate the clinical data needed from the CANOPY clinical trial to support a potential EUA for VYD222; our interactions with the U.S. FDA regarding the EUA submission for VYD222; the outcome of the VYD222 EUA submission and the timing thereof; the development and regulatory pathways for authorization or approval of VYD222 or other product candidates; unexpected safety or efficacy data observed during preclinical studies or clinical trials; the predictability of clinical success of VYD222 or other 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 in connection with current or future clinical trials; 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 of concern; changes in expected or existing competition; changes in the regulatory environment; the uncertainties and timing of the regulatory authorization or approval process; whether our platform approach enables us to rapidly, serially generate new antibodies to address viral threats; whether VYD222 or any other product candidate is able to demonstrate and sustain neutralizing activity against relevant, major or predominant SARS-CoV-2 variants, particularly in the face of viral evolution; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of VYD222 or any other product candidate following EUA or approval, if granted; 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 manufacture sufficient commercial quantities of VYD222; the complexities of manufacturing mAb therapies and our reliance on contract manufacturers to do so; our ability to establish a sales, marketing and distribution infrastructure to commercialize VYD222 or any other product candidates for which we may obtain regulatory approval or EUA; whether we can obtain and maintain third-party coverage and adequate reimbursement for VYD222 or any other product candidate; whether our research and development efforts will identify and result in safe and effective therapeutic options for infectious diseases other than COVID-19; 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.

# INVIVYD IS POISED TO ENTER A TRANSFORMATIONAL PERIOD, WITH A NEAR-TERM OPPORTUNITY TO DELIVER A MUCH NEEDED THERAPEUTIC



- In January 2024, Invivyd announced the submission of a request for Emergency Use Authorization (EUA) to U.S. FDA for VYD222 for the pre-exposure prevention of COVID-19 in immunocompromised adults and adolescents
- VYD222 EUA submission is based on positive initial results from the ongoing CANOPY Phase 3 pivotal clinical trial and ongoing *in vitro* neutralization activity against major SARS-CoV-2 variants, including JN.1

**Company continues preparations for potential commercial launch of VYD222 if EUA is granted**

# INVIVYD IS ON A MISSION TO RAPIDLY DELIVER ANTIBODIES THAT PROTECT VULNERABLE POPULATIONS FROM VIRAL THREATS, STARTING WITH COVID-19

**>9M**

immunocompromised people in the U.S. alone who may not adequately respond to COVID-19 vaccination[1]

**Zero**

authorized or approved monoclonal antibodies (mAbs) in the U.S. to prevent symptomatic COVID-19

**Near-Term Opportunity**

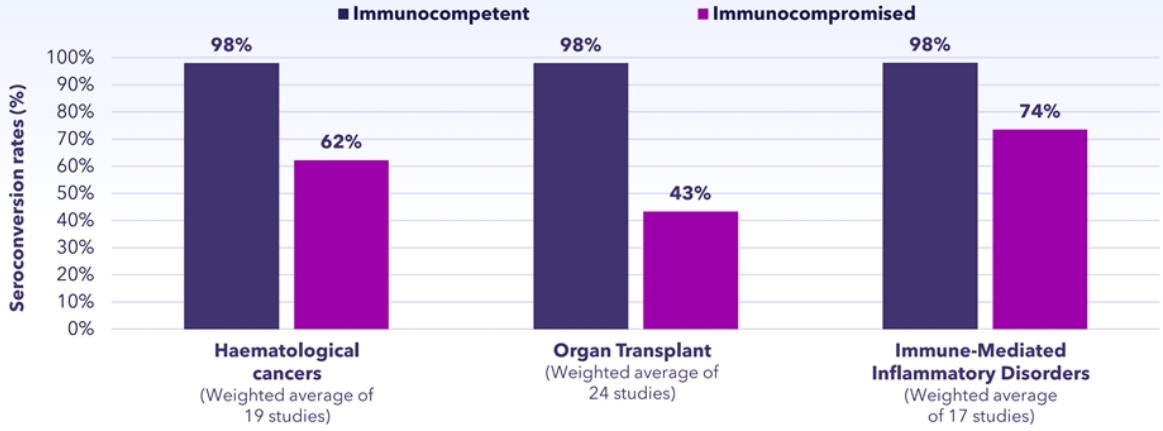
EUA pathway provides the potential opportunity to rapidly bring **VYD222**, a mAb candidate, to immunocompromised adults and adolescents for the pre-exposure prevention of COVID-19

