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Matinas BioPharma Receives Institutional Review Board Approval to Commence NIH-Sponsored Phase 2a Study With MAT2203 – An Orally Delivered, Encochleated Formulation of Amphotericin B –

- NIH IRB Approves Study of MAT2203 - Oral, Encochleated Formulation of Amphotericin B

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- Phase 2a Top line data expected in 2016-

BEDMINSTER, N.J., Oct. 05, 2015 (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 it has received approval from the Institutional Review Board (IRB) of the National Institutes of Health (NIH) on a protocol providing for the National Institute of Allergy and Infectious Diseases (NIAID) to conduct a Phase 2a clinical study with MAT2203, a lipid-crystal nano-particle formulation of amphotericin B, the Company's lead anti-infective product candidate with a novel mechanism of absorption and distribution to infected tissues.

"Matinas BioPharma is proud to partner with the NIH/NIAID, which has a long-standing commitment to fighting infectious diseases and developing better means of treating these potentially life-threatening illnesses," said Roelof Rongen, President and CEO of the Company. "This significant study will increase our understanding of MAT2203 and our underlying proprietary lipid-crystal nano-particle delivery platform technology, which we are applying to other infectious disease targets. We believe MAT2203 could represent a disruptive treatment option for fungal infections, especially given the significant limitations of, and increased resistance to, currently available therapies."

NIAID researchers will proceed with a Phase 2a, open-label, dose-titration study 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. Often, these patients develop candida infections which are resistant to treatment with standard anti-fungal regimens. This study is designed to enroll up to 16 patients, and will 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. Patient enrollment in this study is expected to

commence in the fourth quarter of 2015.

The trial is being conducted at the NIH Clinical Center in Bethesda, MD, under the direction of Principal Investigator Alexandra Freeman, M.D., of NIAID's Laboratory of Clinical Infectious Diseases. Per the terms of the underlying Clinical Trial Agreement, Matinas will provide MAT2203 to NIAID, and the company will be able to use the data from this clinical study to support further development of MAT2203. Results from this study are expected in 2016.

Recently, the U.S. Food and Drug Administration (FDA) designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status. MAT2203 is also being explored for treatment of additional infections including cryptococcal meningoencephalitis, and aspergillosis, and it may have the potential for Orphan Drug Designation in certain 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, 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 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 cochleate to nano-encapsulate existing drugs, making them safer, more tolerable, less toxic and orally available. The Company's lead drug candidate is MAT2203, an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). The Company also intends to file an investigational new drug application (IND) for MAT2501, which is an orally-administered, encochleated formulation of amikacin (a broad spectrum aminoglycoside antibiotic agent) for gram-negative and intracellular 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[®] (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 and connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#).

About the National Institutes of Health (NIH)

NIH, the nation's medical research agency, includes 27 Institutes and Centers and is a component of the U.S. Department of Health and Human Services. NIH is the primary federal agency conducting and supporting basic, clinical, and translational medical research, and is investigating the causes, treatments, and cures for both common and rare diseases. For more information about NIH and its programs, visit <http://www.nih.gov/>. NIAID conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at <http://www.niaid.nih.gov>.

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 clinical studies for MAT2203, the anticipated timing of regulatory submissions, the ability to obtain required regulatory approval, the Company's ability to identify and pursue development and partnership opportunities for its MAT9001 on favorable terms, if at all, 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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