

# INVIVYD INC.

## Invivyd Announces REVOLUTION Program Progress and Advancement of Novel, Potential First- and Best-in-Class Measles Monoclonal Antibody Candidate VMS063 for Treatment and Prevention of Measles

April 9, 2026

- *Confirmed, pooled, blinded COVID-19 events in the ongoing Phase 3 DECLARATION study of VYD2311 accumulated to date (~ 50% of study progress) can already provide sufficient statistical power to support the high end of anticipated VYD2311 efficacy*
- *Invivyd conducted a pre-specified sample size re-estimation analysis when 1,500 of 1,818 enrolled patients reached Day 45 of 90 total days (April 6<sup>th</sup>), designed to add robustness given future event rate variability; that upsizing was triggered and increases confidence in overall study statistical power*
- *DECLARATION upsizing provides ~500 additional subjects and will likely shift study result timing modestly, by approximately two months, from original “mid-year” guidance to Q3 2026*
- *Invivyd and the U.S. FDA have aligned on an initial Pediatric Study Plan for the BLA-directed pivotal pediatric immunobridging and safety “DRUMMER” clinical trial for VYD2311*
- *Invivyd today announced the discovery and advancement of VMS063, a novel, highly potent, broadly in vitro neutralizing, high resistance barrier, half-life-extended, potentially first- and best-in-class monoclonal antibody candidate for the treatment and prevention of measles*
- *Invivyd has begun IND-enablement and regulatory outreach to support rapid VMS063 development; goal is expedited development with target IND readiness in late 2026*
- *Management to host conference call this morning, April 9<sup>th</sup>, at 8:30AM ET*

NEW HAVEN, Conn., April 09, 2026 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced progress in its REVOLUTION clinical program for VYD2311, a novel monoclonal antibody investigational candidate for the prevention of symptomatic COVID-19. Invivyd also announced today the discovery and advancement of a novel, potentially first- and best-in-class measles monoclonal antibody candidate for treatment and prevention of measles discovered using Invivyd's proprietary technology.

### **DECLARATION Study Update and New “DRUMMER” Study**

The DECLARATION Phase 3 pivotal study is Invivyd's Biologics License Application (BLA)-directed clinical trial assessing the safety and efficacy of single and multi-dose VYD2311 for the pre-exposure prophylaxis of COVID-19 compared to placebo over 90 days. The study includes a prospectively designed, conservative, algorithmic sample size re-estimation pooled, blinded analysis aimed at ensuring adequate COVID-19 clinical events and associated statistical power given the variability of COVID-19 attack rates in community. As of the sample-size re-estimation analysis, conducted when the first 1,500 (of 1,818 total) subjects reached Day 45 (April 6<sup>th</sup>), clinical events already accrued to date can support statistical powering for the high end of anticipated VYD2311 efficacy levels with approximately half of the base DECLARATION study still to go. The sample size re-estimation algorithm was designed conservatively with the aim of accomplishing strong statistical power to accommodate a range of potential VYD2311 efficacy results and COVID events in the trial, and upsizing was triggered.

DECLARATION study upsizing includes approximately 500 additional subjects, in addition to 1,818 total randomized subjects in the initial population. Depending on recruitment rates, top-line results are now expected to shift from “mid-year” 2026 (defined as either 2<sup>nd</sup> or 3<sup>rd</sup> quarter), to in the third quarter of 2026. Invivyd will provide more detailed timing guidance as recruitment proceeds. The upsizing, combined with event accumulation to date, provides strong additional confidence and projected statistical support for a wider range of observed VYD2311 efficacy levels.

Invivyd has also aligned with the U.S. Food and Drug Administration (FDA) on an initial Pediatric Study Plan for an efficient safety and immunobridging study to support potential BLA for VYD2311 in children aged 0-11 years. The “DRUMMER” study will be actioned only if the pivotal DECLARATION study is successful. Invivyd will provide more detailed guidance on DRUMMER study design and timing when appropriate.

“We are thrilled with our progress in the DECLARATION study. Pooled, blinded COVID-19 event accumulation is already robust, and our conservative upsizing algorithm means that we can move to higher confidence in statistical power with very modest additional time. This re-sizing was designed prospectively with our rapid recruitment speed in mind and our desire for the most robust potential dataset. We have an extraordinary, high-value opportunity to change infectious disease medicine near-term,” noted Marc Elia, Chairman of the Invivyd Board of Directors. “We are pleased to add more confidence to our efforts to cement

long-term change in COVID-19 prevention by making the multi-billion dollar category of repeat mRNA COVID vaccine boosts a second-line option, if indeed these vaccines remain on the market at all going forward. We continue to make great progress in the REVOLUTION program with the U.S. FDA, including aligning on a rapid pathway to pediatrics. This pathway, combined with our measles and previous RSV discoveries, should indicate that we are building on our work in COVID to create a fully integrated multi-virus platform company capable of rapidly generating high value medicines that have immediate utility in American infectious disease.”

### **Novel Measles Antibody VMS063**

Invivyd today also announced the discovery and advancement of a novel, highly potent, half-life-extended, high resistance barrier measles monoclonal antibody candidate, VMS063. VMS063 targets the measles Fusion (F) protein and is designed to lock the trimeric measles Fusion protein into a pre-fusion configuration, thereby preventing cell entry, similar to approved pediatric respiratory syncytial virus (RSV) monoclonal antibodies. VMS063 could be the first precision therapy for measles, as well as a potentially important passive prophylaxis option to supplement or enhance measles vaccination for certain populations at increased risk of symptomatic disease.

