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Matinas BioPharma Announces Interim Data from NIH-Conducted Phase 2a Clinical Study of Orally-Administered MAT2203 for the Treatment of Chronic Refractory Mucocutaneous Candidiasis

– NIH investigators present collaborative interim data of MAT2203 study at The American Society for Microbiology's ASM Microbe 2017 Conference –

– Two out of two patients met the primary endpoint in achieving ≥ 50% clinical response with MAT2203 –

– MAT2203 was well tolerated with no serious adverse events reported –

– Both patients elected to continue treatment in open-label extension study –

– Management to host conference call Monday, June 5th at 8:30 am ET –

BEDMINSTER, N.J., June 03, 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 that investigators from the National Institutes of Health ("NIH") presented interim data from two patients enrolled in the collaborative Phase 2a clinical study of Matinas' lead anti-infective product candidate MAT2203 for the treatment of chronic refractory mucocutaneous candidiasis ("CMC") infection, at The American Society for Microbiology's ASM Microbe 2017 Conference being held June 1–5 in New Orleans, LA. Two out of the two patients with long-standing azole resistant mucocutaneous candidiasis met the primary endpoint of the Phase 2a study, achieving ≥ 50% clinical response with treatment of MAT2203. MAT2203 was well tolerated with majority of adverse events observed being mild in severity and unrelated to study drug.

Matinas management will host a conference call and live webcast for investors, analysts and other interested parties to review the interim data on Monday, June 5, 2017 at 8:30 a.m. ET (details below).

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.

The abstract entitled, "Oral Encochleated Amphotericin B (CAMB) in the Treatment of Chronic Azole Resistant Mucocutaneous Candidiasis," was presented today in poster session focused on new antifungal agents, by Alexandra Freeman, M.D., of the National Institute of Allergy and Infectious Diseases (NIAID) Laboratory of Clinical Infectious Diseases, Principal Investigator of the Phase 2a study sponsored by Matinas BioPharma. To access the poster, click here.

"We are incredibly pleased with the interim safety and efficacy results of this Phase 2a study of MAT2203. While we understand the results are representative of just two patients, these patients are difficult to treat because of their severe underlying immunocompromising condition. With the statistical success hurdle that was prospectively set at a 20% patient-response probability, seeing a clinical response in two out of two patients brings us very close to the 3 out of 16 clinical responders required for the study to meet its primary endpoint, " said Roelof Rongen, Chief Executive Officer.

"We believe that with these interim results, we have made a significant step toward establishing proof-of-concept for treating fungal infections in immunocompromised patients, and importantly have begun to demonstrate in a clinical setting the depth and breadth of our cochleate technology to deliver amphotericin B orally as a chronic treatment. We are encouraged by these initial results and believe they have the potential to be predictive of the completed study outcome, and look forward to continuing the study to further understand the potential of MAT2203. We are extremely grateful to the patients for their participation and to the NIH for conducting this study," commented Raphael J. Mannino, Ph.D., Matinas BioPharma's Chief Scientific Officer.

The interim data presented showed that the first two patients in this study, both with Job's Syndrome and long-standing azole resistant mucocutaneous candidiasis for >20 years, achieved ≥ 50% clinical response after 14 days of treatment at an efficacious orally administered dosage of MAT2203, thus meeting the primary endpoint. Job's Syndrome, also known as Autosomal dominant Hyper IgE Syndrome (AD-HIES), is a hereditary condition rendering the patients severely immunocompromised and exposes them to chronic infections, including CMC, often involving the oral, esophageal and vaginal mucosas and nails. Both patients suffered from chronic azole resistant oral CMC (or oral thrush) as their primary infection and had an inadequate response to current oral antifungal therapy. Clinical efficacy criteria were met at 400mg and 200mg of MAT2203 oral suspension twice daily in patient 01 and patient 02, respectively, with improvement upon exam in clinical symptoms and semi-quantitative fungal cultures of the oral thrush condition. The clinical severity score for oral thrush (composed of oral pain, burning, dysphagia, odynophagia, and presence of plaques) decreased by 57% for patient 01 and by 85% for patient 02, with corresponding reduction in fungal culture counts. Both patients reported meaningful quality-of-life improvements.

MAT2203 was generally well tolerated and there were no signs of nephrotoxicity, hypokalemia or hepatoxicity (measured by ALT and AST). Indicators of kidney and liver toxicity remained within normal limits throughout a 6-8 week treatment period.

As expected, oral thrush promptly returned after stopping treatment with MAT2203. Therefore, Matinas' preliminary clinical data indicate that MAT2203 is promising as an oral systemically-absorbed broad-based antifungal without the toxicity of parenteral amphotericin B.

Both of the patients have elected to enroll in the open-label extension study.

“These results are very encouraging. I have patients like these individuals in my practice and they are very difficult to treat because they are immunocompromised and often resistant to azoles. There is a need for new drugs that can overcome resistance and be administered safely for extended periods. Seeing the data from the first two patients, I am optimistic that MAT2203 can be administered safely for long-periods and can treat resistant mucosal disease. Moving forward, I would like to see MAT2203 studied for the treatment and prevention of invasive fungal disease,” commented Peter G. Pappas, MD, FACP, William E. Dismukes Professor of Medicine in the Division of Infectious Diseases in the Department of Medicine at the University of Alabama at Birmingham and the Principal Investigator for the Mycoses Study Group Education and Research Consortium.

The Phase 2a study is being conducted at the National Institutes of Health Clinical Center in Bethesda, MD, under the direction of Dr. Freeman. The ongoing 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 will enroll up to 16 patients, and study endpoint in the statistical analysis plan is defined as a response in three or more patients. The study includes 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. In March 2017, the Company announced that the Institutional Review Board of the NIAID, NIH granted approval for a 6-month open-label safety extension of the Phase 2a study.

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, aspergillus, and prophylaxis (prevention) of invasive fungal infections in patients of 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.

Conference Call and Webcast Information

Matinas will host a conference call and live webcast for investors, analysts and other interested parties on Monday, June 5, 2017 at 8:30 am ET to provide an update and overview for the clinical development of MAT2203. Joining Matinas management on the call will be Dr. Edmund C. Tramont, MD, National Institute of Health, Allergy and Infectious Diseases, Associate Director for Special Projects, Former Director, Division of AIDS and Co-Investigator of the study.

The conference call and live webcast will be accompanied by presentation slides. To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The live webcast and accompanying slides will be accessible on the Events page of the Investors section of Matinas’ website, www.matinasbiopharma.com, and will be archived for 60 days.

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 and autoimmune disorders. 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 orally using our proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. 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 June 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 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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Source: Matinas BioPharma Holdings, Inc.