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Matinas BioPharma's Lead Antifungal Product Candidate MAT2203 Granted QIDP and Fast Track Designations for Treatment of Aspergillus by U.S. FDA

Third QIDP Designation Granted by FDA for a Matinas BioPharma Product This Year

BEDMINSTER, N.J., Dec. 17, 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 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 the treatment of aspergillus.

MAT2203 is an orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B, a powerful, intravenously-administered antifungal agent. This novel product is designed to provide targeted delivery to the site of infection along with a significantly improved safety and tolerability profile. [As previously reported, QIDP and Fast Track designations have been granted for the use of MAT2203 in the treatment of invasive candidiasis](#), a condition with increasing rates of drug resistance to establish anti-fungal products.

"Invasive aspergillosis is the most common cause of infectious pneumonic mortality in patients undergoing hematopoietic stem cell transplantation, and untreated patients have a nearly 100 percent mortality rate. Even when invasive aspergillosis is managed with antifungal therapy, mortality rates remain very high – between 39 percent and 75 percent in transplant patients – depending on the type of transplant," stated Roelof Rongen, President and Chief Executive Officer of Matinas BioPharma. "While advances in the treatment of blood-borne cancers and bone-marrow and solid-organ transplantation have prolonged the lives of patients with hematopoietic disorders and end-organ disease, the increasing number of individuals treated with immunosuppressive therapy has potentiated the spread of fungal infections such as aspergillus, candida, and drug-resistant mutant-strains."

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, the Company's Co-founder and Chief Business Officer, commented, "MAT2203 has the potential to bring a much needed effective, broad-spectrum and significantly less toxic antifungal to at-risk patients with invasive and resistant fungal infections. QIDP and Fast Track designations for MAT2203 in yet another indication propels this program forward and marks an important step closer to providing a much needed solution to patients and clinicians."

[Matinas previously reported 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 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. The Company expects to report data from this study in 2016.

About Invasive Aspergillosis

Invasive aspergillosis is a deadly disease in immunocompromised individuals. If left untreated, mortality associated with the disease is nearly 100%, but even with aggressive medical management of the infection, mortality rates remain high. *Aspergillosis* is not required to be reported to the CDC, thus epidemiologic data are scarce; however, several recent epidemiologic reports suggest that *Aspergillus* infections are most prevalent in hospital settings and in patients with suppressed immune systems. Of particular concern is the worldwide rise in azole-resistant strains that pose a significant threat to patients with immunodeficiency and patients undergoing immunosuppressive therapy. FDA has recognized this emerging threat and included *Aspergillus* on the list of qualifying pathogens for QIDP designations.

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 or dose-related adverse events reported, including little or no nephrotoxicity as compared to placebo. A Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis is expected to commence during the first quarter of 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 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) used to treat different types of multidrug-resistant bacterial infections, including nontuberculous mycobacterium infections (NTM) and various multidrug-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) and 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 maintain and derive benefit from the QIDP designation and to obtain Fast Track and/or Orphan drug designations for MAT2501, 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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