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Matinas BioPharma Announces Unanimous DSMB Approval to Progress into Second Cohort of Patients in the EnACT Study of MAT2203 (Oral Amphotericin B) for the Treatment of Cryptococcal Meningitis

– DSMB evaluated both safety and efficacy data in recommending cohort progression–

– Enrollment in second cohort of patients expected to commence imminently with next DSMB evaluation anticipated mid-2021 –

BEDMINSTER, N.J., Oct. 19, 2020 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today announced that the independent Data and Safety Monitoring Board (DSMB) of the EnACT study (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) has completed a pre-specified review of the first cohort and unanimously recommended progression to the second cohort of patients. Enrollment in this next randomized EnACT cohort, with 40 active-treatment patients, is expected to begin shortly, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

“Cohort progression in the EnACT study is an important milestone for the development of MAT2203,” commented Theresa Matkovits, Ph.D., Chief Development Officer of Matinas BioPharma. “The unanimous DSMB recommendation is very encouraging and supports our views of the overall safety and efficacy profile of MAT2203. We look forward to promptly commencing enrollment in the next cohort of EnACT, which will provide more robust evidence about the efficacy and safety of MAT2203.”

“Cryptococcal meningitis is a deadly fungal disease which results in severe, invasive infections of the brain and imposes a major burden and high mortality in vulnerable immunocompromised patients around the world,” continued Dr. Matkovits. “We believe that an oral amphotericin B formulation, with targeted drug delivery directly to infected tissues throughout the body, substantially reduces the risk of toxicity without sacrificing efficacy. Based on this profile, MAT2203 has the potential to provide an invaluable solution for physicians and patients and ultimately advance the standard of care for the treatment of severe, invasive fungal infections.”

“Overall, we are pleased with the safety and performance of MAT2203 following 5 days of initial intravenous (IV) amphotericin B. In the next stage of the trial, we will continue to test MAT2203 following only 2 days of initial IV amphotericin B, and we would be very pleased to see similar performance,” commented David Boulware, M.D., M.P.H, Professor of Medicine at the University of Minnesota and Principal Investigator for the trial.

“Cohort progression in EnACT is also another step forward in further validating the potential of our LNC platform delivery technology,” commented Raphael J. Mannino, Ph.D., Chief Scientific Officer of Matinas BioPharma. “DSMB approval to proceed to the second patient cohort is a promising signal that MAT2203 is orally bioavailable and successfully crosses the blood brain barrier. Continued success in EnACT will further demonstrate that oral, LNC delivery of therapeutic agents to the brain is possible, and we remain optimistic that our LNC platform could become an important alternative to other traditional, but problematic, delivery vehicles such as lipid nanoparticles or viral vectors, across a wide variety of therapeutic applications.”

EnACT is a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the National Institutes of Health (NIH), evaluating the safety, tolerability and efficacy of MAT2203 in approximately 100 HIV-infected patients with cryptococcal meningitis. MAT2203 utilizes the Company’s LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B.

The induction period for all patients in each cohort of EnACT is 14 days, followed by an additional 4 weeks of treatment with MAT2203 for all patients during a maintenance period. In total, the trial includes four cohorts of patients, with each cohort increasing the treatment duration of MAT2203 vs. IV amphotericin B. The first cohort received IV amphotericin B for the first five days of the induction period, followed by nine days of oral administration of MAT2203. The second cohort of 40 actively treated patients will receive IV amphotericin B for the first two days of the induction period, followed by twelve days of oral administration of MAT2203. The primary efficacy endpoint will be measured at Day 14, the last day of the induction period, and will include a measure of reduction in fungal count in the cerebral spinal fluid. A control arm, which includes standard of care IV amphotericin B, is included with each cohort. An independent DSMB oversees the safety of the study and reviews all data from each cohort for safety and efficacy and makes a recommendation to proceed to the next cohort of patients.

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 developing next generation therapeutics to advance standards of care for patients in areas of significant unmet medical need. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

MAT9001, the Company's lead product candidate for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia. MAT9001 is currently in a second head-to-head comparative study against Vascepa® (ENHANCE-IT), with topline data expected in the first quarter of 2021.

In addition, Matinas is developing a portfolio of products based upon its proprietary lipid nano-crystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them more targeted, less toxic and orally bioavailable.

MAT2203, the Company's lead product candidate utilizing its LNC platform, is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, to treat serious invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT will promptly begin enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

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 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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