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): November 23, 2026

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.)**

205 Church Street
New Haven, CT **06510**
(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 November 23, 2026, Invivyd, Inc. (the "Company") issued a press release entitled "Invivyd Announces Positive DECLARATION Trial Data for Monoclonal Antibody VYD2311, and Ushers in a New Era for Immunization." A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

On November 23, 2026, the Company posted an updated corporate presentation on its website at www.invivyd.com. A copy of the presentation is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference into this Item 8.01.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 23, 2026
99.2	Corporate Presentation, dated November 23, 2026
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: November 23, 2026

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

Exhibit 99.1

INVIVYD INC.

Invivyd Announces Positive DECLARATION Trial Data for Monoclonal Antibody VYD2311, and Ushers in a New Era for Immunization

- *VYD2311 (ibramvibart) achieved high, durable antiviral activity predictive of 70-90% protection from symptomatic COVID-19 infection for both single- and multi-dose intramuscular arms*
- *Highly attractive safety and tolerability profile observed for single- and multi-dose VYD2311 arms, supporting broad population use*
- *Positive dialogue with U.S. FDA and HHS leadership has resulted in progress toward regulatory consistency between Invivyd monoclonal antibodies and related vaccines (e.g., COVID-19). Based on FDA feedback, upon planned VYD2311 BLA submission, Invivyd anticipates review for accelerated approval either by, or with input from, CBER*
- *Invivyd anticipates submitting a BLA based on DECLARATION and LIBERTY data to FDA in Q1 2027*
- *Investor call to be held at 8:30 am EST on November 23, 2026*

NEW HAVEN, Conn., Nov. 23, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced all interim analysis primary and secondary endpoints were met in the DECLARATION Phase 3 trial of VYD2311 (ibramvibart). VYD2311, administered via intramuscular injection (IM), demonstrated high and durable antiviral activity, consistent with Invivyd's target 70-90% protection from RT-PCR confirmed symptomatic COVID-19, versus placebo. VYD2311 demonstrated an overall highly attractive safety and tolerability profile in both single- and multi-dose arms. Invivyd intends to submit a Biologics License Application (BLA) seeking accelerated approval of VYD2311 for the prevention of symptomatic COVID-19 based on the positive interim analysis of the Phase 3 DECLARATION trial and the supportive data from the Phase 3 LIBERTY trial comparing VYD2311 and an mRNA-based COVID-19 vaccine.

The interim DECLARATION analysis, designed to support accelerated approval, includes placebo-controlled safety, neutralizing antibody titers, and predicted clinical benefit of VYD2311 from 2,359 subjects randomized 1:1:1 to receive a single 250mg IM dose of VYD2311, monthly 250mg IM doses of VYD2311, or volume-matched IM saline placebo. Clinical COVID-19 events from the trial remain fully blinded to support traditional approval as Invivyd continues to gather further events.

"Today marks the dawn of a new era in our 300-year history of human immunization. Today's data point to a possible healthier future for millions of Americans facing the threat of COVID-19. People have long sought new options for protection against COVID infection, and we intend to make VYD2311 available soon," said Marc Elia, Chairman and Chief Executive Officer of Invivyd. "Our mission continues: to make products that give people the immune protection they cannot create on their own. More, our technological and regulatory progress makes us enthusiastic to rapidly advance multiple novel monoclonal antibodies that can complement vaccines and treat infection, including mAbs for RSV, measles, mumps, rubella, Lyme, and others as our discovery advances.

Americans need high-quality solutions to important medical problems without the requirement for inflammation or exposure to a pathogen."

"Invivyd is making possible what has been elusive for years: giving people true protection from symptomatic COVID infection without experiencing inflammation and the safety and tolerability challenges of COVID-19 vaccines," said Robert Redfield, M.D., former director of the Centers for Disease Control and Prevention. "The unmet need in America today is to stop COVID infection and all of its downstream problems with a simple, safe, scalable medical solution. Invivyd's work with monoclonal antibodies, starting with adintrevimab, and then pemivibart, and now including VYD2311, has the potential to quickly become standard of care and stop COVID in its tracks."

In the DECLARATION interim analysis, VYD2311 generated mean antiviral titers consistent with expected clinical protection of 70-90% over the 90-day trial period for both dose arms. By contrast, COVID-19 vaccines are estimated by manufacturers to confer only a 30-35% reduction in medically attended COVID-19 for 90 days, falling to 15-20% thereafter (Slide 77 linked here). Invivyd expects single dose VYD2311 to protect from symptomatic COVID, medically attended or not, for approximately one year, without requiring inflammation, exposure to spike protein or liposomal mRNA. Multiple VYD2311 doses would confer higher protection against symptomatic COVID for longer, subject to an individual's choice.

Safety data for both single- and multi-dose arms was in-line with saline placebo, consistent with the intramuscular delivery of a high-quality antiviral monoclonal antibody.

Invivyd believes data from DECLARATION and also from the LIBERTY study, in which VYD2311 demonstrated superior safety and tolerability compared to an mRNA-based COVID-19 vaccine, combined with data from previous Invivyd randomized, placebo-controlled trials EVADE (adintrevimab) and CANOPY (pemivibart), compare highly favorably to the evidentiary basis used to approve updated COVID-19 vaccines.

