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Matinas BioPharma Presents Positive Preclinical Efficacy Data of MAT2203 in Mouse Model of Cryptococcal Meningoencephalitis

BEDMINSTER, N.J., June 02, 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 presentation of preclinical efficacy data at The American Society for Microbiology's ASM Microbe 2017 Conference, demonstrating its lead anti-infective product candidate MAT2203, which utilizes the Company's proprietary cochleate lipid-crystal nano-particle drug delivery technology, exhibits positive results as an effective oral anti-fungal agent for the treatment of cryptococcal meningoencephalitis.

Cryptococcal meningoencephalitis (CM) is an important infection in immunocompromised patients, including HIV/AIDS, that is responsible for an estimated half million deaths annually. Amphotericin B deoxycholate is a broad-spectrum fungicidal drug that is the standard treatment for cryptococcal disease, however, its use is limited by toxicities and intravenous administration. MAT2203 is the Company's orally-administered, encochleated formulation of amphotericin B ("CAMB"), which 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.

Raphael Mannino, Ph.D., Chief Scientific Officer of Matinas presented the abstract titled, "Efficacy of Oral Encochleated Amphotericin B (CAMB) in a Mouse Model of Cryptococcal Meningoencephalitis," in a poster session as a part of the Antimicrobial Pharmacokinetics: Antifungal PK/PD Studies track at The American Society for Microbiology's ASM Microbe 2017 Conference being held June 1–5 in New Orleans, LA. The poster includes data from two experiments in mouse models of cryptococcal meningoencephalitis, the first is a model of survival and the second is a model of delivery of MAT2203 to the brain tissue. To access the poster, click here.

"Data from the two experiments presented in the poster demonstrate that MAT2203 retains the broad spectrum fungicidal activity of amphotericin B after oral administration and the unique tissue targeted penetration of MAT2203," said Roelof Rongen, Chief Executive Officer. "The mortality results are consistent with what we have seen in models of invasive candidiasis and invasive aspergillosis and the fluorescence images of brain tissue further support the unique ability of cochleates to penetrate deep into infected organs."

In the mortality experiment mice inoculated with *C. neoformans* were randomized to one of seven treatment groups: MAT2203, MAT2203 + Fungizone, Fungizone + flucytosine,

flucytosine, fluconazole, MAT2203 + fluconazole, or control. Therapy was delayed 72 hours post-inoculation and then daily treatment commenced for 28 days and mice were followed for up to 150 days and sacrificed when moribund. The primary endpoint of this study was mortality. Results showed that MAT2203 combined with flucytosine was able to match the efficacy of the guideline recommended therapy for cryptococcal meningitis in humans, Fungizone injection combined with flucytosine (MAT2203 + flucytosine 102 d vs. Fungizone + flucytosine 80 d, p=0.44). Both groups were superior to untreated control (19 d, p=0.003). MAT2203 (49 d), fluconazole (53 d), flucytosine (47 d), MAT2203 + fluconazole (56 d) and were also superior to control (p=0.003).

The second experiment evaluated the ability of MAT2203 to penetrate into brain tissue of infected mice compared to non-infected mice. Two groups of three mice were included in the experiment. One group was infected as above and the other group was left un-infected. In each group, a subset of animals was treated orally with Rh-MAT2203 (fluorescently labeled MAT2203) for 3 days, while another subset was untreated. Evidence of infection with yeast cells was clearly visible by phase contrast microscopy in animals infected with *C. neoformans* whereas un-infected animals showed no evidence of yeast cells. Flourescence imaging demonstrated the presence of Rh-MAT2203, which was clearly more visible in the brain tissue of infected mice treated with Rh-MAT2203 compared to the uninfected mice treated with Rh-MAT2203. This demonstrates the ability of MAT2203 to penetrate into the brain tissue of mice infected with *C. neoformans*.

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 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.

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.