

**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): October 30, 2025

Invivyd, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-40703
(Commission
File Number)

85-1403134
(IRS Employer
Identification No.)

209 Church Street
New Haven, CT
(Address of Principal Executive Offices)

06510
(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 October 30, 2025, Invivyd, Inc. posted an investor 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation, dated October 30, 2025
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.

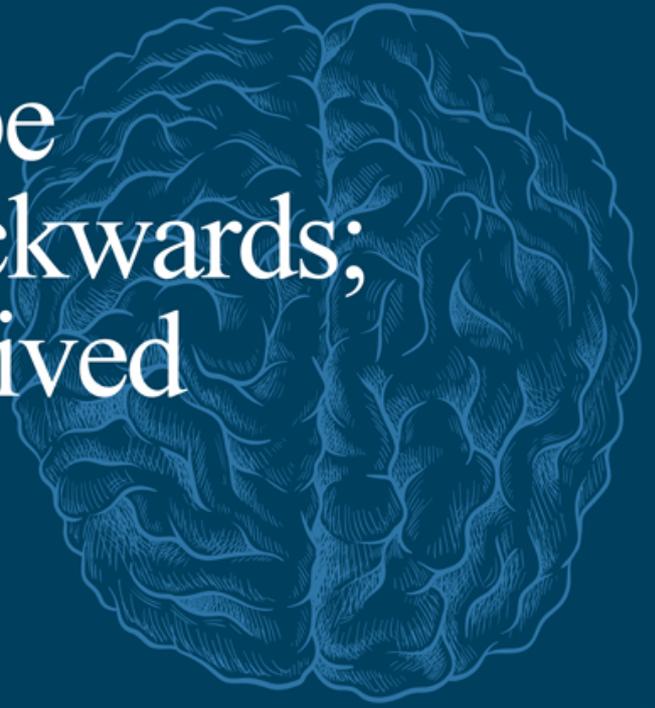
Date: October 30, 2025

By: /s/ Jill Andersen

Jill Andersen

Chief Legal Officer and Corporate Secretary

Life can only be
understood backwards;
but it must be lived
forwards...



KIERKEGAARD

October 30, 2025

Invivyd

© 2025 Invivyd, Inc. All trademarks used in this presentation are the property of their respective owners.

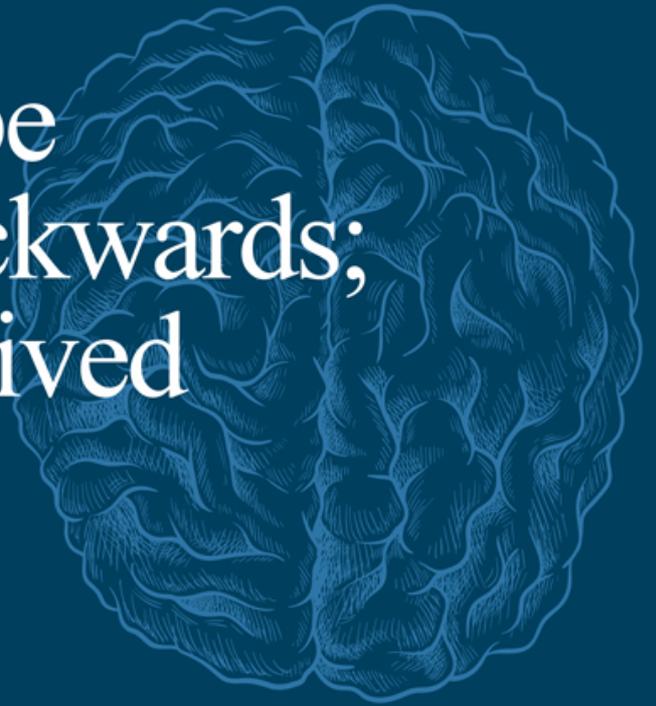
CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

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, expectations about the COVID landscape; beliefs about limitations of COVID vaccines and the expected advantages of monoclonal antibodies (mAbs), including the potential to engineer mAbs for consistent high activity against SARS-CoV-2 variants; expectations regarding durability and stability of the company’s antibodies; plans related to the company’s research and development activities, and the timing and potential results thereof; the potential of VYD2311 as a mAb candidate; expectations regarding the company’s clinical trial designs and enrollment, regulatory pathway, product profile, target patient population, indication and potential administration paradigm for VYD2311; PEMGARDA® (pemivibart) as a mAb for pre-exposure prophylaxis (PrEP) of COVID-19 in certain immunocompromised patients; estimates regarding the size of target patient populations and the potential market opportunity for the company’s product candidates, as well as its market position; the company’s commercialization plans, strategies, goals and expectations; the potential of the company’s pipeline and discovery efforts, including for COVID, Long COVID, respiratory syncytial virus (RSV) and measles; the company’s business strategies and objectives, and ability to execute on them; the company’s future prospects; 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, progress and results of the company’s discovery, preclinical and clinical development activities, including the initiation of the DECLARATION clinical trial, and finalization and initiation of other aspects of the REVOLUTION clinical program, such as the LIBERTY clinical trial, subject to final alignment with the U.S. Food & Drug Administration (FDA); clinical trial site activation or enrollment rates; 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; 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; how long the emergency use authorization (EUA) granted by the FDA for PEMGARDA for COVID-19 PrEP in certain immunocompromised patients will remain in effect and whether such EUA is revised or revoked by the FDA; changes in the regulatory environment; the outcome of the company’s engagement with regulators; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways; the company’s ability to generate the data needed to support a potential Biologics License Application (BLA) submission for VYD2311; the ability to maintain a continued acceptable safety, tolerability and efficacy profile of any product candidate following regulatory authorization or approval; the success of the company’s in-house sales force, and company’s ability to maintain and expand sales, marketing and distribution capabilities to successfully commercialize any authorized or approved product candidates; changes in expected or existing competition; the company’s reliance on third parties; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; variability of results in models and methods used to predict activity against SARS-CoV-2 variants; whether the epitopes that pemivibart and VYD2311 target remain structurally intact; whether the company’s product candidates are 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, and availability of quantities of commercial launch product in the future, if authorized or approved; macroeconomic and political uncertainties; 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 presentation are described under the heading “Risk Factors” in the company’s Annual Report on Form 10-K for the year ended December 31, 2024 and its Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, 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 presentation contains hyperlinks to information that is not deemed to be incorporated by reference in this presentation.