Invivyd has been in ongoing discussions with American regulatory and health policy leadership at the Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA) and believes the discussion has achieved understanding of the need for regulatory pathways for monoclonal antibody prophylaxis equitable to vaccine prophylaxis. Upon Invivyd's VYD2311 BLA submission for accelerated approval, Invivyd anticipates FDA to begin formalizing regulatory processes consistent with this goal in order to enable more rapid innovation on behalf of Americans. Invivyd currently expects that BLA review of VYD2311, and future Invivyd prophylactic monoclonal antibodies, will be conducted either by, or with input from, CBER.

Conference Call & Webcast

Listeners can register for the webcast via this link. Analysts wishing to participate in the question-and-answer session should use this link. A replay of the webcast will be available via the company's investor website approximately two hours after the call's conclusion. Those who plan on participating are advised to join 15 minutes prior to the start time.

About VYD2311

VYD2311 is a novel monoclonal antibody (mAb) candidate being developed for COVID-19 to continue to address the urgent need for new prophylactic and therapeutic options. The pharmacokinetic profile and antiviral potency of VYD2311 may offer the ability to deliver clinically

meaningful titer levels through more patient-friendly means such as an intramuscular route of administration.

VYD2311 was engineered using Invivyd's proprietary integrated technology platform and is the product of serial molecular evolution designed to generate an antibody optimized for neutralizing contemporary virus lineages. VYD2311 leverages the same antibody backbone as pemivibart, Invivyd's investigational mAb granted emergency use authorization in the U.S. for the pre-exposure prophylaxis (PrEP) of symptomatic COVID-19 in certain immunocompromised patients, and adintrevimab, Invivyd's investigational mAb that has a robust safety data package and demonstrated clinically meaningful results in global Phase 2/3 clinical trials for the prevention and treatment of COVID-19.

About DECLARATION

DECLARATION is a Phase 3, randomized, triple-blind, placebo-controlled trial to evaluate VYD2311 efficacy and safety in prevention of symptomatic COVID in a broad population of participants including adults and adolescents both with and without risk factors for progression to severe COVID-19 at three months. Participants will receive either a single dose or monthly doses of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. Total enrollment of the trial is approximately 2,400 participants.

About LIBERTY

LIBERTY is a Phase 3, randomized, double-blind clinical trial to evaluate the safety, serum virus neutralizing antibody responses, and pharmacokinetics of VYD2311, an mRNA COVID vaccine, and co-administered VYD2311 with an mRNA COVID vaccine. Total enrollment of the trial was approximately 210 participants.

About Invivyd

Invivyd, Inc. (Nasdaq: IVVD) is a biopharmaceutical company devoted to delivering protection from serious viral infectious diseases, beginning with SARS-CoV-2. Invivyd deploys a proprietary integrated technology platform unique in the industry designed to assess, monitor, develop, and adapt to create best in class antibodies. In March 2024, Invivyd received emergency use authorization (EUA) from the U.S. FDA for a monoclonal antibody (mAb) in its pipeline of innovative antibody candidates. Visit https://invivyd.com/ to learn more.

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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," "future," "intends," "plans," "potential," "predicts," "projects," and "target" 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, expectations about the company's research and development activities, including the scope, timing, and results thereof; the potential of VYD2311 as a novel mAb candidate, including expectations about the protection from symptomatic COVID-19 infection versus placebo and the potential duration of protection, based on VYD2311 antiviral titer data from the DECLARATION interim analysis; expectations about the company's clinical trial designs, regulatory pathway and submissions, product profile, indication, patient populations, and administration paradigm for VYD2311; the company's beliefs,

based on DECLARATION and LIBERTY data, regarding the safety and tolerability of VYD2311; the company's plans to submit a BLA to the FDA seeking accelerated approval of VYD2311, and the timing thereof; the potential role of CBER with respect to VYD2311, as well as future Invivyd prophylactic mAbs; expectations about the public health landscape, potential role mAbs can play in infectious disease, and a possible new era for immunization; the potential to create a new standard of care; the potential of Invivyd to rapidly advance multiple novel mAbs that can complement vaccines and treat infection; the company's strategies and objectives; 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; 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 outcome of the company's engagement with regulators, including American regulatory and health policy leadership; potential changes in the regulatory environment; uncertainties related to the regulatory approval process, and available development and regulatory pathways, including eligibility for any expedited regulatory review and approval approaches; the company's ability to finalize its planned BLA submission seeking accelerated approval of VYD2311, and uncertainties regarding the FDA's acceptance and review, as well as the outcome, of any such BLA submission, including the scope of prescribing information and indication of VYD2311, if approved; uncertainties regarding the involvement of CBER with respect to the company's planned VYD2311 BLA submission; the ability of the DECLARATION clinical trial to continue to generate data to support conversion of any accelerated approval of VYD2311 to traditional approval; uncertainties regarding clinical trial enrollment, event accumulation rates, and statistical powering; 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; variability of results in models and methods used to predict activity against SARS-CoV-2 variants; whether the epitope that VYD2311 targets remains structurally intact and 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 ability to maintain a continued acceptable safety, tolerability, and efficacy profile of any product candidate following regulatory authorization or approval; the risk that a lack of awareness of mAb therapies and regulatory scrutiny of mAb therapies may adversely impact the development or commercial success of the company's product candidates; changes in expected or existing competition; the company's reliance on third parties; complexities of manufacturing mAb therapies; macroeconomic and political uncertainties; 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, 2025, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, each as 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

