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Matinas BioPharma and NIH/NIAID Initiate Open-Label Extension to Phase 2a Study of MAT2203 in Chronic Mucocutaneous Candidiasis

– Matinas BioPharma to commence 6-month safety open-label extension to Phase 2a study with National Institutes of Health (NIH) –

– On track to report Phase 2a topline data for MAT2203 in 2Q 2017 –

BEDMINSTER, N.J., March 06, 2017 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE MKT:MTNB), a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today announced the Institutional Review Board of the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) has granted approval for a 6-month open-label safety extension of the Phase 2a study of Matinas' lead anti-infective product candidate, MAT2203 being conducted at NIH.

MAT2203 is the Company's orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B. Matinas BioPharma'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

Many of the patients expected to enroll into this Phase 2a study have underlying immune-deficiencies that predispose them to chronic mucocutaneous candidiasis, and recurrence is highly likely after study drug is stopped. Therefore, study participants who are tolerating the MAT2203 and are clinical responders, will be permitted to enroll into a study extension for up to 6 months. The goal of this open-label extension is to assess the long-term safety and efficacy of MAT2203 in patients with chronic mucocutaneous candidiasis. Clinical evaluations will be conducted to assess clinical response and laboratory samples will be collected to assess microbiology response. In addition, adverse events will be collected and safety laboratory tests will be monitored.

"Given the significant unmet medical need for individuals with chronic mucocutaneous candidiasis, we are thrilled to be able to offer patients in our Phase 2a study the opportunity to continue in a 6-month, open-label extension study of MAT2203," stated Roelof Rongen, Chief Executive Officer. "The additional six months of safety data will be invaluable to our MAT2203 clinical development program and we look forward to furthering our understanding of this potentially game-changing novel formulation of amphotericin B."

The ongoing 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 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 study may 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 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 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 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. Currently, there are two Phase 2 studies underway with MAT2203. The first is an open-label Phase 2a NIH/NIAID-sponsored clinical study with MAT2203 in immunocompromised patients with refractory mucocutaneous candidiasis. The second is a Phase 2 study of MAT2203 in patients with vulvovaginal candidiasis (VVC). Data from both studies is expected to be announced in the first half of 2017. The FDA has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) for the treatment of invasive candidiasis and the treatment of aspergillosis, as well as for the 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 developing innovative anti-infectives for orphan indications. 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 MAT2203, currently in Phase 2, is 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, currently in Phase 1, 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, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies 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, 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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Source: Matinas BioPharma Holdings, Inc.