Life can only be
understood backwards;
but it must be lived
forwards...

KIERKEGAARD



Invivyd

October 30, 2025. © 2025 Invivyd, Inc. All trademarks used in this presentation are the property of their respective owners.

Invivyd is committed to developing *best-in-class antibody protection and treatment* of viral threats

COVID

PEMGARDA® (pemivibart)

VYD2311

LONG COVID

SPEAR Study Group

RSV

Discovery-stage program

MEASLES

Discovery-stage program



agenda

01 The COVID Situation

02 Invivyd Antibodies

03 REVOLUTION Clinical Program

04 Future Commercial Landscape

Perceived as
a “respiratory”
virus because of
transmission, but
actually a *vascular,
prothrombotic,
immunomodulatory
novel virus*



Influenza

Entry via sialic acid receptor
Largely bronchoepithelial cells



RSV

Entry via CX3CR1
Largely bronchoepithelial cells



SARS-CoV-2

Entry via ACE2
Epithelial and endothelial cells

COVID vaccines aren't the problem:
humans are. Humans don't *make* long
lasting antibodies against coronaviruses.

“ Our findings raise concern that humoral immunity against SARS-CoV-2 may not be long lasting... the results call for caution regarding antibody-based “immunity passports,” herd immunity, and perhaps vaccine durability, especially in light of short-lived immunity against common human coronaviruses. ”

Otto Yang, UCLA, July 2020
New England Journal of Medicine

Omicron made COVID even harder for vaccines.

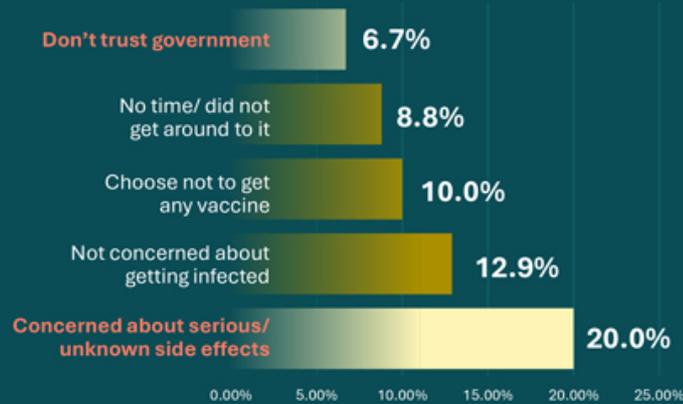
“There is no world, I think, where [the effectiveness] is the same level... we had with [the] Delta [variant],” Stéphane Bancel told the Financial Times



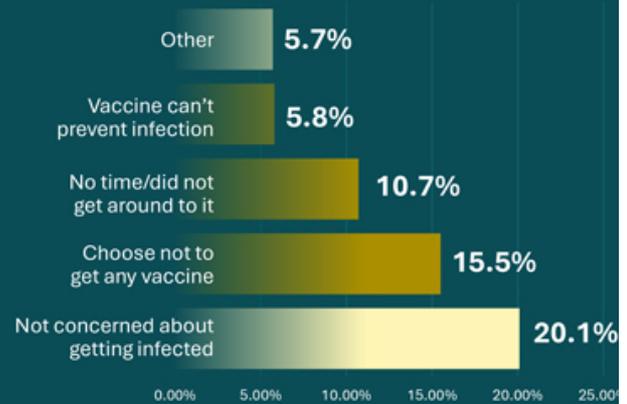
Financial Times, November 30, 2021

Americans have avoided COVID vaccines due to safety fears and mistrust

COVID



FLU



A national CDC survey of adults during June – July 2024 found that the most common reasons for non-vaccination during the 2023 – 24 respiratory virus season were concerns about serious and unknown side effects for COVID-19 vaccine (40%) and lack of concern about getting sick for flu vaccine (37%) among adults aged ≥ 18 years, and lack of knowledge for RSV vaccine (36%) among adults aged ≥ 60 years.

Source: Centers for Disease Control and Prevention, Reasons for non-vaccination with COVID-19, influenza, and RSV vaccines during the 2023–24 respiratory virus season, November 8, 2024.

