# Invivyd Files Citizen Petition Urging FDA to Focus on Monoclonal Antibodies For Endemic-Virus-Era COVID-19 Prevention, and to Re-Assess COVID-19 Vaccine Efficacy

May 14, 2025

WALTHAM, Mass., May 14, 2025 (GLOBE NEWSWIRE) -- Invivyd, Inc. (Nasdaq: IVVD) today announced it has submitted a Citizen Petition with the U.S. Food and Drug Administration (FDA) calling on the Agency to evolve from historical approaches to the development of vaccines and monoclonal antibodies (mAbs) for COVID-19 prevention, in order to rebuild American's trust in scientific data, public health recommendations, and preventatives, including mAbs and vaccines, when effective. Americans will need a robust arsenal to manage COVID-19 and other viral infectious disease for decades to come.

Over the last few years, Americans have undergone an extraordinary change, as has SARS-CoV-2. In 2020, Americans were immunologically naïve to any exposure to the virus that causes COVID-19 when original vaccine efficacy studies were conducted, but today virtually all Americans have some immunologic memory from either subsequent vaccination or infection from circulating virus.

Further, during the first two years of the pandemic, and critically, during the original vaccine field studies, the SARS-CoV-2 virus moved from Wuhan through Delta lineages, which were highly susceptible to human immune pressure, to highly immune evasive Omicron lineages beginning late 2021. Indeed vaccines produce lower antiviral titers following vaccination against Omicron lineages than they did against original Wuhan lineages.

Finally, the biological phenomena leading to the rapid waning of vaccine efficacy over months is now better understood than it was in 2020, requiring prospective long-term evaluation in clinical trials rather than the short-term studies that provide published vaccine efficacy estimates on product labels.

By contrast, developers of monoclonal antibody COVID-19 prophylaxis medicines, such as Invivyd, have conducted recent placebo-controlled safety, antiviral activity, and efficacy studies in contemporary, seropositive populations, against evasive virus, and over the long term.

Leveling the playing field can unlock the ability of industrial sponsors like Invivyd to more rapidly develop and scale non-vaccine solutions for the major populations of Americans that would benefit from high quality alternatives. With this in mind, Invivyd filed a Citizen Petition with FDA, urging FDA to evaluate anew COVID-19 mRNA vaccine effectiveness and consider new clinical trials that assess COVID-19 vaccines 1) in a randomized placebo-controlled trial conducted in a modern U.S. population that includes seropositive patients in both study drug and placebo arms; 2) against contemporary immune-evasive Omicron viruses; and 3) to measure efficacy over a duration of 6 months or longer to ensure adequate protection. Such a data-driven approach would resemble the process undertaken to support modern monoclonal antibody development. This approach is critical to ensure that COVID-19 vaccines maintain a positive risk-benefit profile based on contemporary data.

In addition, in order to optimize patient access to alternative preventative medicines like mAbs, the Citizen Petition recommends that FDA should make clear that Biologics License Application (BLA) approval is appropriate based on serum virus neutralizing antibody (sVNA) titers, which are gold standard surrogate endpoints. Use of sVNA surrogate data from a clinical trial as the basis for approval – traditional or accelerated – and translation of sVNA titer to estimates of clinical benefit as virus variants evolve, would offer substantial benefits to patients and vulnerable populations, healthcare providers and care teams, sponsors, and regulators.

**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.

**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," "potential," "predicts," "projects," and "future" 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, the company's beliefs related to the COVID-19 landscape and development of vaccines and mAbs for COVID-19 prevention, including

those beliefs expressed in its Citizen Petition filed with the FDA; the company's recommendations to the FDA described in its Citizen Petition, and the anticipated impacts and benefits thereof; the potential for industrial sponsors like Invivyd to more rapidly develop and scale non-vaccine solutions for the major populations of Americans that would benefit from high quality alternatives; Invivyd's devotion to delivering protection from serious viral infectious diseases; and other statements that are not historical fact. The plans, intentions or expectations disclosed in the company's forward-looking statements may not actually be achieved, 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 actual results to differ materially from the results described in or implied by the forward-looking statements, including, without limitation: the FDA's response to the company's Citizen Petition, and the timing thereof; whether or not the company's recommendations to the FDA described in its Citizen Petition are implemented; uncertainties related to the regulatory authorization or approval process, and available development and regulatory pathways for authorization or approval, particularly for mAbs; changes in the regulatory environment; changes in expected or existing competition; 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 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, 2024, 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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