VMS063 demonstrates highly potent in vitro neutralization of measles virus in gold-standard assays including in pseudovirus assays (high picogram / milliliter IC50s) and authentic measles virus assays (low single digit nanogram / milliliter IC50s) across relevant measles lineages such as currently circulating B3, D8, and ancestral Edmonston lineages, as well as against multiple polymorph variants derived from current clinical sequencing. The epitope targeted by VMS063 on the measles F protein is conserved across all described measles variants in global circulation across the past ~50 years. VMS063 is half-life extended to support the best possible prophylactic and therapeutic profile following a single dose, and exhibits excellent biophysical characteristics associated with high developability, stability, and manufacturing yields. Invivyd has moved VMS063 towards IND-enabling studies and manufacturing for near-term clinical development.

The United States is facing a critical measles virus inflection point in 2026, with measles incidence reaching levels not seen in decades. In 2025, outbreaks spanned more than thirty states and the first measles deaths in a decade were reported on U.S. soil. As of March 2026, U.S. disease burden in 2026 is on track to exceed 2025. As pediatric and community vaccination rates dip below the thresholds required for herd immunity, a significant “immunity gap” has emerged. More than nine million school-age children are estimated to be unprotected against measles in the U.S. today along with many millions more adults who are immune compromised. More, as one of the most infectious viruses known to exist, and as a virus uniquely capable of destroying human immunologic memory, measles has the potential to impose a substantial burden on the healthcare system as infection spreads.

“There is no authorized or approved treatment for symptomatic measles, which, while often self-limiting, carries meaningful probability of serious complications including encephalitis and other inflammatory acute manifestations of disease, up to and including death.” said Michael Mina, M.D., Ph.D., Chief Medical Officer of Invivyd. “The measles vaccine is among the greatest achievements in the history of public health and remains the cornerstone of measles prevention. But vaccines have limits, and for too long, clinicians have lacked an adequate option for a range of patients left vulnerable, including infants too young for vaccination, pregnant women, and immunocompromised persons. These populations represent millions of Americans facing a rapidly resurging virus with nothing between them and infection. This is the gap we are proudly working to fill.”

The potential therapeutic and prophylactic applications of VMS063 include the following unmet needs and major medical use cases:

- 1) Treatment of symptomatic measles, with the aim of shortening duration of symptoms and reducing severe complications such as encephalitis or opportunistic infections subsequent to measles’ post-acute “immune amnesia.”
- 2) Pre- and post-exposure passive prophylaxis to prevent or respond to outbreaks, and to provide a more physiologic, targeted alternative to the measles vaccine, with the aim of re-establishing functional eradication without requiring additional vaccination or vaccination of vaccine-hesitant populations.
- 3) Early childhood passive prophylaxis (akin to RSV) to cover the pre-vaccine pediatric risk window and bridge infants to safe, optimal vaccination. Such strategy can include the aim of improving measles vaccination by safely delaying vaccination to enable greater early childhood immunologic and neurocognitive development prior to vaccination.

Invivyd plans to provide further discovery updates on additional pathogens that may offer similar opportunities for advancing standard of care via monoclonal antibody later in 2026.

### **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 (NCT07298434) 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 a monthly dose of VYD2311, each administered via intramuscular (IM) injection, compared to placebo. Total enrollment of the trial is expected to be 1770 participants.

#### **About VMS063**

VMS063 is a monoclonal antibody candidate engineered via Invivyd's proprietary antibody discovery platform to target a highly conserved protein of a measles virus. The antibody has shown sub-nanomolar potencies across all variants tested in vitro to date.

#### **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," "intends," "plans," "potential," "predicts," "projects," "future," 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, plans related to the company's research and development activities, and the timing and potential results thereof; expectations regarding the company's clinical trial designs, enrollment, event accumulation and progress, regulatory pathway, product profile, indication, patient populations, and administration paradigm for VYD2311, including the company's REVOLUTION clinical program and the timing of results related thereto; the potential of VYD2311 as a novel mAb candidate for the prevention of COVID-19; the estimated market for COVID-19 vaccination; the company's devotion to delivering protection from serious viral infectious diseases; the potential of VMS063 as a potential first- and best-in-class mAb candidate for treatment and prevention of measles; expectations regarding the measles landscape, including the potential burden of measles on the healthcare system, and beliefs about the potential therapeutic and prophylactic applications of VMS063; the potential of Invivyd to create a fully integrated multi-virus platform company capable of rapidly generating high value medicines that have immediate utility in American infectious disease; the company's expectations about potential pipeline expansion and future announcements related thereto; 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 with respect to VYD2311 and VMS063; whether or not any preclinical candidate identified by the company is determined to be suitable for clinical development; clinical trial site activation, enrollment, and event accumulation rates; 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; the predictability of clinical success of the company's product candidates based on neutralizing activity in nonclinical studies and the assessment of other in vitro properties; potential variability in neutralizing activity of product candidates tested in different assays, such as pseudovirus assays and authentic assays; unexpected safety or efficacy data observed during preclinical studies or clinical trials; variability of results in models and methods used to predict neutralizing activity; 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 BLA submission for VYD2311; how long the EUA granted by the FDA for pemivibart will remain in effect and whether such EUA is revised or revoked by the FDA; the ability to maintain a continued acceptable safety, tolerability, and efficacy profile of any product candidate following regulatory authorization or approval; whether the epitopes that pemivibart and VYD2311 target remain 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 risk that a lack of awareness of mAb therapies and regulatory scrutiny of mAb therapies to prevent or treat COVID-19 or other infectious diseases 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, 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](http://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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