We want to break the **COVID** stalemate



Infection nobody wants

Vaccines few trust

Option 3



agenda

01 The COVID Situation

02 Invivyd Antibodies

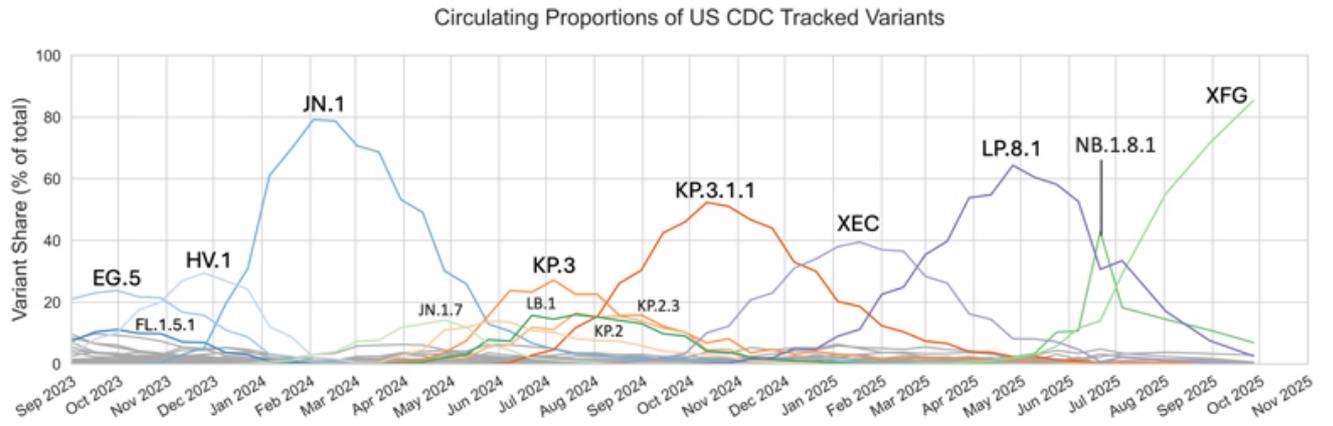
03 REVOLUTION Clinical Program

04 Future Commercial Landscape

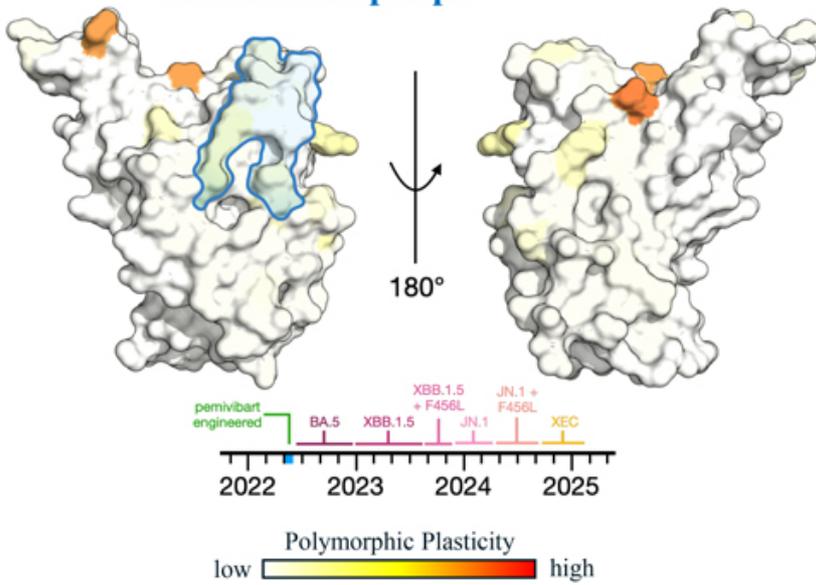
COVID
today demands
a *monoclonal*
antibody

In contrast to vaccines,
monoclonal antibodies
can be engineered for
consistent high activity

SARS-CoV-2 changes rapidly



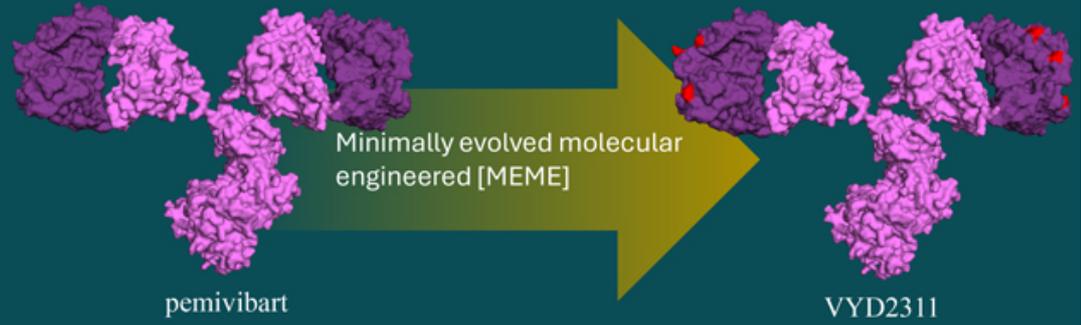
Pemivibart epitope



BUT our epitope hasn't changed: **by design**

SARS-COV-2 Spike RBD Amino Acid Residue Plasticity Index (RPI) demonstrates target dynamics over the past 3 years

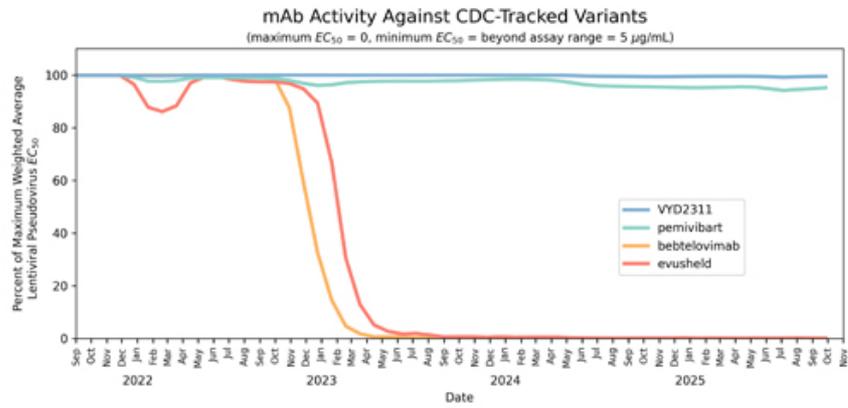
We innovate
to stay ahead
and improve
performance



Humans have limited antibody diversity and capability.
Invivyd has no such limit.

