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Matinas BioPharma Commences Dosing in Phase 1 Study of Orally Administered Aminoglycoside Antibiotic MAT2501

– MAT2501 previously received Orphan Drug and Qualified Infectious Disease Product designations for treatment of nontuberculous mycobacterium infections by U.S. FDA –

– Phase 1 data expected in the first half of 2017 –

BEDMINSTER, N.J., Dec. 05, 2016 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (OTCQB:MTNB), 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, announced today that it has commenced dosing in the Phase 1 clinical study of its lead antibiotic product candidate MAT2501, under development for the treatment of nontuberculous mycobacterium infections (NTM) as an initial indication. Data from this study is expected to be announced in the first half of 2017.

[MAT2501](#) is Matinas BioPharma's orally-administered, encochleated formulation of the broad spectrum IV-only aminoglycoside antibiotic agent amikacin, which utilizes the Company's proprietary lipid-crystal nano-particle 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.

"We are thrilled to have started the dosing of subjects in this Phase 1 study of MAT2501, the third dosing commencement in a human study by the Company over the last three months. We have made great strides on the clinical development front this year across our entire pipeline. The start of this study represents an important step forward in advancing our proprietary cochleate formulation of amikacin into human clinical trials, which we believe could be a game-changing orally available aminoglycoside antibiotic treatment," said [Roelof Rongen, Chief Executive Officer](#).

"We now have two product candidates in the clinic and expect the first half of 2017 to be an exciting time for our Company and its stockholders. We anticipate important clinical data from this Phase 1 study of MAT2501, as well as our ongoing Phase 2 studies with MAT2203, our orally delivered formulation of the antifungal amphotericin B," added Mr. Rongen.

This Phase 1 study is a double-blind, placebo-controlled, single ascending dose study to evaluate the safety, tolerability, and pharmacokinetics of MAT2501 in healthy adult subjects. The primary objectives of the study are to assess the pharmacokinetic (PK) profile of amikacin following single ascending oral doses of MAT2501 as well as safety and tolerability.

Secondary objectives include the assessment of the effect of food on the PK of amikacin following a single oral dose of MAT2501.

MAT2501 is specifically designed to provide targeted delivery of the potent antibiotic amikacin while providing a significantly improved safety and tolerability profile, in order to allow for chronic dosing of this potent antibiotic agent. 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. FDA guidance for the treatment of patients with of NTM infections refractory to guideline therapy includes a treatment duration in the range of 12 to 18 months. The profile of MAT2501 was designed to allow for safe and tolerable use of amikacin during such long-term treatment.

The U.S. Food and Drug Administration (FDA) has already designated MAT2501 as a Qualified Infectious Disease Product (QIDP) and as an Orphan Drug for the treatment of NTM. 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.

The Company also intends to explore the development of MAT2501 for the treatment of a variety of multi-drug resistant, gram negative bacterial infections.

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 IV-only aminoglycoside antibiotic agent amikacin, which 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 recently received [FDA clearance to initiate a Phase 1 clinical study of MAT2501 under the open IND for the treatment of non-tuberculous mycobacterium infections](#). The [FDA has also designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections](#). The Company intends to initially develop MAT2501 for the treatment of NTM infections and will also explore the development of MAT2501 for the treatment of a variety of multi-drug resistant, gram negative bacterial infections. If approved, we believe MAT2501 would become the first orally bioavailable aminoglycoside and represent a significant improvement over existing therapies from a treatment and health economic perspective.

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.

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.