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Matinas BioPharma Awarded up to $3.75 Million from the Cystic Fibrosis Foundation to Support Development of Oral Amikacin (MAT2501) for the Treatment of NTM Infections in Cystic Fibrosis Patients

BEDMINSTER, N.J., Nov. 20, 2020 (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 that it has been awarded up to $3.75 million from the Cystic Fibrosis Foundation (CFF). The award will support preclinical development of MAT2501, Matinas' lipid nano-crystal (LNC) oral formulation of the broad-spectrum aminoglycoside amikacin, toward an indication to treat nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

"We are grateful to the Cystic Fibrosis Foundation for their support in accelerating the development of MAT2501 as a potential best in class treatment for NTM lung disease. These are debilitating, potentially life-threatening, and increasingly prevalent pulmonary infections, especially in patients with cystic fibrosis," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "We believe that an orally bioavailable amikacin, which takes advantage of our LNC delivery platform, would be the first oral aminoglycoside and would represent a significant improvement over currently available therapy. Furthermore, an oral, well tolerated, and targeted aminoglycoside would also potentially be of considerable value in treating other acute bacterial infections, especially gram-negative infections, where oral options are very limited and drug resistance is an increasing challenge. We look forward to continuing to work with the CF Foundation on realizing the potential of our LNC delivery platform."

The CFF award will allow Matinas to rapidly advance the development of MAT2501 and will support preclinical *in vitro* and *in vivo* studies, along with several of the toxicology studies necessary to progress MAT2501 into Phase 2. Pending a successful preclinical program, the CFF has indicated to Matinas a willingness to consider a request for further monetary support for the continuation of clinical studies, including dose determination and Phase 2 efficacy studies in CF patients suffering from NTM lung disease.

MAT2501 has been designated as a Qualified Infectious Disease Product (QIDP) and as an Orphan Drug for the treatment of NTM by the U.S. Food and Drug Administration (FDA). Orphan Drug designation of MAT2501 provides for a seven-year marketing exclusivity period

against competition in the United States upon FDA approval, as well as other incentives and exemptions, including waiver of Prescription Drug User Fee Act (PDUFA) filing fees and tax credits for the cost of the clinical research. 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, provides for a potential total of 12 years of marketing exclusivity.

About NTM Lung Disease

NTM lung disease is a chronic, debilitating condition arising from an NTM infection in the lungs and is associated with significant patient morbidity and mortality. The signs and symptoms of NTM lung disease often overlap with the underlying lung conditions that increase risk for NTM, like cystic fibrosis, bronchiectasis, COPD, and asthma. The most common pathogens for NTM infections in the United States are *Mycobacterium avium complex* (MAC), which accounts for more than 80% of all NTM infections in the U.S. Patients with NTM lung infections frequently require lengthy hospital stays and prolonged courses of antibiotics to manage their disease.

The prevalence of human disease attributable to NTM has increased over the past two decades and is now growing at more than 8% per year and is even more prevalent than tuberculosis in the U.S. In 2018, it was estimated that between 75,000 and 100,000 patients were diagnosed with NTM lung disease in the U.S. alone.

About MAT2501

MAT2501 is an oral, encochleated formulation of the broad-spectrum aminoglycoside antibiotic agent amikacin, which utilizes the Company's proprietary LNC platform to achieve oral bioavailability, limit toxicity and enable targeted delivery to sites of infection. Currently, amikacin can only be delivered parenterally or through inhalation and is used to treat a variety of chronic and acute bacterial infections, including both NTM infections and various multidrug-resistant gram-negative bacterial infections. IV and inhaled amikacin, however, are associated with major side effects including nephrotoxicity and ototoxicity (permanent loss of hearing) with long-term use. Matinas believes that MAT2501's ability to orally deliver high levels of amikacin directly to the lung and without use-limiting toxicity, distinguishes it from all available therapies and could provide an important solution for patients and physicians.

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

nano-crystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them more targeted, less toxic and orally bioavailable.

MAT2203, the Company's lead product candidate utilizing its LNC platform, is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, 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 will promptly begin enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

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 anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT2203 and 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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