We see remarkable durability and stability of our antibodies

Engineered against stable epitopes – beyond human immune capability





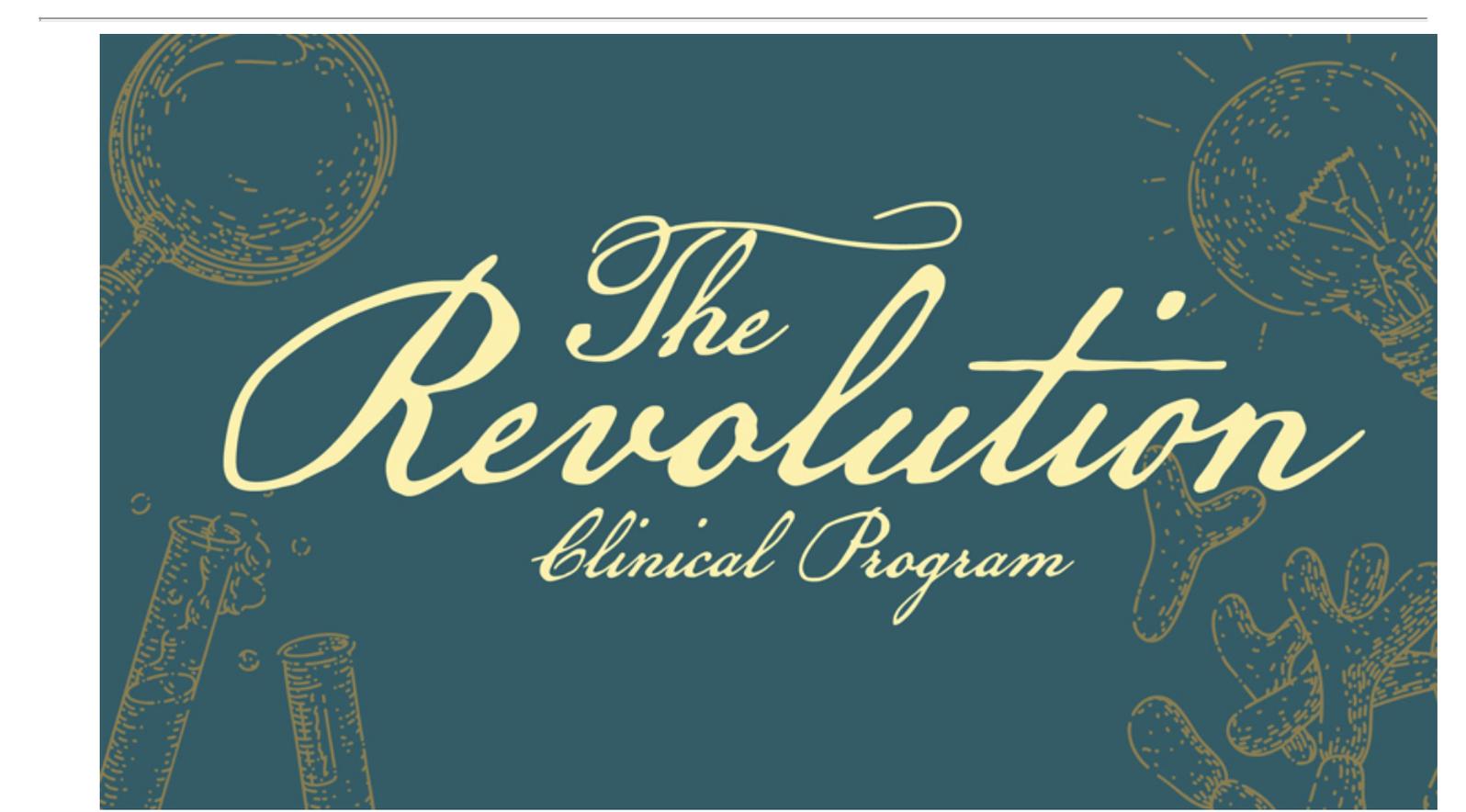
agenda

01 The COVID Situation

02 Invivyd Antibodies

03 REVOLUTION Clinical Program

04 Future Commercial Landscape



*The
Revolution
Clinical Program*

VYD2311/REVOLUTION Clinical Program



Phase 1/2 Study

Randomized, double-blind, placebo-controlled trial was conducted to evaluate safety, tolerability, pharmacokinetics, and immunogenicity in healthy participants



Pivotal Efficacy Study

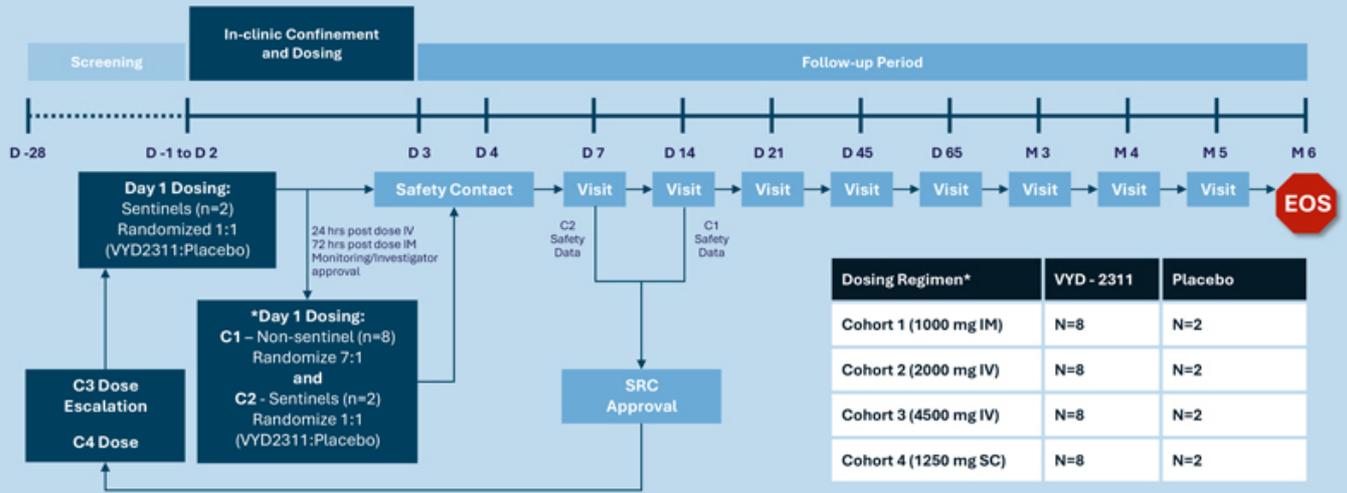
'DECLARATION' Phase 3, placebo-controlled efficacy trial in prevention of symptomatic COVID



Vaccine Study

'LIBERTY' Safety/Tolerability comparison with COVID mRNA vaccines (and co-administration)

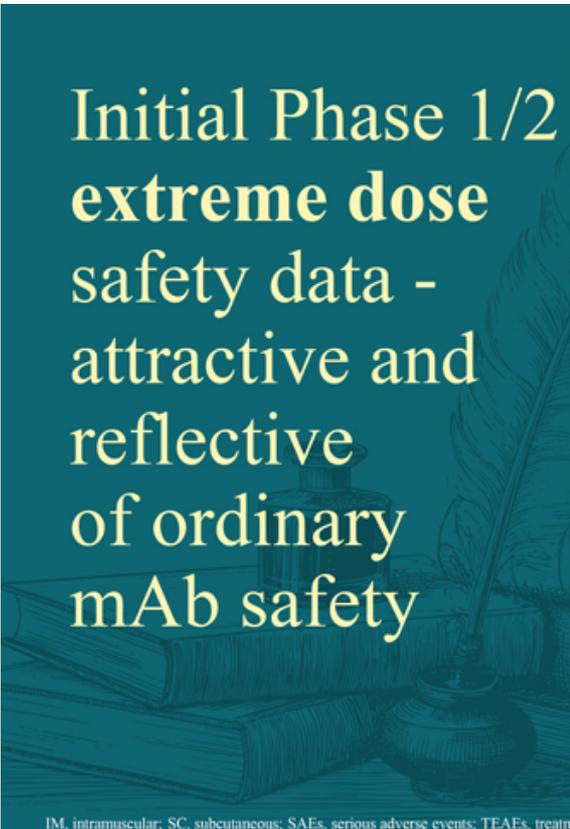
VYD2311 Phase 1/2 study – Stress tested safety at **extremely** high doses



EOS – end of study; IM – intramuscular(y); IV – intravenous(y); SRC – Safety Review Committee.

