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Matinas BioPharma Initiates EnACT Study of MAT2203 (Oral Amphotericin B) for the Treatment of Fungal Cryptococcal Meningitis

BEDMINSTER, N.J., Oct. 14, 2019 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical stage biopharmaceutical company, today announced that it has initiated its Phase 2 EnACT clinical study, which will explore the use of MAT2203 for both induction and maintenance therapy in HIV-patients with cryptococcal meningitis, a life-threatening fungal infection most commonly observed in immunocompromised individuals.

“We are extremely pleased to advance clinical development of MAT2203 for the treatment of cryptococcal meningitis,” commented Theresa Matkovits, Ph.D., Chief Development Officer of Matinas. “Antifungal resistance poses a major threat to the lives of vulnerable immunocompromised patients, and MAT2203 could provide an invaluable oral and safe treatment for severe fungal infections in these patients. EnACT is an important study to highlight the benefits provided by our lipid nano-crystal (LNC) drug delivery technology and is a key part of our strategy to ultimately position MAT2203 as a potential first-line therapy for the treatment of a variety of invasive fungal infections, including cryptococcal meningitis. We plan to provide updates on EnACT later in 2019 and over the course of 2020, as we advance past the maximum tolerated dose (MTD) portion of this study and advance from cohort-to-cohort during the efficacy stages.”

EnACT (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) is an open-label, sequential cohort study, financially sponsored by the National Institutes of Health (NIH) with David Boulware, M.D., M.P.H, Professor of Medicine at the University of Minnesota acting as principal investigator for the study in collaboration with Dr. David Meya, Ph.D. of Makerere University. This trial utilizes MAT2203, which applies the Company’s LNC drug delivery technology to orally deliver amphotericin B, an otherwise IV-only, highly toxic, fungicidal drug for the treatment of HIV-patients with cryptococcal meningitis. Oral MAT2203 is designed to target delivery directly to infected tissues, protecting the body from unnecessary exposure to amphotericin B, and is expected to be a safer alternative to the traditional IV-forms of this highly potent drug with a lower propensity for renal toxicity. The study consists of two distinct parts; Part 1 is designed to determine the maximum tolerated dose among people living with HIV but who do not have a fungal infection. Part 2 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.

As previously reported, the 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 granted orphan drug designation to MAT2203 for the treatment of cryptococossis. Adding orphan drug designation to the QIDP for the treatment of cryptococcal meningitis, which is within the scope of this FDA-granted orphan drug designation, potentially positions MAT2203 for up to 12 years of marketing exclusivity, if approved.

About MAT2203

MAT2203 is an orally-administered formulation of amphotericin B (a broad spectrum fungicidal agent) applying Matinas' proprietary lipid nano-crystal (LNC) delivery technology platform to create a potentially better tolerated and more conveniently administered version of this potent drug. Currently, IV-only administered amphotericin B has shown little to no clinical resistance and is a major broad-spectrum fungicidal product. However, IV amphotericin has significant treatment-limiting side effects, most notably kidney toxicity.

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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