Reference: 1. Estimated market opportunity based on Invivyd-sponsored market research and internal analysis

# MANY IMMUNOCOMPROMISED PEOPLE HAVE AN IMPAIRED IMMUNE RESPONSE TO COVID-19 VACCINES

## Immunocompromised people are less likely to have detectable SARS-CoV-2 antibodies following vaccination than immunocompetent people

Seroconversion rates (detectable Abs) in immunocompromised people vs. immunocompetent controls after two COVID-19 vaccine doses[1] [*pre-Omicron*]

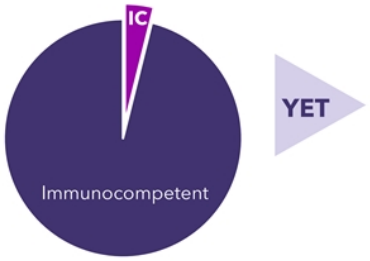



References: 1. Lee BMJ 2022; Abs, antibodies

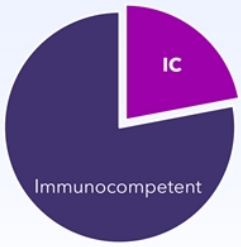
# DESPITE VACCINATION, IMMUNOCOMPROMISED PEOPLE REMAIN AT HIGHER RISK FOR SEVERE COVID-19 OUTCOMES

**The recent INFORM[1] study, conducted during the Omicron period, found that in a sample of nearly 12 million people:**

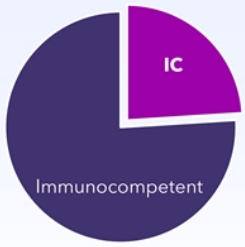
Immunocompromised (IC) people represented only **3.9% of the study population...**