*After C1 sentinel participants (1:1 VYD 2311; placebo) have completed 72 hrs of safety monitoring, the remaining C1 participants and the C2 sentinel participants can begin dosing. C1 non-sentinel participant dosing can occur in parallel with dosing of all C2 participants.

Upon SRC approval, C3 sentinel participants (1:1 VYD 2311; placebo) can begin dosing followed by remaining C3 participants. After C4 sentinel participants have completed 72 hours of safety monitoring, the remaining C4 non-sentinel participants can begin dosing.



Initial Phase 1/2 extreme dose safety data - attractive and reflective of ordinary mAb safety

VYD2311 administered IV at up to 4500 mg in Phase 1/2, which was as much as **18 years** of antibody at the dose to be used in the Declaration study

Injection site reactions

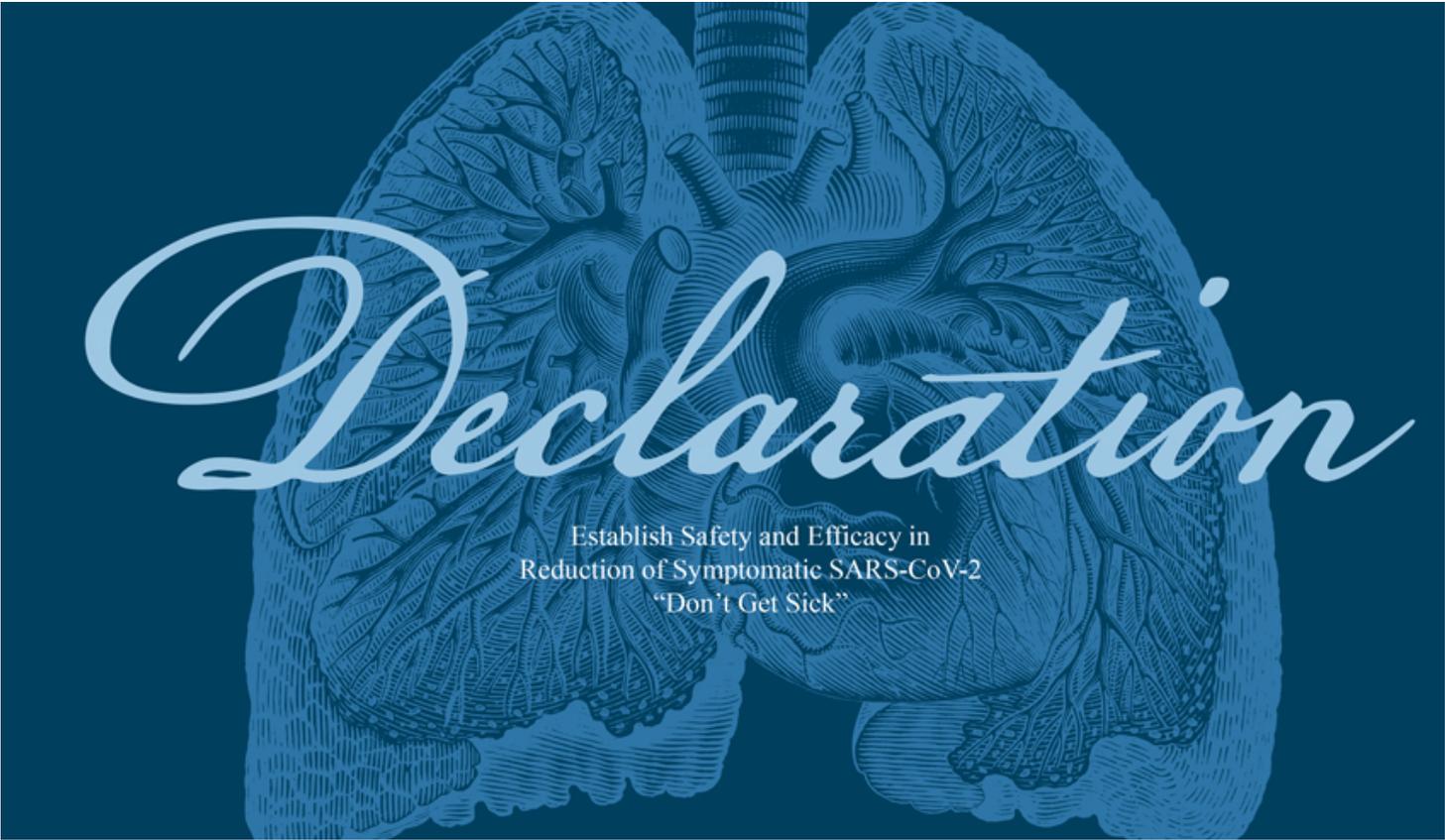
- IM: 1 (12.5%) VYD2311 participant with mild pain, duration 1 hour, not requiring treatment
- SC: 8 (100%) VYD2311 participants all mild, of short duration, not requiring treatment

Infusion related reactions

- 3 (37.5%) VYD2311 participants receiving 4500 mg infusion
- 2 mild and 1 moderate, duration 3 to 20 minutes, the moderate reaction had study drug interruption and received paracetamol and loratadine, resumed full infusion without recurrence

No deaths, SAEs, hypersensitivity reactions, severe TEAEs, or other significant TEAEs

No trends in laboratory, vital signs, ECG values, or physical examination findings indicating a safety risk



Declaration

Establish Safety and Efficacy in
Reduction of Symptomatic SARS-CoV-2
“Don’t Get Sick”

We aim to demonstrate a substantial reduction in your risk of getting COVID

○ **2020-2023** *PANDEMIC COVID*

Key Medical Concerns:

“SARS” death, P02 saturation management, ventilation, proning, late anti-inflammatories