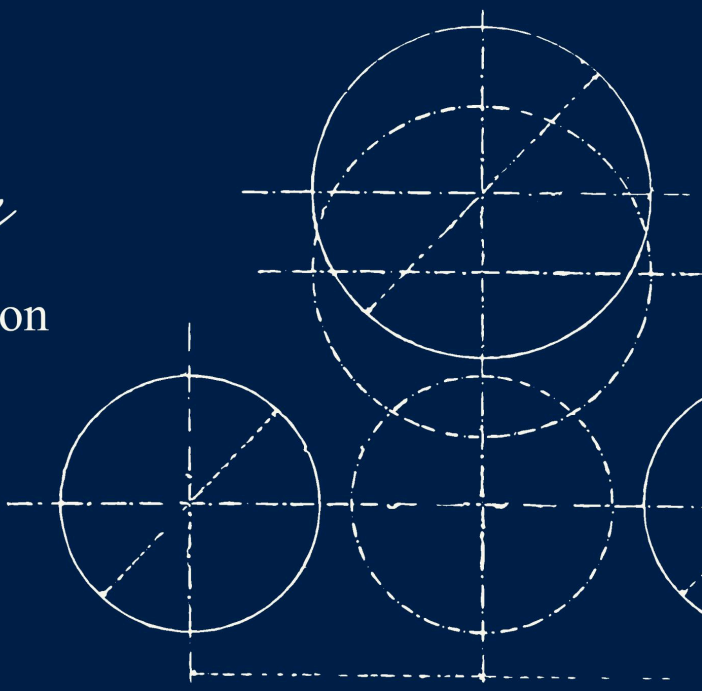
INVIVYD INC.

Declaration Study

VYD2311: A New Era in Immunization

Results of the Interim Analysis

November 2026



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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. 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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, 2025, and its Quarterly Report on Form 10-Q for the quarter ended September 30, 2026, each as 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.

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Agenda

01 **Executive Summary**

02 DECLARATION Topline Data

03 Regulatory & Next Steps

04 Commercial Opportunity

05 Q&A

OUR DECLARATION

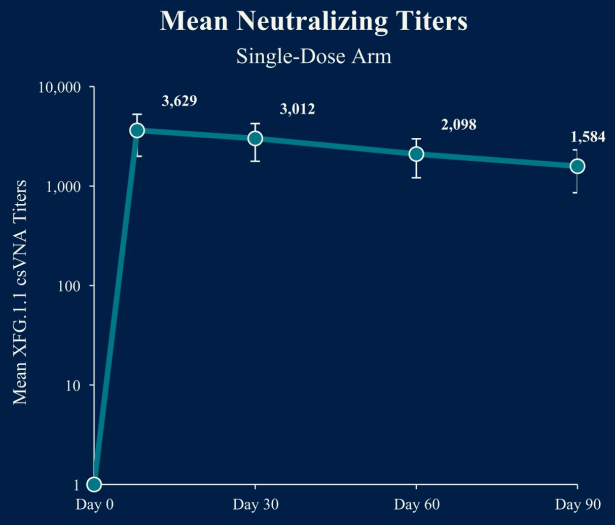
A new era in infectious disease

A better way to stay well

Immunity on demand

A revolution in COVID prevention

In DECLARATION, a single dose of VYD2311 delivers our target titers, predicting robust protection from symptomatic COVID-19



70-90%

predicted protection from symptomatic COVID-19 based on titers at Day 90

Abbreviations: csVNA: Calculated Serum Virus Neutralizing Antibody.

Overall safety appears indistinguishable from saline placebo

	Placebo (Saline IM) *(N=783)*	*VYD2311 IM Pooled Arms* *(N=1,568)*
Treatment-Related AE	**21.5%**	**18.4%**
Any AE	39.2%	37.9%

Note: Pooled Arms combine participants from single-dose and multi-dose arms. Abbreviations: AE: Adverse Event; IM: Intramuscular

DECLARATION VYD2311 related adverse events of note

Zero

hypersensitivity

anaphylaxis

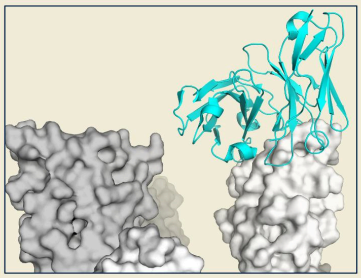
myocarditis

major adverse cardiac events

death

VYD2311 continues Invivyd's functionally identical mAb series

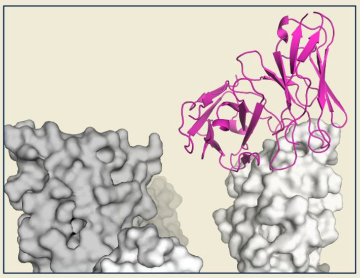
Adintrevimab Fv
Bound to Wuhan (WT) RBD



EVADE
Phase 2/3 · PrEP cohort

71% *Reduction*
in risk of symptomatic COVID-19 at D90 in seronegative individuals [1]