IC individuals accounted for **22% of COVID-19 hospitalizations**




IC individuals accounted for **24% of COVID-19 deaths**

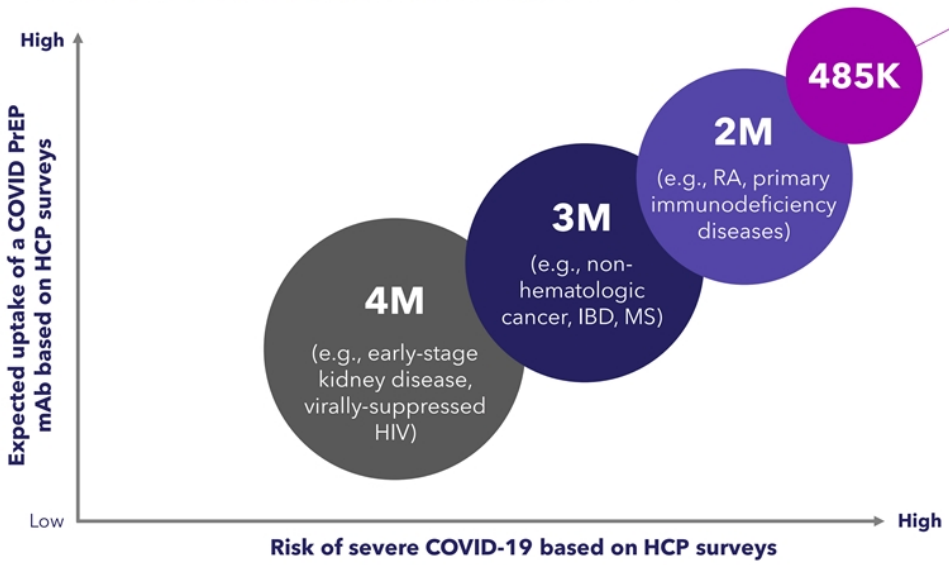



Even though **>80% of the IC population had received ≥3 COVID-19 vaccines**

References: 1. Evans Lancet Reg 2023

# SIGNIFICANT MARKET OPPORTUNITY WITH >9M IMMUNOCOMPROMISED PEOPLE AT INCREASED RISK FOR SEVERE COVID-19 IN THE U.S.

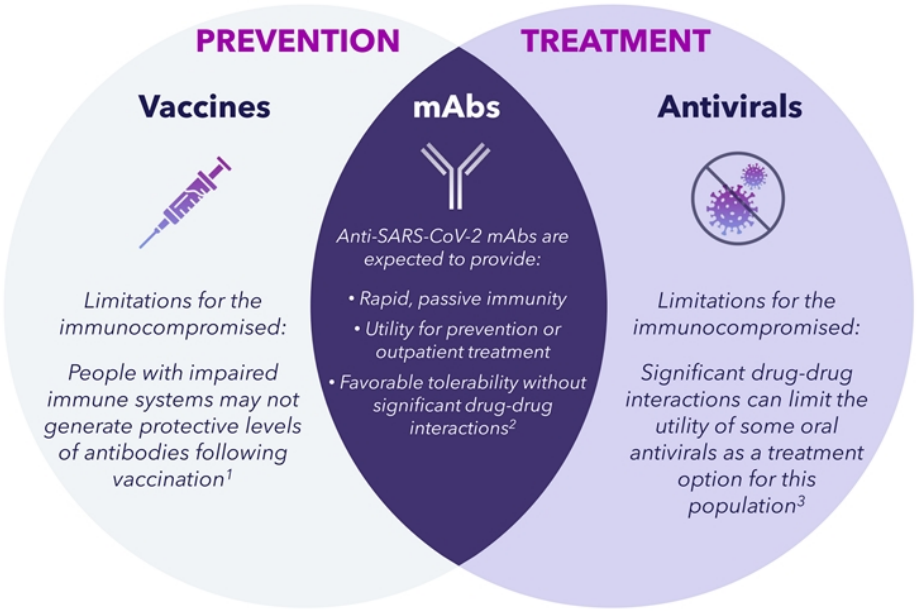
**Estimated U.S. total addressable market (TAM) for PrEP**



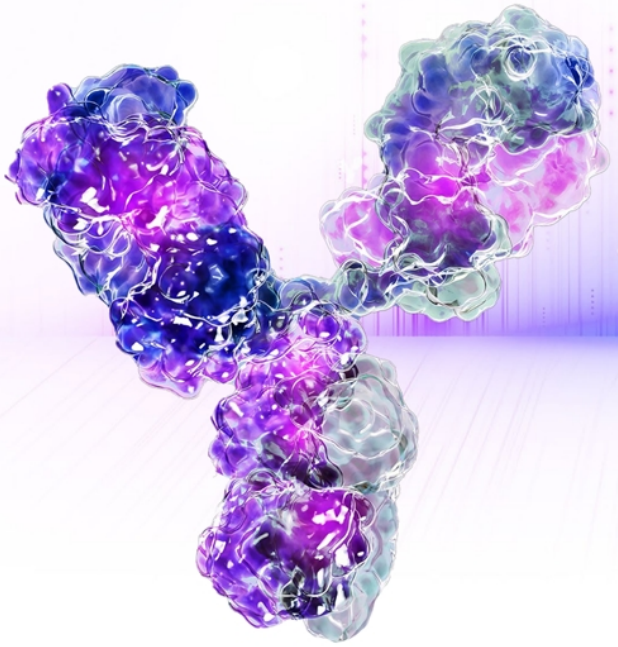

- Of the estimated **485K immunocompromised (IC) people at highest risk**:
  - 67K: stem cell transplants
  - 86K: solid organ transplants (liver/lung/kidney)
  - 332K: hematologic/lymphatic cancers
- Care for these populations is often associated with specialized centers

Reference: Illustrative graph and estimated market opportunity based on Invivyd-sponsored market research and internal analysis.
PrEP: Pre-exposure prophylaxis (prevention); RA: rheumatoid arthritis; IBD: inflammatory bowel disease; MS: multiple sclerosis; HIV: human immunodeficiency virus; HCP: Healthcare professional

