June 20, 2016

# Matinas BioPharma Presents Preclinical Data of MAT2501 at ASM Microbe/ICAAC 2016

## Data on improved toxicity of oral encochleated amikacin compared to intravenous amikacin

BEDMINSTER, N.J., June 20, 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, today presented preclinical data on its investigational drug, MAT2501 (orally-administered encochleated amikacin) for chronic and acute bacterial infections, including non-tuberculous mycobacteria (NTM) and multi-drug resistant gram-negative bacterial infections, at the American Society for Microbiology's Interscience Conference of Antimicrobial Agents and Chemotherapy (ASM Microbe/ICAAC 2016) scientific meeting being held June 16$^{th}$ – 20$^{th}$ in Boston, MA.

The abstract entitled *"Oral Encochleated Amikacin Demonstrates Reduced Toxicity Compared to Intravenous Amikacin in Rats"* was presented today in a poster session focused on antimicrobial resistance and the approaches on how to fight against it. MAT2501 is a broad spectrum aminoglycoside antibiotic agent delivered in the Company's proprietary lipid-crystal nano-particle cochleate formulation technology.

"This study of our orally administered cochleate technology, in comparison to I.V. administration of amikacin, continues to increase our belief in our potential to deliver this powerful anti-infective at a lower toxicity and offer a new treatment option for immunocompromised patients with chronic and resistant gram-negative infections," said Roelof Rongen, Chief Executive Officer. "We look forward to continue exploring the benefit and potential of our formulation of amikacin utilizing our proprietary lipid-crystal nano-particle cochleate technology."

In the study, rats were administered 50 or 200 mg/kg/day doses of oral MAT2501 and were studied in 0.66 M NaCl, in 1mM bile salts, or in 2 mM bile salts for 7 days. In comparison, rats were administered amikacin utilizing intravenous (I.V.) delivery at 200 mg/kg/day oral and at 50 mg/kg/day. Parameters that were evaluated include mortality/morbidity, clinical observations, body weights, plasma drug levels, toxicokinetic analysis, clinical pathology, necropsy observations, organ weights, and histopathology. Across dose groups MAT2501 provided 100 fold lower plasma levels of amikacin than the I.V. dose. There was a noteworthy trend toward a lower exposure on Day 7 versus Day 1 in several dose groups. The various changes seen in all treatment groups were of minimal toxicologic significance. The study found that in three different vehicle formulations, MAT2501 was well-tolerated at

50 and 200 mg/kg for 7 days.

The Company recently received Orphan Drug and QIDP designations by the U.S. Food and Drug Administration (FDA) for MAT2501 for the treatment of non-tuberculous mycobacteria (NTM) infections and expects to commence the initial study in the Phase 1 program in 2016.

**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 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. 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.