

May 28, 2019



## **Matinas BioPharma Announces Publication of MAT2203 Preclinical Cryptococcal Meningitis Data in the American Society for Microbiology Journal, mBio**

- *Efficacy of oral delivery of amphotericin B (MAT2203) demonstrated comparable efficacy to IV amphotericin, with similar survival of animals and reduction in fungal burden –*
- *Cryptococcal meningitis is one of the most frequent and opportunistic infections in Human Immuno-Deficiency Virus (HIV) patients –*
- *~250,000 deaths worldwide annually despite therapy, and upwards of 15% of HIV/AIDS-related deaths –*
- *Company plans to commence NIH-funded Phase 2 study in patients with cryptococcal meningitis in the second half of 2019 –*

BEDMINSTER, N.J., May 28, 2019 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, today announced the publication of efficacy results from preclinical animal models evaluating MAT2203 for the treatment of cryptococcal meningitis in the American Society for Microbiology Journal, [mBio](#), in a manuscript titled, “*Efficacy of Oral Encocchleated Amphotericin B (CAmB) in a Mouse Model of Cryptococcal Meningoencephalitis.*”

[MAT2203](#) is an orally-administered formulation of amphotericin B (a broad spectrum fungicidal agent) utilizing Matinas’ proprietary [lipid nano-crystal \(“LNC”\) delivery technology platform](#). The Company’s LNC delivery platform utilizes lipid nano-crystals which can encapsulate small molecules, nucleic acid polymers such as oligonucleotides, vaccines, peptides, proteins and other medicines potentially making them safer, more tolerable, less toxic and orally bioavailable. 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 a major broad-spectrum fungicidal product. However, it has significant treatment-limiting side effects, most notably nephrotoxicity.

Cryptococcal meningitis is a highly lethal fungal infection of the brain, and the incidence of this condition is strongly related to suppression of the immune system, such as in HIV/AIDS. Despite advances in the treatment HIV/AIDS, *Cryptococcus* accounts for 15% of AIDS-related deaths globally with an estimated 278,000 cases annually among HIV-infected

persons. In the United States, one third of cases occur in people without HIV, but with other immune system deficits, such as subjects receiving corticosteroids or chemotherapy, organ transplantation, or liver disease.

Dr. David Boulware, M.D., MPH with the University of Minnesota, remarked, “Globally, access to injectable formulation of amphotericin is extremely limited, and all oral regimens of cryptococcal therapies are urgently needed. The data from Dr. Williamson’s team are exciting, demonstrating in a mouse model that this MAT2203 formulation of oral amphotericin may have similar survival as the injectable form, but with much less toxicity. If this can be replicated in humans, this would be a game-changer for antifungal therapy worldwide.”

In the published manuscript, scientists from the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), demonstrated robust efficacy using an orally administered lipid nano-crystal formulation of amphotericin B (MAT2203) in an animal model in infected mice with cryptococcal meningitis, which, historically, is highly predictive of clinical efficacy. In one experiment, MAT2203 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 amphotericin B injection and superior to the untreated control group, which showed 100% mortality at Day 20. In a second set of experiments, MAT2203 was administered orally for 28 days with flucytosine after a 3-day infection incubation period and resulted in up to 80% survival out to 200 days, comparable to that of injected amphotericin B administered with flucytosine. Treatment with the nano-crystal formulation also resulted in fungal clearance of cryptococcal fungal organisms comparable to that of injected amphotericin B and flucytosine. A fluorescent-tagged formulation of the nano-crystal formulation was also demonstrated to cross the blood brain barrier to deposit drug within brain tissue.

All treatment groups demonstrated superior survival compared to the untreated control groups, which exhibited 100% mortality after 25 days and also demonstrated superiority to the anti-fungal fluconazole. Furthermore, the formulation was found to be without significant toxicity in a rat model. Based on these results, the Company believes that their proprietary LNC delivery technology may have the potential to treat other diseases of the Central Nervous System.

“This study of MAT2203, in comparison to administration of amphotericin B by injection, continues to support our belief in the potential to deliver this powerful anti-fungal agent, with little off-organ toxicity, and may offer an important new treatment option for immunocompromised patients with severe and life-threatening fungal infections,” commented [Theresa Matkovits, Ph.D., Chief Development Officer of Matinas](#) “We believe our proprietary LNC platform delivery of amphotericin B positions MAT2203 to become a best-in-class antifungal drug. We look forward to continue exploring the broad-spectrum benefit and potential of our formulation of amphotericin B utilizing our proprietary lipid nano-crystal technology with the support of the National Institutes of Health, and other governmental agencies.”

MAT2203 is currently being developed toward an initial indication for the treatment of cryptococcal meningitis, supported by non-dilutive funding from the NIH through key efficacy milestones. The Company plans to meet with the U.S. Food and Drug Administration (FDA) to review the MAT2203 development plan and design for a Phase 2 study in patients with

cryptococcal meningitis and expects to initiate the study in the second half of 2019. The University of Minnesota and Infectious Diseases Institute will lead a Phase 2 study supported via National Institutes of Health award [R01NS110519-01](#). Dr. Boulware will serve as the U.S. Principal Investigator of the Phase 2 study.

The FDA has granted MAT2203 both Fast Track and Qualified Infectious Disease Product (QIDP) designations for the treatment of invasive candidiasis and aspergillosis and for the prevention of IFIs in patients on immunosuppressive therapy.

## **About Matinas BioPharma**

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on creating value through the streamlined development of MAT9001 for the treatment of cardiovascular and metabolic conditions and the application of its lipid nano-crystal ("LNC") platform technology to solve complex challenges relating to the safe and effective delivery of small molecules, gene therapies, proteins, peptides and vaccines.

The Company is actively pursuing the development of MAT9001 with the support of a world-class team of clinical key opinion leaders and regulatory consultants. MAT9001 is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia, which has shown superiority versus Vascepa® (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoprotein CIII and PCSK9 levels.

In addition, the Company's proprietary, disruptive technology utilizes lipid nano-crystal cochleates to encapsulate small molecules, nucleic acid polymers, vaccines and other medicines potentially making them safer, more tolerable, less toxic, and orally bioavailable.

For more information, please visit [www.matinasbiopharma.com](http://www.matinasbiopharma.com) and connect with the Company on [Twitter](#), [LinkedIn](#) and [Facebook](#).

**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 anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT9001 and MAT2203, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, 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 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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