# IN ADDITION TO PREVENTION, MONOCLONAL ANTIBODIES ALSO HAVE COMPELLING POTENTIAL IN THE TREATMENT OF COVID-19




References: 1. Lee BMJ 2022; 2. McCreary JAMA Netw Open 2023; 3. Marzolini Clin Pharmacol Ther 2022



# Our Platform & VYD222

# INVYMAB™ PLATFORM APPROACH IS DESIGNED FOR RAPID, SERIAL GENERATION OF NEW ANTIBODIES TO ADDRESS VIRAL THREATS

*The company's proprietary INVYMAB platform approach combines state-of-the-art viral surveillance and predictive modeling with advanced antibody discovery and engineering*

### VIRAL SURVEILLANCE & PREDICTIVE MODELING

Continuous monitoring of viral evolution and mapping of common mutational escape routes with the aim to predict potential future variants of concern

### ANTIBODY DISCOVERY

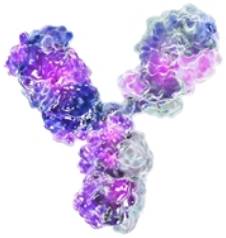
Deep B-cell mining to isolate broadly neutralizing mAbs that target rare viral epitopes that are not under strong immune pressure, increasing the probability of sustained utility

### ANTIBODY ENGINEERING

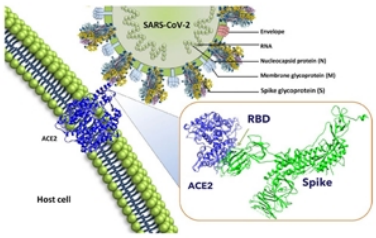
Industry-leading antibody engineering to improve potency, breadth, biophysical properties, and developability of candidates discovered through B-cell mining

### STREAM OF MAB CANDIDATES

# VYD222: A CANDIDATE FOR THE PRE-EXPOSURE PREVENTION OF COVID-19 IN IMMUNOCOMPROMISED ADULTS AND ADOLESCENTS



**Broadly neutralizing, half-life extended** mAb candidate in development for the pre-exposure prevention of COVID-19 in immunocompromised adults and adolescents




**Binds to the spike protein receptor binding domain (RBD) of SARS-CoV-2**, interfering with the virus's ability to infect human cells

EVADE — Ph 2/3 clinical trial of ADG20 for COVID-19 prevention

STAMP — Ph 2/3 clinical trial of ADG20 for COVID-19 treatment

**Engineered from adintrevimab** (ADG20), a mAb candidate that Invivyd previously studied in 2 clinical trials with clinical endpoints; data from the EVADE trial expected to accelerate VYD222 development

Reference: Saxena SK VirusDis 2020 (SARS-CoV-2 figure)

