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Matinas BioPharma Receives Qualified Infectious Disease Product (QIDP) and Fast Track Designations From U.S. FDA for MAT2203 for the Treatment of Cryptococcal Meningitis

Fourth QIDP and Fast Track Designations Granted by FDA for MAT2203

BEDMINSTER, N.J., July 25, 2019 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, announced today that the U.S. Food and Drug Administration (FDA) has designated MAT2203, Matinas' proprietary oral amphotericin B product, as a Qualified Infectious Disease Product (QIDP) with Fast Track status for the treatment of cryptococcal meningitis. As previously reported, the FDA has designated MAT2203 as a QIDP with Fast Track status for three other indications, specifically, the prevention of invasive fungal infections due to immunosuppressive therapy, treatment of invasive candidiasis, and treatment of invasive aspergillus.

MAT2203 is Matinas' orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B. The Company's proprietary lipid nano-crystal 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, without the toxicity historically associated with this drug which has limited its use.

"Cryptococcal meningitis is a life-threatening condition most commonly observed in immunocompromised individuals. It has emerged as one of the most frequent and deadly opportunistic infections in human immunodeficiency virus (HIV) patients," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "These QIDP and Fast Track designations for MAT2203 are another major step forward for this program, positioning Matinas for eligibility for an additional five years of marketing exclusivity in cryptococcal meningitis if MAT2203 is approved by the FDA. We are currently planning to initiate our first clinical study for MAT2203 as a treatment for cryptococcal meningitis, fully funded by the National Institutes of Health (NIH). We view this study as an important demonstration of the capability of our unique drug delivery platform, including the important potential for carrying therapies across the blood-brain barrier which could have far-reaching implications."

Jabbour added, "With the addition of this fourth regulatory designation for MAT2203, we continue to build value for MAT2203 by securing these QIDP designations with Fast Track

status in areas of critical clinical unmet need.”

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.

About MAT2203

MAT2203 is an orally-administered formulation of amphotericin B (a broad spectrum fungicidal agent) utilizing Matinas’ proprietary lipid nano-crystal (“LNC”) delivery technology platform to create a potentially better tolerated and more conveniently administered version of this fungicidal drug. Currently, IV-only administered amphotericin B has shown little to no clinical resistance and is a major broad-spectrum fungicidal product. However, it has significant treatment-limiting side effects, most notably nephrotoxicity.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on development of its lead product candidate, MAT9001, for the treatment of cardiovascular and metabolic conditions. The Company is actively pursuing the development of MAT9001 with the support of a world-class team of clinical key opinion leaders and regulatory consultants. MAT9001 is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia, which has shown superiority versus Vascepa® (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoprotein CIII and PCSK9 levels.

In addition, the Company's proprietary, disruptive lipid nano-crystal (“LNC”) platform technology helps to solve complex challenges relating to the safe and effective delivery of small molecules, gene therapies, proteins, peptides and vaccines, potentially making them safer, more tolerable, less toxic and orally bioavailable.

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 anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT9001 and MAT2203, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, 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 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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