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Matinas BioPharma Receives Issuance of Key U.S. Patent for Novel Lipid-Crystal Nano-Particle Cochleate Formulation Technology

Patent Includes Pharmaceutical Use Claims for Lead Anti-Infective Product Candidates MAT2203 (Encochleated Amphotericin B) and MAT2501 (Encochleated Amikacin)

BEDMINSTER, N.J., June 22, 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, today announced that it received a Notice of Issuance from the U.S. Patent and Trademark Office (“USPTO”) for U.S. Patent Application Serial No. 14/609,235 entitled, “Cochleates Made with Soy Phosphatidylserine.” The patent has been issued as U.S. Patent No. 9,370,572 and provides intellectual property protection through 2033.

The issued patent claims cover proprietary methods related to the composition, methods, formulation and use of [Matinas BioPharma’s lipid-crystal nano-particle cochleate formulation technology](#). The patent also includes pharmaceutical treatment of use claims for the Company’s orally-administered lead anti-infective product candidates, [MAT2203](#) (encochleated amphotericin B, a broad spectrum fungicidal medication) and [MAT2501](#) (encochleated amikacin, a broad spectrum aminoglycoside antibiotic agent).

Roelof Rongen, Chief Executive Officer, said, “The issuance of this key patent is a significant addition to our intellectual property portfolio as the intentional design of our proprietary cochleate platform has shown enhancement of oral bioavailability and targeted delivery across a wide range of biopharmaceutical formulations making them safer, more tolerable, less toxic and orally bioavailable.”

“One of our core strategic objectives is to continue to add to our robust intellectual property estate as we move through the clinical development of our lead product candidates. Though our cochleate delivery technology can be considered a true platform technology, there are enhancements and inventions which occur as we formulate each drug candidate which should allow us to add valuable patents in support of these key assets,” stated Jerome D. Jabbour, President. “Our patent portfolio, combined with our trade secrets and the regulatory exclusivity we are positioning our products to be eligible to receive, should provide Matinas and its stockholders with significant protection as we invest in the development and commercialization of these important products.”

The Company's cochleate lipid-crystal nano-particle encapsulation technology was developed under the leadership of co-inventor, Dr. Raphael J. Mannino, Matinas BioPharma's Chief Technology Officer, in collaboration with Rutgers University, The State University of New Jersey, which has granted the Company exclusive worldwide licenses under applicable patents and offers a drug delivery solution with three differentiated and disruptive features: oral availability, multi-organ protection and enhanced safety, and targeted delivery to the site of the infection and inflammation with the ability to effectively penetrate tissues.

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 expected during 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 MAT2501

MAT2501 is an orally-administered, encochleated formulation of the broad spectrum IV-only aminoglycoside antibiotic agent amikacin, which utilizes the Company's proprietary lipid-crystal, nano-particle delivery technology. Amikacin is currently used to treat different types of chronic and acute bacterial infections, including NTM infections and various multi-drug resistant gram negative bacterial infections. IV-administered amikacin is associated with major side-effects including nephrotoxicity and ototoxicity (permanent loss of hearing) with long-term use. MAT2501 is specifically designed to provide targeted delivery of the potent antibiotic amikacin while providing a significantly improved safety and tolerability profile. In preclinical studies [MAT2501 demonstrated oral bioavailability and target delivery of amikacin directly to the site of infection](#) in both pulmonary (lung) and disseminated NTM infections. Matinas recently received [FDA clearance to initiate a Phase 1 clinical study of MAT2501 for the treatment of non-tuberculous mycobacterium infections](#). The [FDA has also designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections](#). The Company intends to initially develop MAT2501 for the treatment of NTM infections and will also explore the development of MAT2501 for the treatment of a variety of multi-drug resistant, gram negative bacterial infections. If approved, we believe MAT2501 would become the first orally bioavailable aminoglycoside and represent a significant improvement over existing therapies from a treatment and health economic perspective.

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.