# VYD222 HAS DEMONSTRATED BROAD *IN VITRO* NEUTRALIZING ACTIVITY AGAINST VARIOUS PRE-OMICRON AND OMICRON VARIANTS

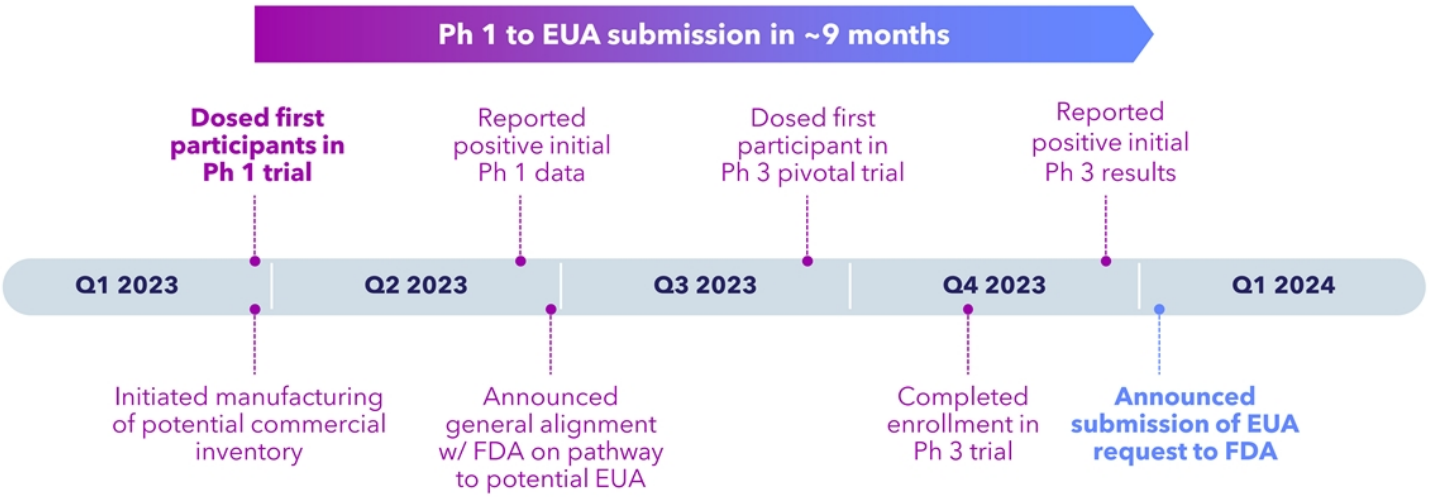
| VARIANT | SUBLINEAGE | VYD222[1] |
|---|---|---|
| WT(D614G) | WT(D614G) | ✓ |
| Delta | B.1.617.2 | ✓ |
| Omicron | BA.4.6 | ✓ |
| | BF.7 | ✓ |
| | XBB.1 | ✓ |
| | XBB.1.5 | ✓ |
| | XBB.1.16 | ✓ |
| | XBB.1.5.10/EG.5 | ✓ |
| | HK.3 | ✓ |
| | BA.2.86 | ✓ |
| | HV.1 | ✓ |
| | JN.1 | ✓ |

**JN.1 is currently the dominant SARS-CoV-2 variant in the U.S.[2]**

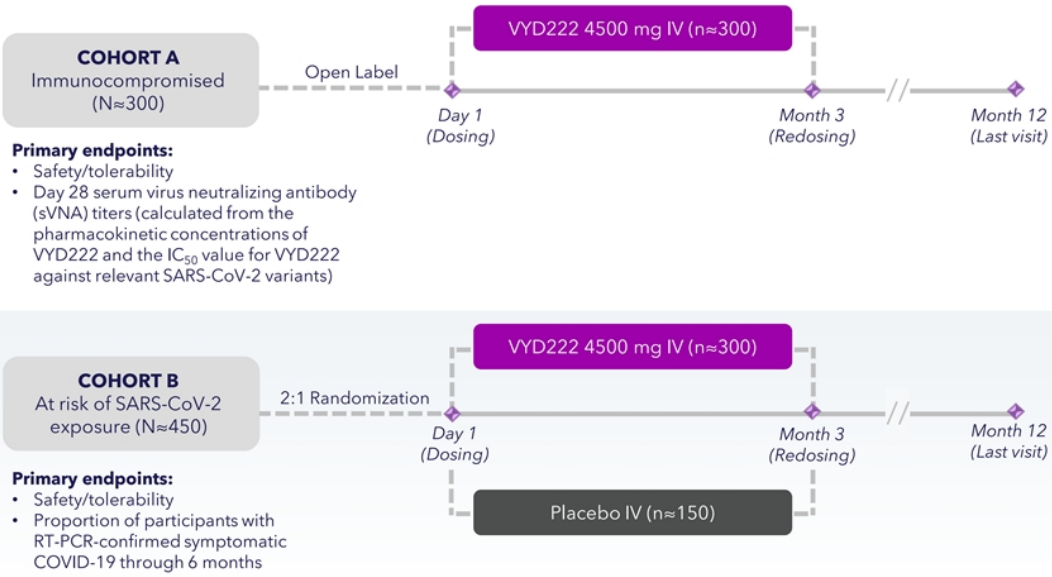
References: 1. VYD222 data generated by CRO using a pseudovirus SARS-CoV-2 neutralizing antibody assay; 2. https://covid.cdc.gov/covid-data-tracker/#variant-proportions (accessed Jan 5, 2024)