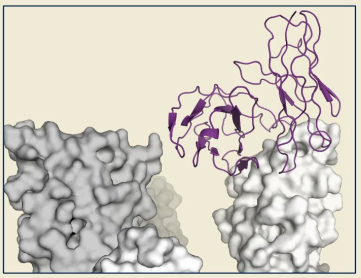
Pemivibart Fv
Bound to Omicron BA.5 RBD



CANOPY
Phase 3 · PrEP

94% *Reduction*
in risk of symptomatic COVID-19 at D90 in seropositive individuals [1]

VYD2311 Fv
Bound to XEC RBD



DECLARATION
Phase 3 · PrEP

70-90% *Estimated Reduction*[2]
in risk of symptomatic COVID-19 at D90 in seropositive individuals

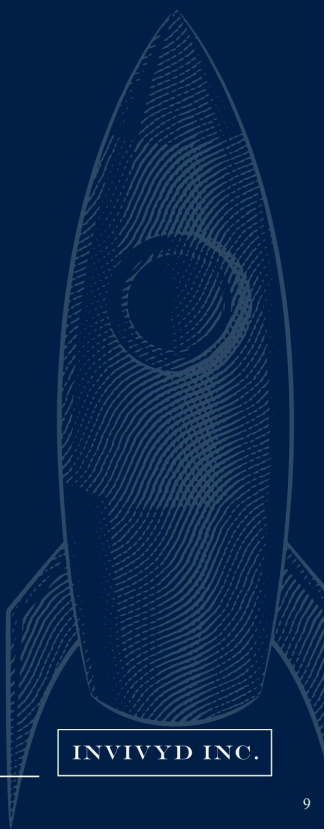
1. Figures provided represent relative risk reduction of COVID-19 versus placebo. 2. Estimated protection obtained by inputting the mean neutralizing titers into the Cox proportional hazards model derived from the Invivyd antibody exposure–response dataset (Yalcin 2026). Abbreviations: RBD: Receptor binding domain; PrEP: Pre-exposure prophylaxis. Source: Wolfe. Clin Infect Dis. 2025; Ison. Open Forum Infect Dis. 2023.

INVIVYD INC.

Immediate Next Steps

Plan to submit a BLA for VYD2311 for *Accelerated Approval* based on DECLARATION and LIBERTY data in Q1 2027

Accelerate launch preparation



Abbreviations: BLA: Biologics License Application.

INVIVYD INC.



Agenda

01 Executive Summary

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Our REVOLUTION clinical program

Liberty

- ✓ Superior VYD2311 safety and tolerability vs. an mRNA-based COVID vaccine
- ✓ Purely additive to human immune response (no vaccine interference)

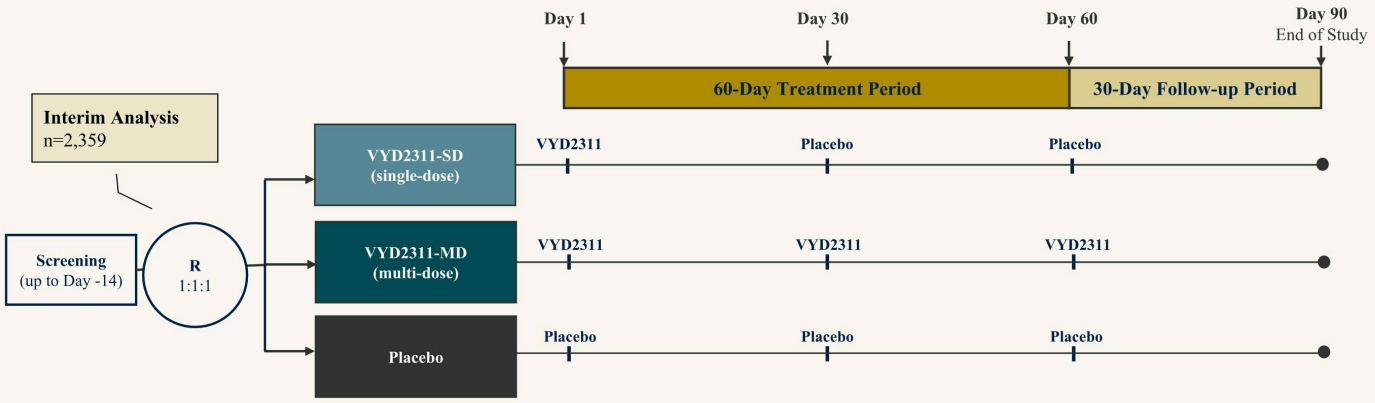
Declaration

- ✓ High, durable antiviral titers consistent with expectations for high protective clinical efficacy
- ✓ Safety indistinguishable from saline placebo

Confirmation

DECLARATION study extension to confirm protective benefit to support traditional approval, via collection of additional PCR+ symptomatic COVID events

Declaration



IA Primary and Key Secondary Endpoints: Titers ≥200 at Day 30, 60, and 90

IA Key Supportive Endpoint: Titers ≥500 and ≥1,000 at Day 30, 60, 90

Abbreviations: IA: Interim Analysis.

