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Matinas BioPharma Initiates Enrollment and Commences Patient Dosing in Phase 2 Study of MAT2203 for the Treatment of Vulvovaginal Candidiasis

- Second Phase 2 study of lead anti-infective candidate MAT2203 -

– On track to report Phase 2 topline data for MAT2203 in the first half of 2017 –

BEDMINSTER, N.J., Nov. 21, 2016 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (OTCQB:MTNB), a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections, announced today that it has initiated enrollment and the first group of patients have been dosed in its Phase 2 clinical study of lead anti-infective product candidate MAT2203 in patients with vulvovaginal candidiasis (VVC).

MAT2203 is Matinas BioPharma's orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B. The Company's proprietary lipid-crystal nano-particle formulation of amphotericin B has a novel mechanism of absorption and distribution to infected tissues and has the potential to transform the way this potent fungicidal agent is administered and used in clinical practice.

This Phase 2 study is a randomized, multicenter, evaluator-blinded study of oral MAT2203 compared to oral fluconazole in adult female patients. Approximately 75 patients with a diagnosis of moderate to severe VVC will be enrolled and randomized into three treatment cohorts of 25 patients each. The first cohort will receive treatment with 200 mg of oral MAT2203 while a second cohort will receive 400 mg of oral MAT2203. The third cohort will be treated with oral fluconazole. The study will assess the efficacy, safety and tolerability of MAT2203.

"The start of patient dosing in our second Phase 2 study of MAT2203 is an important step forward in the advancement of the clinical development strategy for our proprietary cochleate formulation of amphotericin B," said Roelof Rongen, Chief Executive Officer.

"We anticipate that this study, along with the Phase 2 of MAT2203 study ongoing at the NIH in severely immunocompromised patients suffering from mucocutaneous candidiasis, will provide further clinical evidence of MAT2203's activity against candida infections. We believe this will place us in a favorable position to move into Phase 3 registration trials with an intended first indication of prophylaxis, or prevention, of invasive fungal infections in patients on immunosuppressive therapy. We are excited to see MAT2203 progressing quickly into the clinic and look forward to reporting topline results from both of these studies

in the first half of 2017," added Mr. Rongen.

Matinas is also currently evaluating MAT2203 in a Phase 2a open-label, dose-titration study being conducted at the National Institutes of Health Clinical Center in Bethesda, MD, under the direction of Principal Investigator Alexandra Freeman, M.D., of the National Institute of Allergy and Infectious Diseases (NIAID) Laboratory of Clinical Infectious Diseases for the treatment of mucocutaneous candidiasis. The study is designed to assess the efficacy, safety, tolerability and pharmacokinetics of MAT2203 in predominantly hereditary immunodeficient patients with a recurrent or chronic mucocutaneous candidiasis infection (esophageal, oropharyngeal, vaginal) who are refractory or intolerant to standard non-intravenous therapies.

The U.S. Food and Drug Administration (FDA) has designated MAT2203 as a QIDP with Fast Track status for the treatment of invasive candidiasis, aspergillus and prophylaxis (prevention) of invasive fungal infections in patients on immunosuppressive therapy. MAT2203 is also being explored for treatment of additional infections, including cryptococcal meningoencephalitis, and is being developed to be eligible for Orphan Drug Designations in various indications.

About Vulvovaginal Candidiasis

Vulvovaginal candidiasis (VVC), more commonly known as a "yeast infection" is usually caused by *Candida albicans*, the most common cause of fungal infections worldwide. An estimated 75% of women will have at least one episode of VVC during their lifetime and 40-45% will have two or more. Current treatments for VVC include topical antifungals and the use of prescription oral antifungals such as fluconazole. According to the CDC, certain species of Candida are becoming increasingly resistant to existing antifungal medications. This emerging resistance intensifies the need for new antifungal agents.

About MAT2203

MAT2203 is an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). Little to no clinical resistance has been reported to date with amphotericin B as compared to the rapidly emerging drug resistance seen in other antifungal therapies. Currently, IV-only administered amphotericin B is the only broad spectrum fungicidal available but its IV-delivery results in significant treatment-limiting side effects, including nephrotoxicity. The ability to provide amphotericin B via MAT2203's proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. In a clinical Phase 1a single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 demonstrated a positive safety and tolerability profile with no serious adverse events reported, including little or no nephrotoxicity as compared to placebo. Enrollment is currently underway for the Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis. The FDA has designated MAT2203 as a Qualified Infectious Disease Product for the treatment of invasive candidiasis, aspergillosis and prevention of invasive fungal infections due to immunosuppressive therapy. MAT2203 is also being explored for treatment of additional anti-fungal indications and may have the potential for Orphan Drug Designation in certain of these indications.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections. The Company's proprietary, disruptive technology utilizes lipid-crystal nano-particle cochleates to nano-encapsulate existing drugs, making them safer, more tolerable, less toxic and orally bioavailable. The Company's lead drug candidate is MAT2203, an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). The Company has an open Investigational New Drug (IND) application for MAT2501, which is an orally-administered, encochleated formulation of amikacin (a broad spectrum aminoglycoside antibiotic agent) for acute bacterial infections, including non-tuberculous mycobacterium (NTM) and multi-drug resistant gram negative bacterial infections.

The Company's lead anti-infective product candidates, MAT2203 and MAT2501, position Matinas BioPharma to become a leader in the safe and effective delivery of anti-infective therapies utilizing its proprietary lipid-crystal nano-particle cochleate formulation technology. For more information, please visit www.matinasbiopharma.com and connect with the Company on Twitter, LinkedIn, Facebook, and Google+.

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 strategic focus and the future development of its product candidates, including MAT2203 and MAT2501, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, 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 maintain and derive benefit from the Qualified Infectious Disease Product (QIDP), Orphan and/or Fast Track designations for MAT2203 and MAT2501, which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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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