

Matinas BioPharma Receives Notice of Allowance of 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., Feb. 10, 2016 (GLOBE NEWSWIRE) -- <u>Matinas BioPharma Holdings</u>, <u>Inc.</u> (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 it received a Notice of Allowance 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." Upon issuance, the patent will provide intellectual property protection through 2033.

The allowed 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).

"Our novel method of preparing drug-loaded cochleates from soy-based phosphatidylserine produces cochleate delivery vehicles with vast potential as a broad-based technology for the delivery of a wide range of bioactive therapeutic products," commented Roelof Rongen, President and Chief Executive Officer. "Importantly, the purposefully designed bilayer structure of our proprietary cochleate platform has unique properties that have been shown to enhance oral bioavailability and targeted delivery of a wide array of biopharmaceutical formulations making them safer, more tolerable, less toxic and orally bioavailable."

Jerome D. Jabbour, Co-Founder and Chief Business Officer, said, "The issuance of this patent is a significant milestone for our intellectual property portfolio. In addition to providing protection related to the structure and production of our disruptive nano-encapsulation process, this patent specifically supports our proprietary pharmaceutical use of MAT2203 and MAT2501. These orally-delivered encochleated drug formulations of two very powerful anti-infective medicines and our unique cochleate bio-delivery platform technology have the potential to transform the way potent medicines are delivered and administered."

As previously announced, Matinas is <u>currently enrolling patients in its National Institutes of Health sponsored Phase 2a study with MAT2203 for the treatment of refractory</u>

mucocutaneous candidiasis. The Company also received U.S. Food and Drug Administration clearance to initiate a Phase 1 clinical study of MAT2501 for the treatment of non-tuberculous mycobacterium infections.

The Company's 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, The State University of New Jersey, which has granted the Company exclusive worldwide licenses under applicable patents. Based on the timing of this Notice of Allowance, Matinas BioPharma expects the forthcoming cochleate formulation patent to be issued in mid-2016.

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 commenced 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 MAT2501

MAT2501 is an orally administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic amikacin which may be used to treat different types of multidrug-resistant bacteria, including non-tubercular mycobacterial infections (NTM), as well as various multidrug-resistant gram negative and intracellular bacterial infections. Currently, amikacin cannot be absorbed enterally and must be given by intravenous, intramuscular or nebulization routes with the significant risk of nephrotoxicity and ototoxicity, which makes it an impractical choice when treating serious infections which often require long courses of therapy, often 12 to 18 months or longer. MAT2501, taking advantage of its disruptive, nanoencapsulation delivery technology, is being developed to provide an orally administered, safer and targeted therapy for improved treatment of these serious and life-threatening bacterial infections in patients, including those who are severely immunocompromised.

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 <u>www.matinasbiopharma.com</u> and connect with the Company on <u>Twitter</u>, <u>LinkedIn</u>, <u>Facebook</u>, and <u>Google+</u>.

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 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 obtain Fast Track and/or Orphan drug designations for MAT2501 and/or MAT2203, 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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