Key Metrics and Endpoints:

Death, Hospitalizations

○ **2023 – END OF TIME** *ENDEMIC COVID*

Key Medical Concerns:

Acute infection and illness; risks of disability, hospitalization, death, end organ damage (neurologic, cardiac, GI, hematologic / thrombotic, renal, pulmonary, etc.), Long COVID, thrombosis and MACE

Key Metrics and Endpoints:

Infections, Long COVID, CV burden, Disability, Death, Hospitalizations

For the benefit
of whom?
Broad Patient
Population

~150M

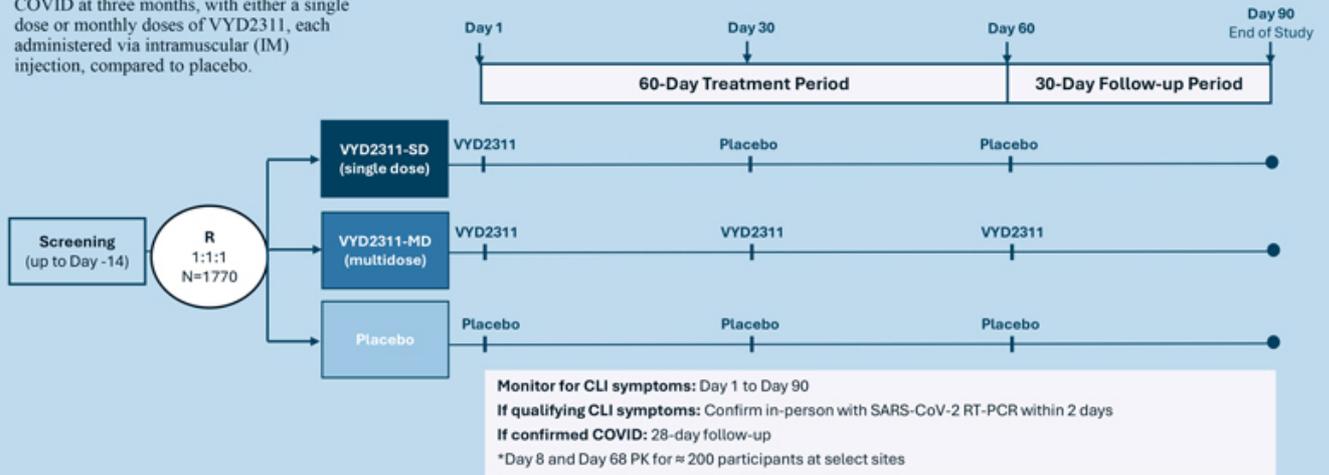
The patient population includes adults and adolescents (12 years and older and weighing at least 40 kg) with and without risk factors for progression to severe COVID

What are we
measuring?

**PCR confirmed
symptomatic
SARS-CoV-2**
(COVID-Like Illness “CLI”
consistent across Invivyd RCTs)

A Phase 3, Randomized, Triple-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of VYD2311 for the Prevention of COVID in Adults and Adolescents

The DECLARATION Phase 3 clinical trial will evaluate prevention of symptomatic COVID at three months, with either a single dose or monthly doses of VYD2311, each administered via intramuscular (IM) injection, compared to placebo.

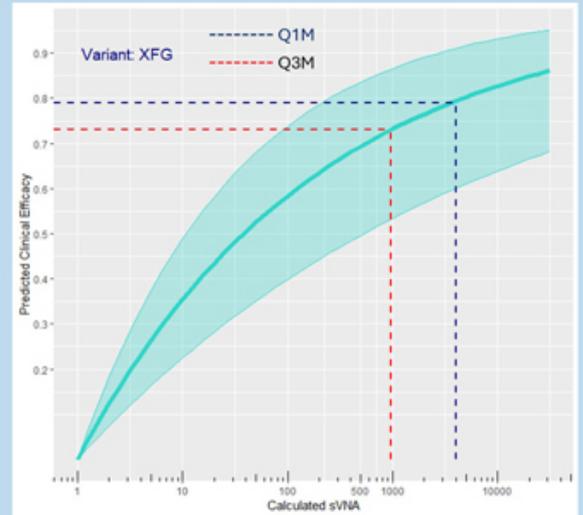


CLI, COVID-like illness; MD, multidose; PK, pharmacokinetics; RT-PCR, reverse transcription-polymerase chain reaction; SD, single dose Reference: Invivyd. Data on File.

250 mg single dose IM targets
70%-90% reduction in
symptomatic COVID vs.
placebo over 3 months

Multi-dose expected higher

Immune correlates of protection
model for predicting efficacy from
neutralizing antibody titers

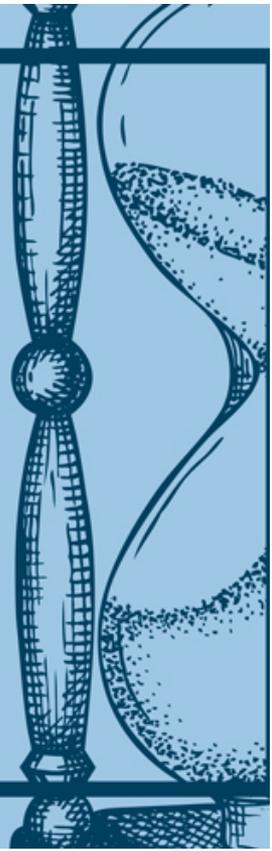


Long Half Life (76 days) and relatively flat titer: protection curve allows **long-term protection** following a **single dose**

At **one-year**, single dose sVNA titer would still confer **greater than 50% protection**

