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Matinas BioPharma's Lead Antifungal Product Candidate MAT2203 Granted QIDP and Fast Track Designations for Prophylaxis of Invasive Fungal Infections by U.S. FDA

- Third QIDP Designation Granted by FDA for MAT2203 –

- Phase 2a study enrollment underway to evaluate MAT2203 for the treatment of chronic mucocutaneous candidiasis at NIH/NIAID -

BEDMINSTER, N.J., Sept. 07, 2016 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (OTCQB:MTNB), 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, announced today that the U.S. Food and Drug Administration (FDA) has designated the Company's lead drug candidate, MAT2203, as a Qualified Infectious Disease Product (QIDP) with Fast Track status for prophylactic treatment of invasive fungal infections due to immunosuppressive therapy.

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. As previously reported, the U.S. FDA has designated MAT2203 as a QIDP with Fast Track status for the treatment of invasive candidiasis and aspergillus.

"Prophylaxis represents an enormous unmet need in the space due to the lack of preventative treatments and incompatibility of currently available antifungals because of their drug-drug interaction, lack of efficacy, probable side-effects risk and toxicity. Patients who receive chemotherapy for the treatment of certain cancers or are on immunosuppressive therapy to facilitate bone marrow/organ transplants or to treat an autoimmune disease are at high risk for contracting invasive fungal infections. Matinas BioPharma's orally-available, broad spectrum fungicidal agent, MAT2203, has demonstrated excellent tolerability in previous studies and has the potential to become the prophylaxis drug of choice for these immunocompromised individuals," stated Roelof Rongen, Chief Executive Officer of Matinas Biopharma.

"We believe this is the first QIDP issued for an orally available, antifungal for the preventative treatment of fungal infections, which represents a tremendous opportunity for the Company. We look forward to continuing the development of MAT2203 and adding

additional evidence for the broad spectrum benefit and potential to effectively prevent serious and potentially life-threatening fungal infections with our formulation of amphotericin B utilizing our proprietary lipid-crystal cochleate delivery technology," added Mr. Rongen.

QIDP designation, provided under the Generating Antibiotic Incentives Now Act (GAIN Act), offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track, priority review and, if MAT2203 is ultimately approved by the FDA, eligibility for an additional five years of marketing exclusivity. The award of Fast Track status enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

Jerome D. Jabbour, Co-Founder and President, commented, "We continue to amass a growing body of compelling data with MAT2203, and we believe this QIDP designation represents a culmination of all of the work we have done so far to demonstrate its potential to bring a much needed preventative, broad-spectrum and significantly less toxic antifungal to patients at increased risk to contract invasive and resistant fungal infections. With important patient data on efficacy and safety from our ongoing Phase 2a trial with MAT2203 expected in the near term, these QIDP and Fast Track designations for MAT2203 in prophylaxis position us extremely well for the balance of our planned development program as we look to utilize the disruptive benefits of our technology platform to fill significant unmet medical need."

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.

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 adverse events reported, including little or no nephrotoxicity as compared to placebo. Enrollment is currently underway for the Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis, with results potentially available in 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® (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+.

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.