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# Matinas BioPharma Announces Publication of Results from the Phase 2 EnACT Clinical Trial of MAT2203 in the IDSA Journal Clinical Infectious Diseases

BEDMINSTER, N.J., Aug. 22, 2023 (GLOBE NEWSWIRE) --Matinas BioPharma (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, announces that University of Minnesota Medical School researchers published results from the Phase 2 EnACT trial evaluating MAT2203 for the treatment of cryptococcal meningitis as a Major Article and Editor's Choice in *Clinical Infectious Diseases*, an official publication of the Infectious Diseases Society of America (IDSA). MAT2203 is an oral and non-toxic, LNC formulation of the potent antifungal drug amphotericin B.

David Boulware, MD, MPH, the senior investigator of the EnACT trial and infectious disease physician at the University of Minnesota, commented, "An orally administered amphotericin that is broad spectrum and non-toxic sounds like the holy grail of antifungal medicines. While further clinical trials are needed in other fungal conditions, the EnACT trial establishes proof of concept for the safe and effective treatment of invasive fungal infections. In this randomized trial of 141 HIV-positive individuals afflicted by life-threatening cryptococcal meningitis, the oral amphotericin MAT2203 product combined with oral flucytosine appears promising for cryptococcal meningitis with antifungal activity, similar survival, and less toxicity than intravenous amphotericin B. With six weeks of LNC-enabled oral amphotericin B, statistically fewer lab abnormalities occurred than with one week of intravenous amphotericin B."

"We are very pleased that the important EnACT data are being shared with the clinical and scientific community at large through publication in this peer-reviewed journal," said Theresa Matkovits, Ph.D., and Chief Development Officer of Matinas. "The results from EnACT in cryptococcal meningitis and our experience with patients enrolled in our Compassionate/Expanded Use Access Program support our belief that MAT2203 has the potential to become an important part of the regimen for treatment of invasive fungal infections, including in the highest-need patients who require longer-term treatment and have limited or no treatment options. The publication of the EnACT data in *Clinical Infectious Diseases* is yet another milestone for our development program. We would like to thank all the EnACT participants, our dedicated investigators, and the entire clinical study team in Uganda for their commitment to this important clinical trial."

**About the EnACT Phase 2 Study**

EnACT was a Phase 2 prospective, randomized, open-label, sequential cohort study,

financially supported by the National Institute of Neurological Disorders and Stroke (NINDS) of the National Institutes of Health (NIH), evaluating the safety, tolerability, and efficacy of MAT2203 in 100 HIV-positive persons with cryptococcal meningitis compared to 41 persons randomized to receive standard of care intravenous amphotericin B.

The EnACT trial included a total of four cohorts of participants, with the first two cohorts testing MAT2203 as early step-down therapy following initial treatment with IV amphotericin B during the induction period, and the second two cohorts testing MAT2203 as potentially all oral therapy. Cohorts 1 and 3 were safety lead-ins to Cohorts 2 and 4, respectively. The induction period for all patients in each cohort (active or control) was 14 days, followed by an additional four weeks of treatment (active or control) during a consolidation/maintenance period.

**About Clinical Infectious Diseases (CID)**

*Clinical Infectious Diseases (CID)* is a leading journal in the field of infectious disease with a broad international readership. The Journal publishes articles on a variety of subjects of interest to practitioners and researchers. Topics range from clinical descriptions of infections, public health, microbiology, and immunology to the prevention of infection, the evaluation of current and novel treatments, and the promotion of optimal practices for diagnosis and treatment. *Clinical Infectious Diseases* is an official publication of the Infectious Diseases Society of America and is among the most highly cited journals in the field of infectious diseases.

**About Matinas BioPharma**

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology.

Matinas' lead LNC-based therapy is MAT2203, an oral formulation of the broad-spectrum antifungal drug amphotericin B, which although highly potent, can be associated with significant toxicity. Matinas' LNC platform provides oral delivery of amphotericin B without the significant nephrotoxicity otherwise associated with IV-delivered formulations. MAT2203 also allows for safe, longer-term use outside of a hospital setting, which could have substantial favorable pharmacoeconomic impact. MAT2203 successfully completed the Phase 2 EnACT program in cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 is being positioned for a single pivotal Phase 3 study in the treatment of aspergillosis and other invasive fungal infections, including mucormycosis, *Candida auris* and other candidiasis, and certain endemic fungal infections in persons with limited treatment options who are unable to be treated with azoles or echinocandins for reasons related to drug-drug interactions, resistance or for whom these antifungal agents are unable to be used for other clinical reasons.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges standing in the way of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos such as RNAi, antisense oligonucleotides, and vaccines. The combination of its unique mechanism of action and flexibility with routes of administration (including oral) positions Matinas' LNC technology to potentially become a preferred next-generation intracellular drug delivery platform. For more information, please visit

www.matinasbiopharma.com.

**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, our collaboration with National Resilience, Inc., the potential of our LNC platform and PS-NP delivery technologies, and the future development of its product candidates, including MAT2203, the Company's ability to identify and pursue development, licensing and partnership opportunities for its products, including MAT2203, or platform delivery technologies 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 continue as a going concern, 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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Source: Matinas BioPharma Holdings, Inc.