

Matinas BioPharma Announces Presentation of Cryptococcal Meningitis Preclinical Data of MAT2203 at AIDSAssociated Mycosis Meeting 2016

Preclinical studies demonstrate comparable survival upon treatment with combination of oral encochleated amphotericin B plus flucytosine compared to injected amphotericin B

BEDMINSTER, N.J., July 13, 2016 (GLOBE NEWSWIRE) -- <u>Matinas BioPharma Holdings</u>, <u>Inc.</u> (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, announces the presentation today of efficacy results in animal models of cryptococcal meningitis resulting from treatment with its investigational drug, <u>MAT2203</u> (<u>orally-administered encochleated amphotericin B</u>), under development for the treatment of serious fungal infections, at <u>AIDS-Associated Mycoses scientific meeting</u> being held July 13th – 15th in Capetown, South Africa.

In a presentation today at the AIDS-Associated Mycoses Meeting scientists from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), showed that they could effectively treat mice infected with cryptococcal meningitis in two experiments using an orally administered lipid-crystal nano-particle formulation of amphotericin B (MAT2203). In the first experiment MAT2203 administered orally was used alone after a 1-day infection incubation period and resulted in 80% survival of mice out to 60 days, which was equivalent to commercial amphotericin B deoxycholate injection and superior to the untreated control group, which showed 100% mortality at Day 20. In the second experiment, MAT2203 was administered orally with flucytosine and by injection as a stand-alone treatment after a 3-day infection incubation period and resulted in 80% survival after 70 days and 40% survival after 90 days, whereas commercial amphotericin B deoxycholate injection resulted in 20% survival after 70 days and 90 days. All treatment groups demonstrated superior survival compared to the untreated control group, which exhibited 100% mortality after 14 days.

"This study in murine models of this highly lethal medical condition of our orally administered cochleate formulation of amphotericin B, in comparison to administration of the commercial formulation of amphotericin B by injection, continues to increase our belief in the potential to deliver this powerful anti-infective at a lower toxicity and offer a new treatment option for immunocompromised patients with severe and life-threatening fungal infections," said Roelof Rongen, Chief Executive Officer of the Company. "We look forward to continue to add evidence for the broad spectrum benefit and potential of our formulation of amphotericin B

utilizing our proprietary lipid-crystal nano-particle cochleate technology."

Cyrptococcal meningitis is a highly lethal fungal infection of the brain, and the incidence of this condition is strongly correlated to diseases of the immune system such as HIV/AIDS. Despite advances in the treatment HIV/AIDS it is estimated that the global burden of HIV-associated cryptococcal meningitis is more than 1-million cases annually world-wide, with an estimated global mortality of approximately 600,000 cases per year.

The Company received QIDP designations by the U.S. Food and Drug Administration (FDA) for its lead program MAT2203 for the treatment of candidida and aspergillus infections, and is enrolling a Phase 2a study in patients with chronic mucocutaneous candidiasis at NIH/NIAID.

About MAT2203

MAT2203 is an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). Little to no clinical resistance has been reported to date with amphotericin B as compared to the rapidly emerging drug resistance seen in other antifungal therapies. Currently, IV-only administered amphotericin B is the only broad spectrum fungicidal available but its IV-delivery results in significant treatment-limiting side effects, including nephrotoxicity. The ability to provide amphotericin B via MAT2203's proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. In a clinical Phase 1a single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 demonstrated a positive safety and tolerability profile with no serious adverse events reported, including little or no nephrotoxicity as compared to placebo. Enrollment is currently underway for the Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis, with results expected during 2016. MAT2203 is also being explored for treatment of additional anti-fungal indications and may have the potential for Orphan Drug Designation in certain of these indications.

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.