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Matinas BioPharma Receives Orphan Drug Designation From U.S. FDA for MAT2203 for the Treatment of Cryptococcosis

MAT2203 previously designated a Qualified Infectious Disease Product with Fast Track status

BEDMINSTER, N.J., Oct. 07, 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 granted orphan drug designation to MAT2203, Matinas' proprietary oral amphotericin B product, for the treatment of cryptococcosis, a life-threatening fungal infection most commonly observed in immunocompromised individuals.

MAT2203 is Matinas' orally-administered formulation of the broad-spectrum fungicidal medication amphotericin B, which is currently in Phase 2 clinical development. This oral formulation utilizes the Company's proprietary lipid nano-crystal (LNC) technology to deliver amphotericin B in a way that targets infected tissues and avoids the toxicity normally seen with intravenously administered amphotericin B. This novel mechanism of delivery has the potential to make MAT2203 an important and valuable treatment for invasive fungal infections like cryptococcal meningitis, which is within the scope of this FDA-granted orphan drug designation.

"Orphan drug designation is yet another major step forward for MAT2203 in the treatment of life-threatening fungal infections, and adds to the prior Qualified Infectious Disease Product (QIDP) and Fast Track designations this product has already received," commented Theresa Matkovits, Ph.D., Chief Development Officer of Matinas. "We believe MAT2203 represents a promising new approach for the treatment of severe fungal infections and addresses one of the most important limitations of current antifungal treatment options. Adding orphan drug designation to the QIDP for the treatment of cryptococcal meningitis potentially positions MAT2203 for up to 12 years of marketing exclusivity, if approved."

The FDA grants orphan drug designation to novel drugs or biologics that treat rare diseases or conditions affecting fewer than 200,000 patients in the U.S. The designation allows the drug developer to be eligible for a seven-year period of U.S. marketing exclusivity upon approval of the drug, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical trial design assistance, and the waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

The FDA has previously designated MAT2203 as a QIDP with Fast Track status for three additional indications, specifically, the prevention of invasive fungal infections due to

immunosuppressive therapy, the treatment of invasive candidiasis and invasive aspergillus.

About MAT2203

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

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. MAT9001 is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia, that was specifically designed to overcome the shortcomings seen from other agents in the omega-3 class. Company leadership has a deep history and knowledge of cardiovascular drug development and is supported by a world-class team of scientific advisors. The company will soon begin enrolling MAT9001 in a confirmatory head-to-head PD study vs Vascepa® (icosapent ethyl), after having shown superiority versus Vascepa in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoprotein CIII and PCSK9 levels in a previous study, with data expected in the fourth quarter of 2020.

In addition, the Company is developing MAT2203, an oral, encochleated formulation of amphotericin B, to treat serious invasive fungal infections. The drug is based on Matinas' proprietary lipid nano-crystal (LNC) platform technology which can help solve complex challenges relating to the safe and effective delivery of potent medicines, potentially making them more targeted, 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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