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Matinas BioPharma's Lead Antibacterial Development Candidate MAT2501 Granted QIDP Designation by U.S. FDA

BEDMINSTER, N.J., Dec. 14, 2015 (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 the U.S. Food and Drug Administration (FDA) has designated the Company's lead antibacterial development candidate, MAT2501, as a Qualified Infectious Disease Product (QIDP) for the treatment of non-tuberculous mycobacterium (NTM) infections.

MAT2501 is an orally-administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic agent amikacin which may be used to treat different types of multidrug-resistant bacteria, including NTM and various multidrug-resistant gram negative bacterial infections.

"Treatment of non-tuberculous mycobacterium, or NTM, infections is difficult given resistance to many antibacterial drugs. NTM can lead to chronic infections requiring treatment regimens for a year or longer under current guidelines, and there is growing concern that resistant NTM may be responsible for a disproportionate share of clinical infections," commented Roelof Rongen, President and Chief Executive Officer of the Company. "The broad spectrum antibiotic, amikacin, has shown very little microbial resistance but its severe side effects and intravenous delivery make it impractical and unsafe for the long-term therapy required to resolve these very serious and often life-threatening infections."

MAT2501 is being developed with Matinas' proprietary, lipid-crystal, nanoparticle delivery technology that aims to provide a safer, more tolerable and convenient formulation of this powerful antibiotic. "Preclinical data shows MAT2501 has the oral bioavailability and targeted delivery directly to the site of infection and the potential to change the treatment paradigm for both NTM lung and disseminated infections," added Mr. Rongen.

Matinas BioPharma is preparing to file an Investigational New Drug (IND) application for MAT2501 with the FDA imminently. QIDP designation, provided under the Generating Antibiotic Incentives Now Act (GAIN Act), offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track, priority review and, if MAT2501 is ultimately approved by the FDA, eligibility for an additional five years of marketing exclusivity.

This marks the second QIDP designation for a Matinas drug candidate. In August 2015, MAT2203, which is entering a Phase 2a clinical trial with the NIH's National Institute for

Allergy and Infectious Diseases, received QIDP and Fast Track designations for the treatment of invasive candidiasis. MAT2203 is an orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B, a powerful, intravenously-administered antifungal agent.

“These government incentives such as QIDP and Fast Track underscore the lack of safe and effective antibacterial and anti-fungal medicines, and we are committed to leveraging our cochleate, lipid-crystal, nanoparticle delivery technology to bring much needed therapies to patients and physicians,” said Jerome D. Jabbour, Co-Founder, Executive Vice President and Chief Business Officer of Matinas.

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, 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 also intends to file an investigational new drug application (IND) for MAT2501, which is an orally-administered, encochleated formulation of amikacin (a broad spectrum aminoglycoside antibiotic agent) used to treat different types of multidrug-resistant bacterial infections, including nontuberculous mycobacterium infections (NTM) and various multidrug-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) and Fast Track designations for MAT2203, which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; our ability to maintain and derive benefit from the QIDP designation and to obtain Fast Track and/or Orphan drug designations for MAT2501, 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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