Baseline characteristics were well-balanced across study arms

	Saline Placebo (N=786)	VYD2311-SD (N=787)	VYD2311-MD (N=786)
Age (Years) - Mean	**51.3**	**51.1**	**51.4**
12 to <18 Years of Age (%)	2.9%	2.8%	2.8%
18 to <65 Years of Age (%)	74.8%	74.8%	74.8%
≥65 Years of Age (%)	22.3%	22.4%	22.4%
High Risk for Severe COVID-19 (%)	**87.7%**	**86.8%**	**86.1%**
Mod-Severe Immunocompromised (%)	**3.1%**	**3.0%**	**3.2%**
Time Since COVID-19 Vaccination or Infection			
≤180 Days (%)	11.8%	11.8%	11.8%
>180 Days (%)	88.2%	88.2%	88.2%
Sex (% Female)	**50.4%**	**50.2%**	**49.9%**
Height (cm) - Mean	**170.0**	**169.3**	**169.9**
Weight (kg) - Mean	**86.7**	**84.6**	**85.2**
Race (%)			
White (%)	51.8%	51.5%	53.4%
Black or African American (%)	40.7%	40.0%	38.3%
Asian (%)	3.6%	5.2%	4.8%
Other / Not Reported (%)	3.9%	3.3%	3.4%

Note: Data from IA Full Analysis Set. Abbreviations: SD: Single-Dose; MD: Multi-Dose.

VYD2311 safety and tolerability was comparable to saline solution

	Saline Placebo (N=783)	VYD2311-SD (N=770)	VYD2311-MD (N=798)
Any AE	**39.2%**	**40.0%**	**35.8%**
Grade 1	27.6%	27.1%	22.9%
Grade 2	10.3%	11.0%	11.5%
Grade 3	1.0%	1.7%	1.4%
Grade 4	0.3%	0.1%	0.0%
Grade 5	0.0%	0.0%	0.0%
Treatment-Related AE	**21.5%**	**20.3%**	**16.7%**
Injection Site Pain	17.0%	15.6%	13.2%
Injection Site Erythema	4.9%	5.2%	3.1%
Injection Site Swelling	2.8%	4.0%	3.5%
Fatigue	1.4%	0.3%	0.8%
Treatment-Related SAE	**0.0%**	**0.0%**	**0.0%**
Treatment Discontinuation due to AE[1]	**0.4%**	**0.6%**	**0.3%**
AESI	**0.0%**	**0.0%**	**0.0%**
Systemic Hypersensitivity Reactions (incl. anaphylaxis)	0.0%	0.0%	0.0%

Note: IA safety analysis set is based on treatment received rather than assigned at randomization. 1. Participants for whom an adverse event was the primary reason for discontinuation from treatment; percentages based on randomized participants (Full Analysis Set).
Abbreviations: AESI: Adverse Events of Special Interest; AE: Adverse Event; SAE: Serious Adverse Event; MD: Multi-Dose; SD: Single-Dose.

INVIVYD INC.

Our interim analysis antiviral endpoints draw directly from COVID-19 vaccine practice

PRIMARY ENDPOINT

≥200 titer

(Titer associated with ≥64% clinical protection)

Endpoint is met if the lower limit of the Clopper-Pearson exact 95% confidence interval of the proportion of participants reaching this titer at Day 90 greater than or equal to 70%

This endpoint is in line with multiple vaccines approved via Accelerated Approval using neutralizing titers as a surrogate endpoint

KEY SUPPORTIVE ENDPOINT

The predicted relative risk reduction of COVID-19 from antiviral titers

Endpoint quantifies the clinical protection from RT-PCR–confirmed symptomatic COVID-19 obtained by inputting the mean neutralizing titers into the Cox proportional hazards model derived from the Invivyd antibody exposure–response dataset (Yalcin 2026)

Virologic endpoint analysis conducted using XFG.1.1

- XFG.1.1 selected for epidemiologic relevance
- VYD2311 has demonstrated consistent pan-variant neutralization across the span of the pandemic
- Multiple virologic saltation events have not changed the epitope or meaningfully modified antiviral activity
- While Invivyd is prepared to make new monoclonal antibodies against COVID-19, it's not clear that will be required

3rd Party Positive Confirmation of Neutralization

D614G	HV.1	LB.1	LP.8.1.2
B.1.617.2 (Delta)	HK.3	KP.2.3	LF.7.9
BA.1	JN.1	KP.3.3.1	NB.1.8.1
BA.2	JD.1.1	KP.3.3.2	XFG
XBB.1.5	GE.1.2.1	MK.3	XFG.17.2.1
XBB.1.16	JN.1.13.1	LP.1	XFG.14.1
XBB.1.5.10	KQ.1	XEC	XFZ
XBB.1.5.1	KP.1.1	LF.7	BA.3.2.2
XBB.2.3	KP.2	MV.1	PQ.2.8.1
FL.1.5.1	KP.3	LP.8.1	XFG.1.1
XBB.1.5.CONV0817	JN.1.50	MC.10.2	
BA.2.86	KP.3.1.1	LF.7.2.1	

