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Matinas BioPharma Initiates Dosing in Phase 1 Study of Potential First Oral Aminoglycoside Antibiotic Drug MAT2501

– Phase 1 study of oral amikacin in healthy volunteers expected to complete in Q1 2022 –

BEDMINSTER, N.J., Oct. 21, 2021 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) platform delivery technology, today announced that it has dosed the first patient in a Phase 1 single ascending dose (SAD) pharmacokinetic study in healthy volunteers with MAT2501. The Company expects to complete enrollment of the Phase 1 SAD study in the first quarter of 2022, with data anticipated during the second quarter of 2022. Pending successful completion of the Phase 1 SAD study, the Company expects to start a Phase 2 program in patients with nontuberculous mycobacterial (NTM) infections by the first quarter of 2023, following required longer-term preclinical toxicology studies to be conducted during 2022.

MAT2501 is being developed to potentially become the first oral aminoglycoside, with the application of Matinas' proprietary LNC platform technology to the broad-spectrum antibiotic drug amikacin. Amikacin is a highly potent antibiotic used to treat chronic and acute bacterial infections, including problematic gram-negative infections. Currently, amikacin's use (IV or inhalation) is severely limited due to associated major side effects including nephrotoxicity and ototoxicity (hearing loss and potentially permanent impairment of balance), as well as inhalation complications with certain approved therapies.

"Following the robust data from MAT2203 in the EnACT trial announced in September 2021, MAT2501 now becomes our second clinical stage product candidate demonstrating the benefits of our LNC platform delivery technology in treating infectious diseases. Our goal with MAT2501 is to develop the first oral aminoglycoside, which could transform the use of this important class of drugs," stated Jerome D. Jabbour, Chief Executive Officer of Matinas. "At its core, our LNC platform facilitates intracellular delivery. We believe that MAT2501's ability to orally, effectively, efficiently and safely deliver therapeutic levels of amikacin that specifically target the lung, without use-limiting toxicity, clearly distinguishes it from other available therapies for the treatment of NTM infections. Furthermore, we believe that the ultimate applicability of MAT2501 will not be limited to the treatment of pulmonary infections, and we expect to evaluate its use in other, more acute bacterial infections, such as gram-negative infections, where the unmet medical need is significant and unfortunately growing due to a lack of effective therapies."

This Phase 1 study is a double-blind, placebo-controlled, SAD study designed primarily to evaluate the safety, tolerability and pharmacokinetics of single ascending oral doses of MAT2501 in healthy adult subjects. Secondary objectives include the assessment of the effect of food on the pharmacokinetics of amikacin following a single oral dose of MAT2501.

Development of MAT2501 has been supported by a $4.2 million Therapeutics Development Award from the Cystic Fibrosis Foundation.

The U.S. Food and Drug Administration (FDA) has designated MAT2501 as a Qualified Infectious Disease Product (QIDP) and as an Orphan Drug for the treatment of NTM. If MAT2501 is ultimately approved by the FDA, the seven-year period of marketing exclusivity from orphan designation combined with the additional five years of marketing exclusivity provided by the QIDP designation, would provide for a potential total of 12 years of marketing exclusivity.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) delivery platform. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop new formulations that take full advantage of the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the complex challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides and vaccines. The combination of a unique mechanism of action and flexibility in both the formulation and route of administration (including oral), position Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle and an important improvement over both lipid nanoparticles and viral vectors.

MAT2203 is an oral, LNC formulation of the highly effective, but also highly toxic, antifungal medicine amphotericin B, primarily used as a first-line treatment for invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. Enrollment in Cohort 3 of EnACT has commenced following unanimous approval from the Data and Safety Monitoring Board (DSMB), with enrollment completion and DSMB evaluation of Cohort 3 data expected in the fourth quarter of 2021.

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic amikacin, primarily used to treat chronic and acute bacterial infections. With the support of the Cystic Fibrosis Foundation, MAT2501 is currently undergoing important preclinical studies and commenced a Phase 1 human clinical trial in the fourth quarter of 2021. MAT2501 would be the first and only oral aminoglycoside and is being positioned with an initial indication for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis.

LYPDISO™, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, intended for the treatment of cardiovascular and metabolic

conditions. This next-generation omega-3 therapy has been shown in two head-to-head studies to provide effective triglyceride-lowering and significantly higher EPA blood levels than Vascepa®. The Company has initiated a process to identity and potentially secure a partner to continue development of LYPDISO.

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 our business activities, our strategy and plans, the potential of our LNC platform delivery technology, and the future development of its product candidates, including MAT2203, MAT2501, 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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Source: Matinas BioPharma Holdings, Inc.

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