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# Matinas BioPharma Commences Patient Enrollment in NIH-Sponsored Phase 2a Study With MAT2203 - Oral Encochleated Amphotericin B

*- First Dosing of Patients Expected in 1Q 2016 -*

*- Topline Data From Phase 2a Clinical Trial With MAT2203 for the Treatment of Refractory Mucocutaneous Candidiasis Expected in 2016 -*

BEDMINSTER, N.J., Feb. 08, 2016 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (OTCQB:MTNB), a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective therapeutics for the treatment of serious and life-threatening infections, today announced that patient screening and enrollment is underway in the National Institutes of Health (NIH) sponsored Phase 2a clinical study of lead anti-infective product candidate [MAT2203](#) for the treatment of refractory mucocutaneous candidiasis infection.

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 is administered.

"The start of patient screening and enrollment is an important step forward in our Phase 2a study designed to provide an increased understanding of MAT2203," commented Roelof Rongen, President and Chief Executive Officer. "Based on MAT2203's favorable Phase 1 results and extensive preclinical data, we anticipate that topline data from this study will have a similar safety and efficacy profile and look forward to reporting results in 2016."

The Phase 2a study is 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. The open-label, dose-titration study is designed to assess the efficacy, safety, tolerability and pharmacokinetics of MAT2203 in hereditary immuno-deficient patients with a recurrent or chronic mucocutaneous candidiasis infection (esophageal, oropharyngeal, vaginal) that is refractory to standard or tolerated non-intravenous therapies. The study will enroll up to 16 patients, and include 14-day dosing and evaluation periods. Depending on clinical response during each treatment period, investigators will have the ability to continue the effective dose for 28 total days or increase the dose of MAT2203 up to two times and extend treatment to a maximum of 54 days.

The U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for the treatment of [invasive candidiasis](#) and [aspergillus](#). MAT2203 is also being explored for treatment of additional infections including cryptococcal meningoencephalitis, and it may have the potential for Orphan Drug Designation in certain indications.

The Company expects to report top-line data from the Phase 2a study in 2016.

### **About Mucocutaneous Candidiasis**

Mucocutaneous candidiasis is a group of syndromes resulting in infections of the skin, nails and mucous membranes. These infections are caused by opportunistic candida yeast, the most common cause of fungal infections worldwide. There are more than 20 species of candida that can cause infection in humans, the most common of which is candida albicans. A variety of disorders including endocrine dysfunctions, hereditary immune-system disorders, alopecia, vitiligo, malabsorption syndromes, neoplasms and other infections may also occur in patients with chronic reoccurring mucocutaneous candidiasis. Current anti-fungal treatment management options are limited and relapse is common following discontinuation of certain therapies. In addition, the increasing resistance of certain strains to standard antifungal treatments is a growing concern.

### **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 or dose-related adverse events reported, including little or no nephrotoxicity as compared to placebo. A Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis commenced during the first quarter of 2016. 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. In addition, the Company is exploring development and partnership options for MAT9001, a prescription-only omega-3 fatty acid-based composition under development for hypertriglyceridemia, which has shown superiority versus Vascepa<sup>®</sup> (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoproteins and PCSK9 levels.

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](http://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) and 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 obtain Fast Track and/or Orphan drug designations for MAT2501 and/or MAT2203, 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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