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Matinas BioPharma Reports Positive Topline Data from Phase 1 Study of MAT2501

- Oral administration of MAT2501 at all tested doses yielded blood levels that were well below the labeled safety limits recommended for IV-administered amikacin -

- MAT2501 was well-tolerated with no serious adverse events observed -

BEDMINSTER, N.J., March 27, 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 reported positive topline data from its Phase 1 single-ascending dose study of MAT2501 in healthy volunteers.

MAT2501 is Matinas BioPharma's orally-administered formulation of the broad spectrum IV-only aminoglycoside antibiotic agent amikacin, which utilizes the Company's proprietary lipid-crystal nano-particle cochleate delivery technology. Amikacin by injection 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. Amikacin by injection generates high blood levels which are associated with major side effects including nephrotoxicity and ototoxicity (permanent loss of hearing) and therefore amikacin blood levels must be monitored closely during use.

This completed Phase 1 study of MAT2501 was a double-blind, placebo-controlled, single ascending dose study primarily aimed to evaluate the safety, tolerability, and pharmacokinetics of MAT2501 in 36 healthy adult subjects. Secondary aims of the study included an assessment of the effects of food on tolerability and pharmacokinetics. There were no serious adverse events reported in the study. Adverse events were mostly mild in severity and gastrointestinal (GI) in nature, as seen with the Phase 1 study of MAT2203 (currently in Phase 2). The incidence of GI adverse events significantly decreased when MAT2501 was administered with food, resulting in improved tolerability. Oral administration of MAT2501 at all three doses yielded blood levels of amikacin that were well below the labeled safety limits recommended for IV-administered amikacin, and consistent with the results from preclinical studies of MAT2501.

"We are very pleased with the outcome of our initial Phase 1 study of MAT2501 and believe that the results of this study support the further development of MAT2501 for the treatment of NTM infections as a first indication," said Roelof Rongen, Chief Executive Officer. "We have shown that the oral administration of MAT2501 at doses we expect to use with patients is well tolerated and yields blood levels well below the labeled safety limits for amikacin. Our plan is to continue to drive development of this important product forward in such a way as to maximize the opportunity we might have in developing and potentially receiving FDA-

approval for what we believe will be the first orally-available aminoglycoside."

Upon completion of its Phase 1 program and meeting with the U.S. Food and Drug Administration (FDA), the Company plans to initiate a Phase 2 study in patients with NTM lung disease refractory to guideline therapy. Matinas intends to also evaluate opportunities or need to conduct human drug-drug interaction studies and studies in special patient populations, such as patients with cystic fibrosis or non-lung *Mycobacterum abscessus* infections. Based on the limited success and utility of inhaled therapies in these uses, as well as the oral dosing mode of our product, Matinas believes that MAT2501 has the potential to become a highly-differentiated therapy for the treatment of NTM if approved by FDA.

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. The FDA has designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections. The Company also intends to develop MAT2501 for the treatment of a variety of multi-drug resistant infections, including gram negative bacterial infections. If approved, Matinas believes 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). MAT2501, the Company's 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, reported positive topline data from the Phase 1 single-ascending dose study in healthy volunteers. Matinas is advancing its MAT2501 Phase 1 program in preparation of a Phase 2 study in patients.

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.