February 19, 2020

Matinas BioPharma Announces DSMB Approval to Commence Part 2 of EnACT Study of MAT2203 (Oral Amphotericin B) for the Treatment of Cryptococcal Meningitis

– Part 2 efficacy portion of EnACT expected to commence Q1 2020 –

BEDMINSTER, N.J., Feb. 19, 2020 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), today announced that the independent Data Safety Monitoring Board (DSMB) for the EnACT study has completed its planned review of initial safety and tolerability data from the Part 1 dose escalation phase and unanimously approved proceeding with enrollment in the Part 2 efficacy phase at 2g of MAT2203 daily, the highest dose tested in Part 1. The 2g dose will be tested in the 2-week induction phase of treatment. Data from Part 1 demonstrated that MAT2203 was safe and well tolerated across all three daily doses tested (1g, 1.5g and 2g). Part 2 of the EnACT study 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 with our progress in the EnACT trial, which remains on track. Early observations of MAT2203, including the initial safety and tolerability data from Part 1, along with the DSMB’s endorsement to proceed with the highest dose tested, continue to show MAT2203’s potential to provide meaningful benefit to this vulnerable patient population,” commented Theresa Matkovits, Ph.D., Chief Development Officer of Matinas. “We look forward to dosing the first patient in Part 2 of the study in the upcoming weeks and expect to provide updates on the anticipated progression from patient cohort to cohort throughout 2020.”

“The dose escalation portion of the EnACT study has provided important safety and tolerability information about using multiple doses per day to increase the total daily dose. The upcoming efficacy portion of the randomized clinical trial in persons with cryptococcal meningitis will allow for further evaluation of the safety and efficacy of MAT2203,” commented David Boulware, M.D., M.P.H, Professor of Medicine at the University of Minnesota and Principal Investigator for the trial. “I am very encouraged by what we have seen to date and excited to advance the EnACT study into the efficacy phase. If successful, an oral amphotericin formulation has the potential to provide an invaluable oral and well-tolerated treatment for severe invasive fungal infections in these difficult to treat patients.”

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 kidney 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 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.

Investor and Media Contacts

Peter Vozzo
Westwicke
443-213-0505
peter.vozzo@westwicke.com

Ian Cooney
Director – Investor Relations & Corporate Development
Matinas Biopharma, Inc.
(415) 722-4563
icooney@matinasbiopharma.com

Source: Matinas BioPharma Holdings, Inc.