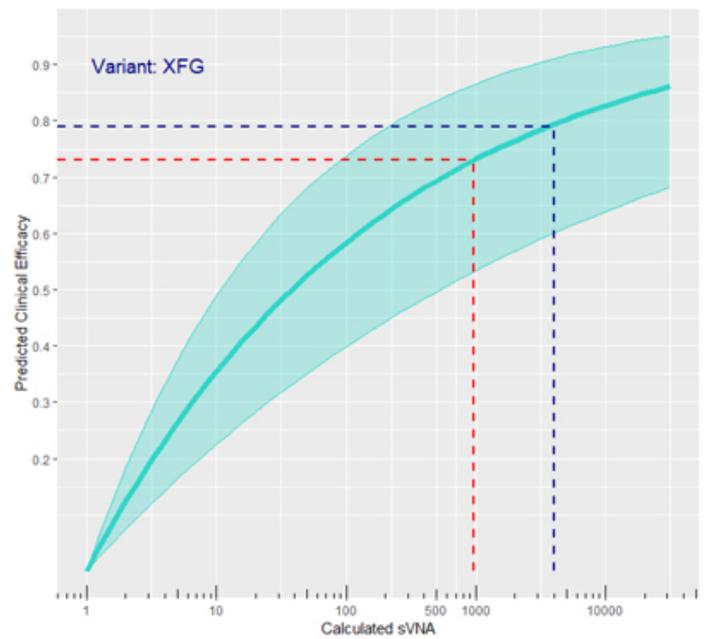
Every 90-day period requires only 1.2 product half-lives

sVNA = serum virus neutralizing antibody

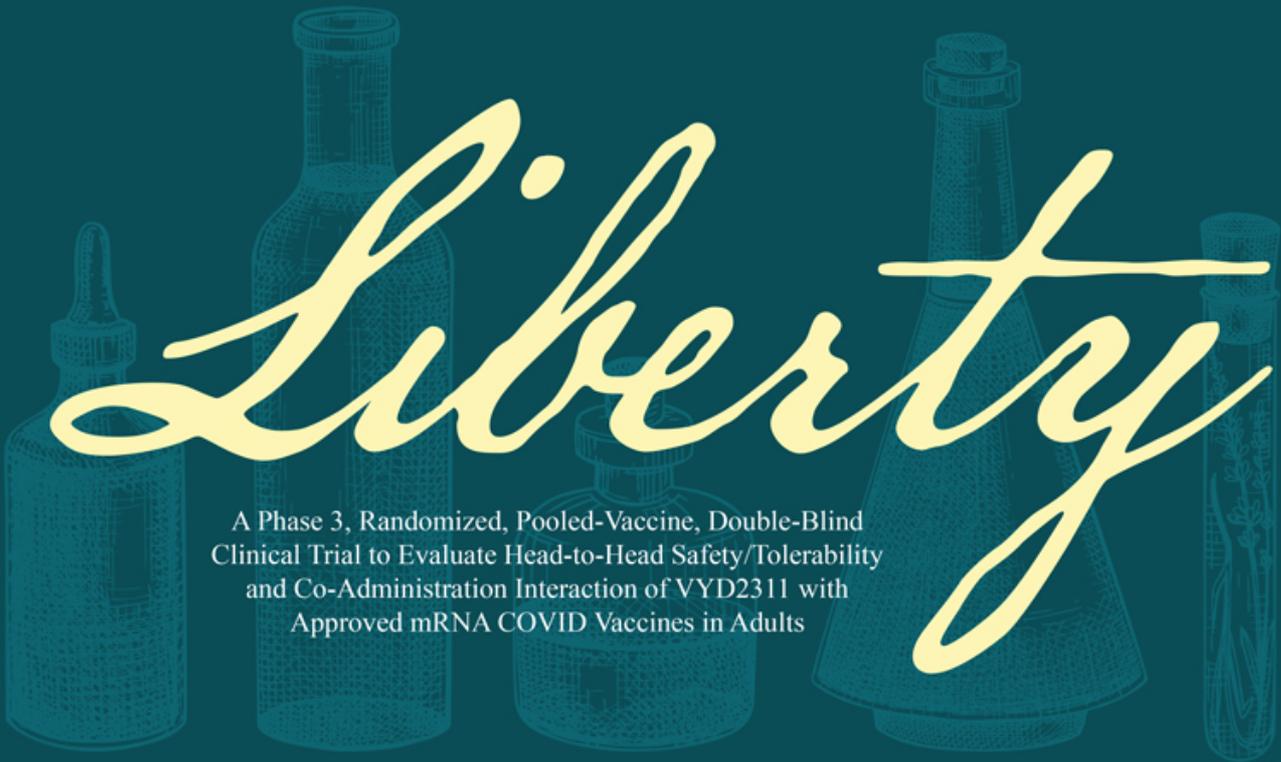


DECLARATION: an opportunity to establish a **Correlate of Protection for Invivyd monoclonal antibodies**

- Streamline development
- Competitive moat
- Accelerate innovation (half life, dose, protection)



mAb	Dose	Mod	Frequency	Concentration at the end of Month 3 (ug/mL)	variant	sVNA	Predicted Efficacy (RRR) non-IC
VYD222	4500 mg	IV	Q6M	190	XFG	906	73%
VYD2311	250 mg	IM	Q1M	58	XFG	4030	79%
VYD2311	250mg	IM	Q3M	14	XFG	959	73%



Liberty

A Phase 3, Randomized, Pooled-Vaccine, Double-Blind
Clinical Trial to Evaluate Head-to-Head Safety/Tolerability
and Co-Administration Interaction of VYD2311 with
Approved mRNA COVID Vaccines in Adults

mRNA vaccination safety and tolerability

Warnings and Precautions (COMIRNATY® and SPIKEVAX® Prescribing Information)

Postmarketing data from use of authorized or approved mRNA COVID-19 vaccines demonstrated increased risks of myocarditis and pericarditis, with onset of symptoms typically in the first week following vaccination. The observed risk has been highest in males 12 years through 24 years of age.

