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Matinas BioPharma Announces FDA Conditional Acceptance of LYPDISO™ as the Brand Name for MAT9001

BEDMINSTER, N.J., Jan. 04, 2021 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today announced the U.S. Food and Drug Administration (FDA) has conditionally accepted LYPDISO™ as the proposed brand name for MAT9001, the Company's investigational drug for treatment of cardiovascular and metabolic conditions. The Company also announced that the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance, approving the Company's application to register the LYPDISO brand name as a federal trademark.

The name LYPDISO (pronounced "Lip-DEE-so") was developed in compliance with FDA's Guidance for Industry, Contents of a Complete Submission for the Evaluation of Proprietary Names. Based on the development program, which included research with physicians and pharmacists, as well as an international name assessment, the Company believes LYPDISO is a proprietary name with strong marketing potential that is also consistent with FDA's goal of preventing medication errors and potential harm to the public by ensuring that only appropriate proprietary names are approved for use. A request for proprietary name review and final approval for LYPDISO will be included when Matinas submits a New Drug Application (NDA) for MAT9001.

"We are pleased that the FDA has conditionally accepted the name LYPDISO for our lead product candidate and that we have also received a Notice of Allowance from the USPTO toward registering this brand as a federal trademark," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "These meaningful steps align with our continued clinical progress, as well as preparation for the commercialization of LYPDISO, if approved. We eagerly await topline data from our ENHANCE-IT head-to-head study vs. Vascepa® in the first quarter of 2021, followed by the commencement of our Phase 3 program for LYPDISO in the second half of 2021. We continue to believe that LYPDISO, if approved, would provide an important and potentially best in class product to help treat patients suffering from cardiovascular and metabolic conditions."

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care for patients in areas of significant unmet medical need. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

MAT9001, the Company's lead product candidate for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia. MAT9001 is currently in a second head-to-head comparative study against Vascepa® (ENHANCE-IT), with topline data expected in the first quarter of 2021.

In addition, Matinas is developing a portfolio of products based upon its proprietary lipid nanocrystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them orally bioavailable, less toxic, and targeted to cells and tissues.

MAT2203 is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, primarily used to treat serious invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT is currently enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

MAT2501 is an oral, encochleated formulation of the broad-spectrum aminoglycoside antibiotic medicine amikacin, primarily used to treat chronic and acute bacterial infections. The Company recently announced that it has been awarded up to \$3.75 million from the Cystic Fibrosis Foundation (CFF) to support development of MAT2501 toward an indication to treat nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

Forward Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's strategic focus and the future development of its product candidates, including MAT9001, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, the Company's ability to identify and pursue development and partnership opportunities for its products or platform delivery technology on favorable terms, if at all, and the ability to obtain required regulatory approval and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk

Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's product candidates are all in a development stage and are not available for sale or use.

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