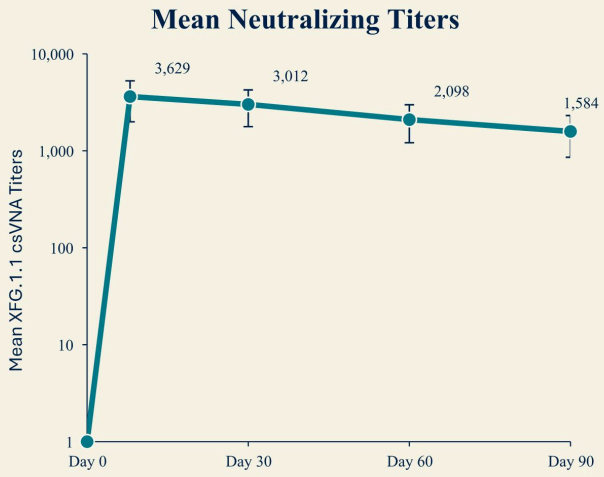
Both single- and multi-dose VYD2311 met and exceeded the primary endpoint by a substantial margin

VYD2311-SD (N=519) SERORESPONSE RATE		VYD2311-MD (N=562) SERORESPONSE RATE	
99.9%	DAY 30[1]	99.9%	DAY 30[1]
99.6%	DAY 60	99.8%	DAY 60
97.3%	DAY 90	100.0%	DAY 90
(95% CI: 95.5%-98.6%, p<0.00001)		(95% CI: 99.3% - 100%, p<0.00001)	

Note: IA PK Analysis Set ccomprised from original n=1,818 participants enrolled before expansion cohort.
1. Single-dose and multi-dose arms were pooled for analysis at Day 30. Abbreviations: csVNA: Calculated Serum Virus Neutralizing Antibody; SD: Single-Dose; MD: Multi-Dose.

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VYD2311 single-dose titers met the key secondary endpoints and predict robust clinical protection



Estimated Relative Risk Reduction in Symptomatic COVID-19

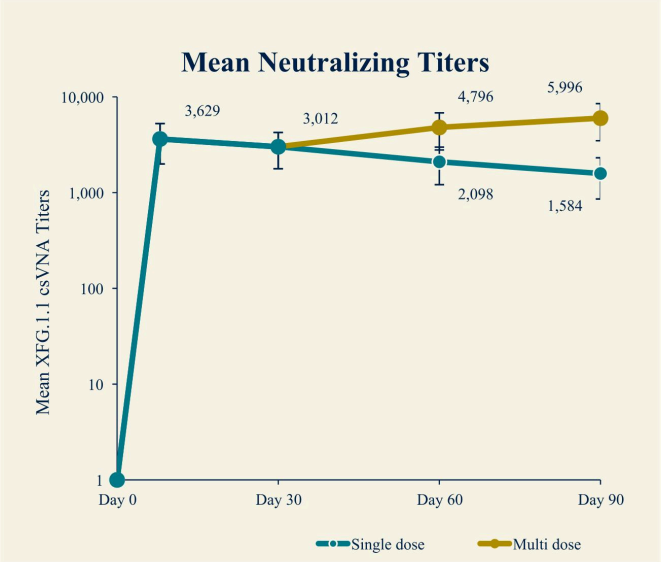
	Day 30	Day 60	Day 90
VYD2311-SD	**77.8%[1]**	**76.2%**	**74.7%**

Estimated by applying Invivyd antibody exposure-response dataset-derived Cox proportional hazards model (Yalcin 2026) to observed titers

Note: IA PK Analysis Set ccomprised from original n=1,818 participants enrolled before expansion cohort. 1. At Day 30, GMT XFG.1.1. csVNA Titers were pooled for the VYD2311-SD and VYD2311-MD cohort.
Abbreviations: csVNA: Calculated Serum Virus Neutralizing Antibody. SD: Single-Dose

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VYD2311 multi-dose titers also met the key secondary endpoints and predict robust clinical protection



Estimated Relative Risk Reduction in Symptomatic COVID-19[1]

	Day 30	Day 60	Day 90	Day 180[3]	Day 365[3]
VYD2311-SD	77.8%[2]	76.2%	74.7%	70%	56%
VYD2311-MD	77.8%[2]	79.7%	80.5%	77%	67%

MD Day 180 and 365 assume no additional doses

Note: IA PK Analysis Set ccomprised from original n=1,818 participants enrolled before expansion cohort. 1. Average relative risk reduction estimated by applying Invivyd antibody exposure-response dataset-derived Cox proportional hazards model (Yalcin 2026) to observed titers 2. At Day 30, GMT XFG.1.1. csVNA Titers were pooled for the VYD2311-SD and VYD2311-MD cohort at Day 30 3. Based on PK analysis projected titers.
Abbreviations: csVNA: Calculated Serum Virus Neutralizing Antibody; SD: Single-Dose; MD: Multi-dose.

