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

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

– Data from third patient cohort confirm antifungal activity above pre-defined threshold target for success, while maintaining a desirable overall safety profile –

– Enrollment in fourth cohort of patients expected to commence early Q1 2022 –

BEDMINSTER, N.J., Dec. 16, 2021 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) platform delivery technology, today announced that the independent Data and Safety Monitoring Board (DSMB) of the EnACT trial (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) has completed a prespecified review of the third cohort and unanimously recommended progression to the fourth and final cohort of patients. Enrollment in the next randomized EnACT cohort, with 40 active-treatment patients, is expected to begin early first quarter 2022.

“Unanimous DSMB approval to proceed to cohort four in the EnACT trial is a strong statement that MAT2203 continues to exceed the prespecified efficacy and safety thresholds assessed in the first two cohorts,” said Theresa Matkovits, Ph.D., Chief Development Officer of Matinas BioPharma. “We have made significant progress advancing MAT2203 through clinical development, and the fourth cohort of EnACT represents a meaningful opportunity to further validate an all-oral treatment regimen with amphotericin B, and position MAT2203 as a potential first-line treatment for cryptococcal meningitis. Ultimately, our goal is to develop MAT2203 to become the preferred therapeutic option for the treatment of most invasive fungal infections and provide physicians and patients with an effective, convenient and safe oral formulation of one of the most potent antifungal agents available.”

“Our team continues to be pleased with the performance of oral MAT2203 for the treatment of cryptococcal meningitis,” commented David Boulware, M.D., M.P.H, Professor of Medicine at the University of Minnesota and Principal Investigator for the trial. “Cohort 3 of the ENACT trial tested whether starting with an all-oral regimen of amphotericin and flucytosine would be

possible. Participants received 5 days of oral combination therapy before a scheduled switch to intravenous amphotericin. In this cohort with 10 participants receiving MAT2203, the direct antifungal therapy activity measured in cerebrospinal fluid continued to be above our pre-defined target threshold for success. We are excited to begin the fourth cohort testing the all-oral regimen of MAT2203 in a larger number of patients beginning in early January."

"The continued progression of EnACT and the impressive data generated to date in this highly vulnerable patient population are a clear demonstration of how our LNC platform can unlock the full therapeutic potential of life-saving medicines," remarked Jerome D. Jabbour, Chief Executive Officer of Matinas. "We believe this is further validation of how our proprietary technology can be used to overcome significant drug delivery challenges and we remain excited by the interest shown in the application of the LNC platform beyond anti-infective therapies."

About the EnACT Study

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 (CM). MAT2203 utilizes the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B.

The EnACT trial includes a total of four cohorts of patients, with the first two cohorts testing MAT2203 as early stepdown therapy following initial treatment with IV amphotericin B during the induction period, and the second two cohorts testing MAT2203 as potential monotherapy. The induction period for all patients in each cohort (active or control) is 14 days, followed by an additional four weeks of treatment (active or control) during a consolidation/maintenance period.

All patients in the induction period of EnACT (both control and MAT2203 arms) receive background therapy of flucytosine, also known as 5-FC, which is specifically recommended to be used with amphotericin B as standard-of-care treatment during induction in patients with CM. During the consolidation/maintenance period, all patients (both control and MAT2203 arms) receive 800 mg/day of fluconazole. An independent DSMB oversees the safety of the study and reviews all available data from each cohort for both safety and efficacy and makes a recommendation on whether to proceed to the next cohort of patients.

In the MAT2203 arm of Cohort 1, 10 patients received IV amphotericin B (with 5-FC) for the first five days of induction, followed by ten days (overlapped on day 5) of oral MAT2203 (with 5-FC). In the MAT2203 arm of Cohort 2, 40 patients first received IV amphotericin B (with 5-FC) for two days, followed by thirteen days (overlapped on Day 2) of oral MAT2203 (with 5-FC). In both Cohorts 1 and 2, treatment with MAT2203 was continued after induction during the next four weeks of consolidation/maintenance treatment, administered with 800 mg/day of fluconazole.

In the MAT2203 arm of Cohort 3, 10 patients received 5 days of oral MAT2203 (with 5-FC), followed by 10 days (overlapped on Day 5) of IV amphotericin (with 5-FC). In the MAT2203 arm of Cohort 4, 40 patients will receive MAT2203 (with 5-FC) for the entire 14-day induction period. In both Cohorts 3 and 4, treatment with MAT2203 will continue after induction during the next four weeks of consolidation/maintenance treatment, administered alongside 800

mg/day of fluconazole.

The primary efficacy endpoint for EnACT is the quantitative microbiologic clearance rate of Cryptococcus yeasts from CSF, termed Early Fungicidal Activity (EFA). This is a quantitative measurement of the efficacy of antifungal agents as well as a key surrogate marker for survival. The primary EFA endpoint is measured from the first CSF culture with 3-4 repeated cultures obtained over the first two weeks of treatment. The prespecified endpoint threshold was achieving EFA >0.20 log10 CFU/mL/day, recognizing that EFAs of less than 0.20 are strongly associated with significantly higher mortality and worse clinical outcomes.

Standard of care active control HIV patients with cryptococcal meningitis (a total of 40 across all 4 cohorts) are included in EnACT, primarily to assess patient safety. The control arms for Cohorts 1, 2 and 3 included 4, 17 and 4 patients, respectively, and we expect that the control arm for Cohorts 4 will include 16 patients. In the control arms, patients receive IV amphotericin (with 5-FC) for 7 days, followed by a high dose of oral fluconazole for 7 days (to complete the 14-day induction period), and then transition to 800 mg/day of fluconazole for the 4-week consolidation phase. Either amphotericin B deoxycholate or liposomal amphotericin B (AmBisome®) can be used in the control arm. EnACT was not powered to formally test comparisons with the control arm standard of care.

The 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 biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) delivery platform. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop new formulations that take full advantage of the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the complex challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides and vaccines. The combination of a unique mechanism of action and flexibility in both the formulation and route of administration (including oral), position Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle and an important improvement over both lipid nanoparticles and viral vectors.

MAT2203 is an oral, LNC formulation of the highly effective, but also highly toxic, antifungal medicine amphotericin B, primarily used as a first-line treatment for invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. The DSMB unanimously approved the progression of EnACT into the fourth and final cohort of patients in December of 2021. Cohort 4 is scheduled to begin in January of 2022, with data expected in the second half of 2022.

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic amikacin, primarily used to treat chronic and acute bacterial infections. With the support of the Cystic Fibrosis Foundation, MAT2501 is currently undergoing important preclinical studies and commenced a Phase 1 human clinical trial in the fourth quarter of 2021. MAT2501 would be the first and only oral aminoglycoside, and is being positioned with an initial indication for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis.

LYPDISO™, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, intended for the treatment of cardiovascular and metabolic conditions. This next-generation omega-3 therapy has been shown in two head-to-head studies to provide effective triglyceride-lowering and significantly higher EPA blood levels than Vascepa®. The Company has initiated a process to identity and potentially secure a partner to continue development of LYPDISO.

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 our business activities, our strategy and plans, the potential of our LNC platform delivery technology, and the future development of its product candidates, including MAT2203, MAT2501, 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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