✓ Neutralizing activity in standardized *in vitro* pseudovirus assays

# INVIVYD IS RAPIDLY ADVANCING VYD222 FOR THE PRE-EXPOSURE PREVENTION OF COVID-19 IN IMMUNOCOMPROMISED ADULTS AND ADOLESCENTS



# VYD222 EUA SUBMISSION IS BASED ON POSITIVE INITIAL RESULTS FROM THE ONGOING PHASE 3 VYD222 CLINICAL TRIAL (CANOPY)




**Initial CANOPY results reported in December 2023:**

- VYD222 produced high sVNA titer levels against XBB.1.5 in immunocompromised participants
- Overall favorable safety and tolerability profile of VYD222 including no study drug-related SAEs; AEs attributed to VYD222 were Grade 1 or 2 (mild or moderate) in severity
- Potential early signal of strong clinical protection from symptomatic COVID-19

Source: ClinicalTrials.gov Identifier: NCT06039449; IV, intravenous; SAEs, serious adverse events; AEs, adverse events

# IF AUTHORIZED, INVIVYD AIMS TO HAVE VYD222 COMMERCIALLY AVAILABLE IN THE U.S. RAPIDLY THEREAFTER

*Commercial preparations are being led by a seasoned team with extensive experience successfully commercializing products within the infectious disease space*

Preparations completed or underway:

- Go-to-market planning (e.g., market research, market sizing/segmentation, brand strategy, field force sizing)
- Market access activities (e.g., payer/pricing research, distribution channels)
- Manufacturing initial commercial inventory
- Establishing necessary internal systems and technology to support the transition to commercial stage

**Invivyd plans to concentrate initially on serving the highest risk IC populations through a highly focused field sales organization which can expand to reach additional IC adults and adolescents over time, if VYD222 is authorized**

# VYD222 IS ONE OF MANY ANTIBODIES IN INVIVYD'S PIPELINE

| PROGRAMS | PLATFORM | INDICATION(S) | DISCOVERY/ PRECLINICAL | IND-ENABLING | PHASE 1 | PHASE 2 | PHASE 3 | STATUS |
|---|---|---|---|---|---|---|---|---|
| **SARS-COV-2** | | | | | | | | |
| **VYD222** | mAb | Pre-exposure prevention | | | | | | Reported positive initial Ph 3 results and submitted EUA request |
| **COVID candidate #2** | mAb | Prevention or treatment | | | | | | Engineering variant matching |
| **COVID candidate #3** | mAb | Prevention or treatment | | | | | | Engineering variant matching |
| **COVID candidate #4** | mAb | Prevention or treatment | | | | | | Engineering variant matching |
| **Adintrevimab** | mAb | Prevention | | | | | | Trials concluded; EUA filing dependent on variant susceptibility |
| **Adintrevimab** | mAb | Treatment | | | | | | |
| **OTHER VIRUSES** | | | | | | | | |
| **Influenza** | mAb combination | Prevention | | | | | | Early discovery |

Investigational therapies are not approved for use by regulatory authorities. The safety and efficacy of pipeline candidates have not been established.

# MANAGEMENT TEAM WITH EXPERTISE IN INFECTIOUS DISEASES AND TRACK RECORD OF SUCCESS

**Dave Hering, M.B.A.**
Chief Executive Officer & Director

Pfizer · NOVARTIS

**Peter C. Schmidt, M.D., MSc**
Chief Medical Officer

ASSERTIO · ZOSANO PHARMA

**Stacy Price, M.S.**
Chief Technology & Manufacturing Officer

AKOUOS · Shire

**William Duke, M.B.A**
Chief Financial Officer

Kaleido BIOSCIENCES · genzyme

**Robert Allen, Ph.D.**
Chief Scientific Officer

SmartPharm THERAPEUTICS · sorrento

**Jill Andersen, J.D.**
Chief Legal Officer & Corporate Secretary

Celgene · NOVARTIS

**Jeremy Gowler**
Chief Operating & Commercial Officer

SANDOZ A Novartis Division · EMERGENT · INVIVYD

INVIVYD

# THANK YOU!