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DECLARATION and LIBERTY
Key Takeaways for VYD2311 and the potential future of protection from COVID-19

Protection	Predicts 70-90% protection from symptomatic COVID-19 from a single dose with additional protection possible on demand
Durability	A year or more from just a single dose (expected protection >50% at one year)
Safety & Tolerability	Indistinguishable from saline solution; superior to an mRNA-based COVID-19 vaccine[1]
Dosing	Multi-dose supportive on-demand dosing with higher titers
Additive Protection	Wholly-additive to human immunity; suitable for combination with vaccination, if desired[2]
Variant Agnostic	Maintained neutralization across all clinically relevant SARS-CoV-2 variants to data

1. mRNA vaccine COMIRNATY® (COVID-19 vaccine, mRNA) was utilized in the LIBERTY study. 2. Subject to FDA approval and product prescribing information



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Accelerated approval is drawn directly from COVID-19 vaccine practice

COVID-19 VACCINES

2020–21
COVID-19 vaccines demonstrated clinical benefit

2022–Current
COVID-19 vaccines used **neutralizing antibodies** as primary endpoints

INVIVYD MABS

2021–22
Invivyd mAb demonstrated clinical benefit

2023–24
Invivyd mAb demonstrated clinical benefit

2026
Invivyd provides neutralizing antibodies with a third demonstration of clinical benefit pending

Source: Wolfe. Clin Infect Dis. 2025; Ison. Open Forum Infect Dis. 2023; Prasad. NEJM. 2025; COMIRNATY FDA Label. Accessed Nov 21, 2026; SPIKEVAX FDA Label. Accessed Nov 21, 2026; mNEXSPIKE FDA Label. Accessed Nov 21, 2026. Nuvoxivid FDA Label. Accessed Nov 21, 2026.

Immune prophylaxis is commonly regulated using neutralizing antibody titers

~16 COVID-19 vaccine update approvals and authorizations (and counting…)

Unclear

when updated placebo-controlled vaccine efficacy will be determined



EXCLUSIVE

Pfizer, BioNTech halt US COVID vaccine study after recruitment struggles

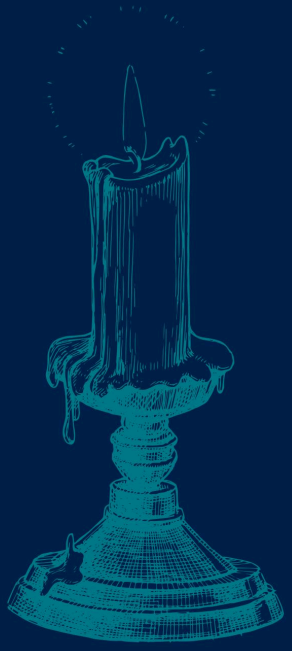
By **Bhanvi Satija**

April 1, 2026 11:39 AM EDT · Updated April 2, 2026

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Source: Reuters. "Pfizer, BioNTech halt US COVID vaccine study after recruitment struggles" Published April 1, 2026. FDA.gov. "SPIKEVAX". Accessed Nov 22, 2026; FDA.gov. "COMIRNATY". Accessed Nov 22, 2026; FDA.gov. "NUVOXIVID". Accessed Nov 22, 2026; FDA.gov. "MNEXSPIKE". Accessed Nov 22, 2026

DECLARATION trial to continue as confirmatory study



Confirmatory Trial Overview

Primary endpoint remains RT-PCR–confirmed symptomatic COVID-19

COVID-19 events accrued to date remain blinded and will contribute to the final clinical efficacy analysis

Enrollment Expansion

Plan to optimize timing and geography of study recruitment to match the most productive portions of DECLARATION to date

Full statistical power may be achieved with additional enrollment similar to initial DECLARATION cohort (n ≈ 1,800)

DECLARATION expansion designed to offer larger potential patient numbers to allow for flexibility



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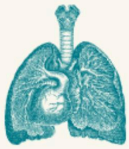
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COVID continues to infect millions of Americans annually…

Preliminary 2025-26 U.S. COVID-19 Burden:
CDC Estimates (Oct 1, 2025 – Oct 3, 2026)



5.7M–15.2M
COVID-19 Illnesses



1.1M–2.8M
COVID-19 Outpatient Visits



180K–280K
COVID-19 Hospitalizations



19K–49K
COVID-19 Deaths

1. 3.3% of U.S. adults reported current long COVID in the 2024 National Health Interview Survey. Source: CDC. "Preliminary Estimates of COVID-19 Burden" Accessed Oct 10, 2026; Jia. Front Public Health. 2026; Lim. BMC Glob Public Health. 2025.

