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Matinas BioPharma Announces Positive Preclinical Efficacy Results of MAT2501 in an In Vitro Model of Mycobacterium abscessus Infection

Company plans to advance MAT2501 into in vivo animal studies under the National Institutes of Health (NIH) NTM screening contract

BEDMINSTER, N.J., March 08, 2017 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE MKT:MTNB), a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today announced positive efficacy results from the study of MAT2501 in an *in vitro* preclinical model of *Mycobacterium abscessus*. This study was conducted in collaboration between Matinas BioPharma and Colorado State University (CSU), supported, in part, through a contract from the Division of Microbiology and Infectious Diseases, NIAID, National Institutes of Health.

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 in clinical practice to treat different types of chronic and acute bacterial infections, including non-tuberculous mycobacterium (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).

In previous preclinical work, MAT2501 demonstrated efficacy in cell-based assays and studies in animals with both lung and disseminated *Mycobacterium avium* infections, the most prevalent organism causing NTM infections in humans. MAT2501 is currently being tested in Phase 1 healthy volunteer studies.

In this *in vitro* preclinical model developed by CSU, bone marrow derived macrophage (BMDM) were isolated from SCID mice, an immunodeficient mouse strain, and placed into culture. Once isolated, the BMDM were infected with *Mycobacterium abscessus* and, once infection was established, were then treated with various escalating doses of MAT2501. The results of this study showed that increasing doses of MAT2501 resulted in increased reduction of the *Mycobacterium abscessus* bacteria.

"These results are encouraging because lung infections with *Mycobacterium abscessus*, a species of multi-drug resistant nontuberculous mycobacteria, are emerging as an important global threat to individuals suffering from immunosuppression or with chronic disease, such as cystic fibrosis. Confirming these results using *in vivo* models will be an important step in

the development of MAT2501 for the treatment of *Mycobacterium abscessus*," stated Diane Ordway, Ph.D., Assistant Professor at Colorado State University, Mycobacteria Research Laboratory, who led the *in vitro* work.

The positive results showing the efficacy of MAT2501 against *Mycobacterium abscessus* in this *in vitro* assay provide the required proof-of-concept (POC) validation needed to advance MAT2501 into *in vivo*, preclinical animal studies. Planning and preparation for these preclinical POC animal studies are in progress.

The research presented in this publication was supported by the National Institute of Allergy and Infectious Diseases (preclinical services contract HHSN272201000009I).

Roelof Rongen, Co-founder and Chief Executive Officer of the Company, stated, "These results represent an important step forward in our understanding of the potential of MAT2501 and its broad utility to treat different types of chronic and acute bacterial infections, NTM infections and various multidrug-resistant gram-negative bacterial infections. We look forward to reporting topline results of our Phase 1 clinical study of MAT2501 for the treatment of NTM infections in the coming weeks."

MAT2501 is 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 five-year period of marketing exclusivity provided by the QIDP designation, combined with the seven-year Orphan Drug exclusivity, 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 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 non-tuberculous mycobacterium (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. In Q4 2016, Matinas initiated a Phase 1 clinical study of MAT2501 under the open IND for the treatment of non-tuberculous mycobacterium infections. Topline data from this Phase 1 study is expected in Q1 2017. The FDA has already designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections. The Company also intends develop 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 in an area of significant unmet medical need.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications. 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 MAT2203, currently in Phase 2, is 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, currently in Phase 1, 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.