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Matinas BioPharma Granted U.S. Orphan Drug Designation for MAT2501 for Treatment of Non-Tuberculous Mycobacteria Infections

- *MAT2501 (encochleated amikacin) previously designated a Qualified Infectious Disease Product by FDA -*
- *MAT2501 demonstrated oral bioavailability and targeted delivery directly to site of non-tuberculous mycobacteria (NTM) infections in preclinical studies -*
- *Phase 1 program expected to commence in 2016 -*

BEDMINSTER, N.J., March 07, 2016 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (OTCQB:MTNB), a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective therapeutics for the treatment of serious and life-threatening infections, today announced that its investigational drug MAT2501 (encochleated amikacin) was granted Orphan Drug Designation by the U.S. Food and Drug Administration (FDA) for the treatment of non-tuberculous mycobacteria (NTM) infections, its lead chronic indication.

“The orphan drug approval for MAT2501 is a noteworthy achievement in our regulatory strategy to advance this potentially game-changing oral aminoglycoside through the clinical development process as we progress into Phase 1 studies this year,” said Roelof Rongen, President and Chief Executive Officer. “MAT2501 has the potential to address significant unmet medical needs in chronic and acute bacterial infections, including NTM and other gram negative bacterial infections.”

[MAT2501](#), an orally-administered, encochleated formulation of the broad spectrum IV-only aminoglycoside antibiotic agent amikacin, utilizes the Company’s [proprietary, lipid-crystal, nanoparticle delivery technology](#). Amikacin is currently used to treat different types of chronic and acute bacterial infections, including NTM infections and various multidrug-resistant gram negative bacterial infections. IV-administered amikacin is associated with major side effects including nephrotoxicity and ototoxicity (permanent loss of hearing) with long-term use.

MAT2501 is specifically designed to provide targeted delivery of the potent antibiotic amikacin while providing a significantly improved safety and tolerability profile. In preclinical studies [MAT2501 demonstrated oral bioavailability and targeted delivery of amikacin directly to the site of infection](#) in both pulmonary (lung) and disseminated NTM infections.

Matinas BioPharma recently received [FDA clearance to initiate a Phase 1 clinical study of MAT2501 for the treatment of non-tuberculous mycobacterium infections](#). The [FDA has also](#)

[designated MAT2501 as a Qualified Infectious Disease Product \(QIDP\) for the treatment of NTM infections.](#)

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 an additional five years of marketing exclusivity provided from the previously announced QIDP designation allows for a total of 12 years of potential marketing exclusivity.

About Nontuberculous Mycobacteria

Nontuberculous mycobacteria (NTM) are naturally occurring organisms found in water, soil, plants and animals. NTM causes many serious and life-threatening diseases, including pulmonary disease, skin and soft tissue disease, joint infections and, in immunocompromised individuals, disseminated infection. The most common clinical manifestation of NTM disease is pulmonary, or lung, disease. NTM lung infection occurs when a person inhales the organism from their environment. While most people do not become ill, some individuals develop a slow, progressive and destructive disease when NTM infects the airways and lung tissue leading to inflammation in the respiratory system. Individuals susceptible to the infection often have an unknown defect in their lung structure or immune system, lung damage from a pre-existing chronic obstructive pulmonary disease (COPD), such as emphysema and bronchiectasis, cystic fibrosis, or an immune deficiency disorder, such as HIV or AIDS.

There are about 50,000 to 90,000 people with NTM pulmonary disease in the United States, with a much higher frequency in older adults, and these numbers appear to be increasing. However, NTM can affect any age group. Without treatment, the progressive lung infection caused by NTM results in severe cough, fatigue, and often weight loss. In some people NTM infections can become chronic and require ongoing treatment. Treatment may be difficult because NTM bacteria may be resistant to many common types of antibiotics. Severe NTM lung disease can have a significant impact on quality of life and can be life-threatening.

About MAT2501

MAT2501 is an orally administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic amikacin which may be used to treat different types of multidrug-resistant bacteria, including non-tubercular mycobacterial infections (NTM), as well as various multidrug-resistant gram negative and intracellular bacterial infections. Currently, amikacin cannot be absorbed enterally and must be given by intravenous, intramuscular or nebulization routes with the significant risk of nephrotoxicity and ototoxicity, which makes it an impractical choice when treating serious infections which often require long courses of therapy, often 12 to 18 months or longer. MAT2501, taking advantage of its disruptive, nano-encapsulation delivery technology, is being developed to provide an orally administered, safer and targeted therapy for improved treatment of these serious and life-threatening bacterial infections in patients, including those who are severely immunocompromised.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections. The Company's proprietary, disruptive technology utilizes lipid-crystal nano-particle cochleates to nano-encapsulate existing drugs, making them safer, more tolerable, less toxic and orally bioavailable. The Company's lead drug candidate is MAT2203, an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). The Company has an open Investigational New Drug (IND) application for MAT2501, which is an orally-administered, encochleated formulation of amikacin (a broad spectrum aminoglycoside antibiotic agent) for acute bacterial infections, including non-tuberculous mycobacterium (NTM) and multi-drug resistant gram negative bacterial infections. In addition, the Company is exploring development and partnership options for MAT9001, a prescription-only omega-3 fatty acid-based composition under development for hypertriglyceridemia, which has shown superiority versus Vascepa[®] (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoproteins and PCSK9 levels.

The Company's lead anti-infective product candidates, MAT2203 and MAT2501, position Matinas BioPharma to become a leader in the safe and effective delivery of anti-infective therapies utilizing its proprietary lipid-crystal nano-particle cochleate formulation technology. For more information, please visit www.matinasbiopharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#).

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 MAT2203 and MAT2501, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, 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 maintain and derive benefit from the Qualified Infectious Disease Product (QIDP), Orphan and/or Fast Track designations for MAT2203 and MAT2501, which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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.