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Matinas BioPharma Announces Publication of Results from Phase 1 Portion of the EnACT Study Investigating Safety and Tolerability of MAT2203

Data published in *Antimicrobial Agents and Chemotherapy* demonstrate MAT2203 (oral amphotericin B) is well tolerated without the side effects commonly seen with IV amphotericin B

BEDMINSTER, N.J., Aug. 20, 2020 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (NYSE AMER: MTNB), today announced the publication of data from the Phase 1 portion of the EnACT (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) study for MAT2203, a novel oral formulation of amphotericin B, investigating its safety and tolerability. The data were published online in *Antimicrobial Agents and Chemotherapy*, ([AAC](#)), a journal of the American Society of Microbiology, in a manuscript entitled "[Safety and tolerability of a novel oral formulation of amphotericin B: Phase I EnACT trial](#)".

"We were pleased with the safety and tolerability of MAT2203 as demonstrated in the Phase 1 trial. Moreover, we are excited about the Phase 2 trial currently underway," commented David Boulware, M.D., M.P.H, Professor of Medicine at the University of Minnesota and Principal Investigator for the trial.

In the published manuscript, trial investigators reported results from the Phase 1A and 1B portions of the study. They concluded that MAT2203 was well tolerated when given in 4-6 divided daily doses without the toxicities commonly seen with IV amphotericin B.

EnACT is a Phase 2 open-label, sequential cohort study of approximately 100 patients, financially supported by the National Institutes of Health, utilizing the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B. This study is a prospective, randomized trial evaluating the safety, tolerability and efficacy of MAT2203 in HIV-infected patients with cryptococcal meningitis, compared to treatment with standard IV-administered amphotericin B as induction therapy, and then followed by maintenance treatment with MAT2203.

As previously reported, the U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for four indications, specifically, the prevention of invasive fungal infections due to immunosuppressive therapy, and the treatment of invasive candidiasis, invasive aspergillus and cryptococcal meningitis. In addition, the FDA has granted orphan drug designation to MAT2203 for the treatment of cryptococcosis.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on development of its lead product candidate, MAT9001, for the treatment of cardiovascular and metabolic conditions. MAT9001 is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia, that was specifically designed to overcome the shortcomings seen from other agents in the omega-3 class. Company leadership has a deep history and knowledge of cardiovascular drug development and is supported by a world-class team of scientific advisors.

In addition, the Company is developing MAT2203, an oral, encochleated formulation of amphotericin B, to treat serious invasive fungal infections. The drug is based on Matinas' proprietary lipid nano-crystal (LNC) platform technology which can help solve complex challenges relating to the safe and effective delivery of potent medicines, potentially making them more targeted, less toxic and orally bioavailable.

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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