… and damage extends well beyond the acute infection

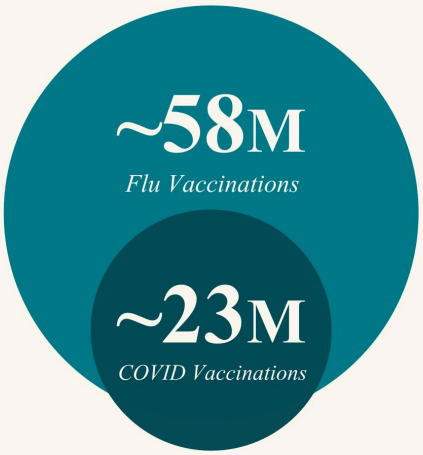
~9M

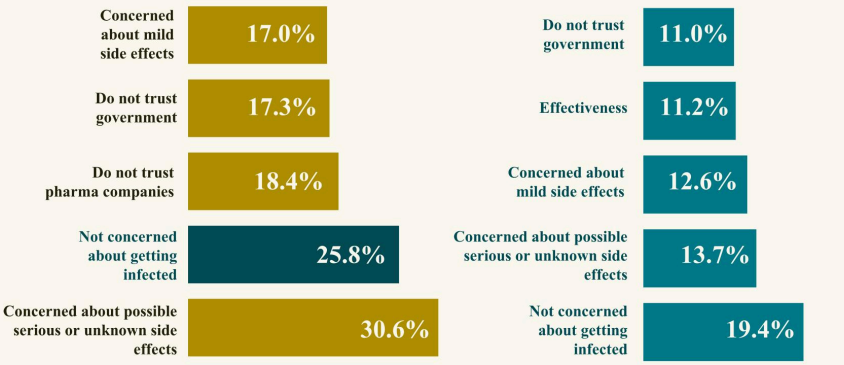
adults in the U.S. reported ***currently experiencing long COVID symptoms***[1]

Each incremental encounter increases risk of post-acute sequelae *even in a boosted population*

Many Americans do not get vaccinated for COVID-19 due to safety fears and mistrust

COVID-19 Vaccinations Administered in Pharmacies and Medical Offices[1]
2025-2026 Season; ≥18 years





National CDC survey of adults (≥18 years) conducted Feb and March 2026. Data are based on responses regarding COVID-19, flu, and RSV vaccination concerns, issues, and motivators. Survey participants instructed to select ALL that apply

1. 18 years and older; Projected pharmacy estimates are based on IQVIA, Longitudinal Prescription Claims (LRx) and vaccinations administered in retail pharmacies. The projected physicians' medical offices estimates are based on IQVIA's Medical Claims (Dx). Vaccinations administered in workplaces, community locations, long-term care settings, and other medical settings such as public health clinics are not represented in these data. Source: CDC. Influenza Vaccinations Administered in Pharmacies and Physician Medical Offices*, Adults, United States. Published Mar 25, 2026; CDC. COVID-19 Vaccinations Administered in Pharmacies and Medical Offices*, Adults 18 Years and Older, United States. Published Mar 25, 2026; National Center for Immunization and Respiratory Diseases, U.S. Centers for Disease Control and Prevention. Vaccination Concerns, Issues, and Motivators: RespVaxView, Accessed Oct 5, 2026.

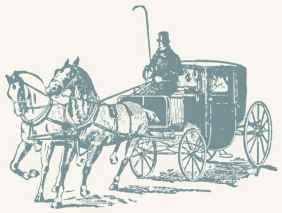
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Compared to standard-of-care COVID vaccines, VYD2311 appears roundly superior

	VYD2311		mRNA COVID VACCINE	
EFFICACY	*70–90%*	expected protection from symptomatic COVID-19 from a single dose at Day 90	*30–35%*	reduction in medically attended COVID-19 for 90 days, as estimated by manufacturer
DURABILITY	*>50%*	expected protection at 12 months modeled w/ single-dose	*15–20%*	reduction in medically attended COVID-19 Day 90-120
SAFETY	*Superior Safety*	safety and tolerability indistinguishable from placebo; superior to an mRNA COVID vaccine[1]	*Highly Reactogenic*	requires inflammatory immune response and exposure to spike protein
BREADTH	*Broadly Neutralizing*	maintained neutralization across all clinically relevant SARS-CoV-2 variants to data	*Strain Specific*	annual strain updates required

1. mRNA vaccine COMIRNATY® (COVID-19 vaccine, mRNA) was utilized in the LIBERTY study. Source: Vicic. Oral Presentation at IDWeek. 2026.

We are looking forward to radically improving on PEMGARDA®





PEMGARDA®

4,500 mg intravenous infusion

1-hour infusion and 2-hour post-infusion monitoring time

Accessible only to moderate-to-severe IC individuals

Boxed warning for anaphylaxis

VYD2311*

Single 250 mg intramuscular injection

Safety and tolerability indistinguishable from placebo

Massive improvement in convenience

Administration at retail pharmacies and other sites of care

*Anticipated if approved and subject to product prescribing information. Abbreviations IC: Immunocompromised

Our commercial efforts have been transitioning from PEMGARDA support to VYD2311 pre-launch market access activity

Seeing strong and broad interest across Pharmacy and Integrated Delivery Networks to stock VYD2311[1]

Examples include:

National retailers with thousands of locations who have the ability to serve consumers that are short on medical providers.

A national grocery retailer with over 1,000 in-store pharmacies across 35 states.

Integrated Health Systems which contain hospitals, outpatient sites, and health plans. The top two alone combine for over 80 hospitals and over 1,400 outpatient care sites.



In 2027, we will be pleased to conduct a **medical and commercial Investor Day** to update on progress

1. Subject to FDA approval and product prescribing information.



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