Adverse Reactions most commonly reported (≥ 10%) (COMIRNATY® and SPIKEVAX® Prescribing Information):

	COMIRNATY®	SPIKEVAX®		
	Participants 12 years of age and older Up to	Participants 12-17 years of age	Participants 18 - 64 years of age	Participants 65 years of age+
Pain at injection site	90.5%	90.6%	86.3%	76.3%
Fatigue	77.5%	58.1%	62.0%	58.1%
Headache	75.5%	Up to 56.3%	58.9%	42.1%
	Chills (up to 49.2%) Muscle pain (up to 45.5%) Joint pain (up to 27.5%) Fever (up to 24.3%) Injection site swelling (up to 11.8%) Injection site redness (up to 10.4%)	myalgia (up to 40.1%) chills (up to 30.2%) axillary swelling/ tenderness (up to 27.8%) Arthralgia (up to 23.9%) nausea/vomiting (up to 17.9%) Swelling at injection site (up to 13.3%)	myalgia (up to 49.6%) arthralgia (up to 41.9%) chills (up to 40.3%) axillary swelling/ tenderness (up to 24.8%) nausea/vomiting (up to 16.7%)	myalgia (up to 47.4%) arthralgia (up to 39.5%) chills (up to 18.4%) axillary swelling/ tenderness (up to 14.3%)

References: Prescribing Information – COMIRNATY Aug 2025; Prescribing Information - SPIKEVAX Aug 2025

Previous Invivyd IM antibody safety

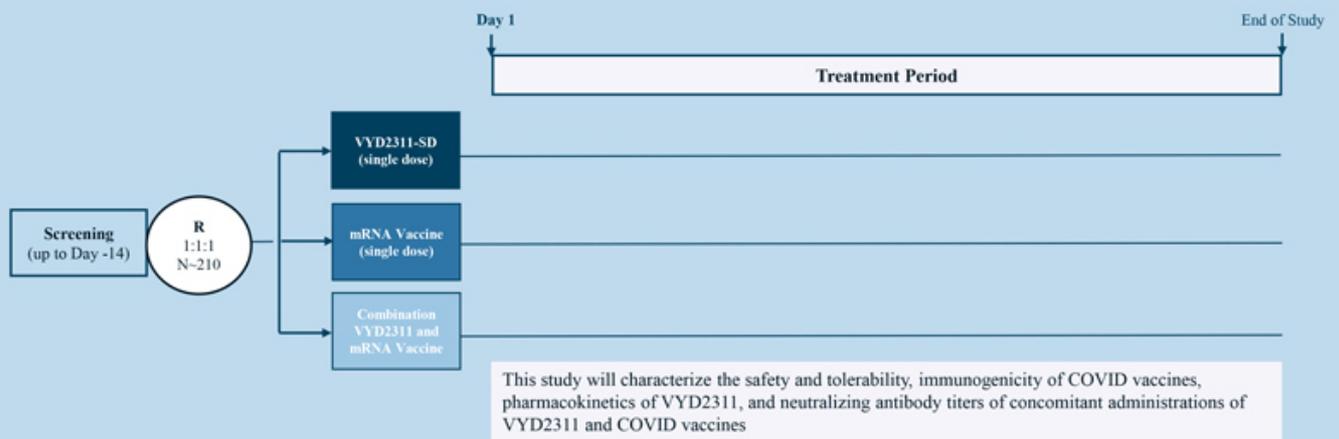
What could we expect from an IM COVID antibody?

- 0 Myocarditis / pericarditis
- 1 hypersensitivity (urticaria) out of 1,293 exposures in drug arm
- EVADE Phase 2/3 clinical trial: 300mg IM adintrevimab (PrEP / PEP)

Ison, M. *Prevention of COVID-19 Following a Single Intramuscular Administration of Adintrevimab: Results From a Phase 2/3 Randomized, Double-Blind, Placebo-Controlled Trial (EVADE)*. Open Forum Infectious Disease. 2023, Jun 13.

TEAE	Adintrevimab %	Placebo %
Injection Site Pain	6.9	7.2
Influenza-like-illness	4.4	3.5
Upper respiratory tract infection	3.2	2.5
Headache	1.7	1.3
Nasopharyngitis	1.5	1.4
Sinusitis	1.5	1.0
Hypertension	1.4	1.7
Respiratory Tract Infection Viral	1.3	1.1
Injection site swelling	1.2	0.6
Injection site erythema	1.2	1.4
Back pain	1.2	1.0
Urinary Tract Infection	1.1	0.7
Fatigue	1.1	0.6
Cough	1.0	0.4

A Phase 3, Randomized, Pooled-Vaccine, Double-Blind Clinical Trial to Evaluate Head-to-Head Safety/Tolerability and Co-Administration Interaction of VYD2311 with Approved mRNA COVID Vaccines in Adults



*Final design to be aligned with FDA

Possible future areas of study for REVOLUTION program



Pediatric safety +
immunobridging



Long-term follow
up efficacy from
DECLARATION



Head-to-head efficacy
with mRNA vaccination



Long COVID
prevention



agenda

- 01 The COVID Situation
 - 02 Invivyd Antibodies
 - 03 REVOLUTION Clinical Program
 - 04 Future Commercial Landscape**
-

COVID Vaccines: Big Revenue, Small Protection

\$3.8B

FY24
U.S. Revenue

18 and over vaccine efficacy (VE) reduction in hospitalization estimate from CDC

2023–2024 vaccine dose, ≥ 7 days	36%
7–59 days earlier	51% (45–56)
60–119 days earlier	42% (35–48)
120–179 days earlier	15% (3–26)

293,000,000 U.S. Pop 12+

147M Flu Vaccine doses in
24-25 flu season

34.2M

COVID vaccinated last
respiratory season

~100 -112M

Received a flu shot, but not COVID last
respiratory season

~146 -158M

Did not receive COVID or flu shot in last respiratory season

Broad recognition from Societies and Guidelines for Antibodies in COVID

SOCIETY / GUIDELINE	PEMGARDA OR MAB	TARGET AUDIENCE
HIV.gov	PEMGARDA	Immunodeficiency
IDSA	Pemivibart	Infectious disease
NCCN – B-Cell Lymphomas	Pemivibart	Oncology
NCCN – Infection Prevention	Pemivibart	Oncology
Immune Deficiency Foundation (IDF)	PEMGARDA	Immunodeficiency
Leukemia and Lymphoma Society (LLS)	Pemivibart	Oncology
MS Society	PEMGARDA	Rheumatology
National Kidney Foundation	PEMGARDA	Solid organ transplant
American Cancer Society	PEMGARDA	Oncology
American College of Rheumatology	mAbs	Rheumatology
American Lung Association	Pemivibart	Oncology
National Council on Aging (NCOA)	PEMGARDA	Elderly
BreastCancer.org	PEMGARDA	Oncology
CLL Society	PEMGARDA	Oncology
American Academy of Allergy, Asthma, and Immunology (AAAAI)	PEMGARDA	Immunology
Vasculitis Foundation	PEMGARDA	Rheumatology



Invivyd poised to
 deliver on
*scalable form factor
 for broad access*



Launch Preparation *Underway*

*If approved