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Matinas BioPharma Announces Positive Opinion by the European Medicines Agency on Orphan Drug Designation for MAT2203 for the Treatment of Cryptococcosis

BEDMINSTER, N.J., July 25, 2022 (GLOBE NEWSWIRE) -- Matinas BioPharma (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology, today announced that the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP) has adopted a positive opinion recommending MAT2203 for designation as an orphan medicinal product for the treatment of cryptococcosis. The U.S. Food and Drug Administration (FDA) previously granted Orphan, Qualified Infectious Disease Product (QIDP) and Fast Track Designations to MAT2203 for the treatment of cryptococcosis. Matinas is currently preparing to evaluate MAT2203 in a pivotal Phase 3 trial in patients with cryptococcal meningitis.

“The positive opinion for Orphan Drug Designation from the EMA is another important milestone for MAT2203 and reflects our commitment to position MAT2203 for global development and approval,” said Theresa Matkovits, Ph.D., Chief Development Officer of Matinas BioPharma. “We believe that MAT2203 has the potential to transform the treatment of cryptococcosis, as well as other deadly invasive fungal infections. This designation reflects the significant need for new therapies to treat fungal disease and we look forward to working with the EMA and FDA to potentially deliver MAT2203 to patients.”

The orphan medicinal product designation by the European Commission is granted to medicines that treat, prevent, or diagnose a life-threatening or chronically debilitating rare disease, with a prevalence in the EU of not more than five in 10,000 people, and with either no currently approved method of diagnosis, prevention, or treatment or with significant benefit to those affected by the disease. The designation potentially provides certain benefits to Matinas, including 10-year EU market exclusivity upon regulatory approval, if received, reductions in EMA application fees, and access to protocol assistance.

The FDA has previously designated MAT2203 as a QIDP with Fast Track Status and Orphan Drug Disease designation for three additional indications: the treatment of invasive candidiasis, and treatment of invasive aspergillosis, and the prevention of invasive fungal infections due to immunosuppressive therapy.

About MAT2203

MAT2203 is Matinas' orally administered formulation of the broad-spectrum fungicidal medication amphotericin B, which is currently completing Phase 2 clinical development. This oral formulation utilizes the Company's proprietary 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 oral delivery has the potential to make MAT2203 an important and invaluable treatment for invasive fungal infections like cryptococcal meningitis, mucormycosis, and invasive aspergillosis.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on improving the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides, and vaccines. The combination of a unique mechanism of action and flexibility with formulation and route of administration (including oral), positions Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors.

The Company is focused on developing an internal and external pipeline of drugs candidates based on the LNC platform. Internally, the Company has two clinical stage assets. MAT2203 is an oral, LNC formulation of the highly potent antifungal medicine amphotericin B, currently in Phase 2 clinical trials; MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside, amikacin, primarily used to treat chronic and acute bacterial infections, and currently in Phase 1. Externally, the Company has established a broad set of relationships with multiple global pharmaceutical collaborators, including BioNTech (mRNA), the National Institutes of Health and Gilead Sciences (antivirals), and Genentech, a member of the Roche Group (small molecules, antisense oligonucleotides, and antibody fragments).

For more information, please visit www.matinasbiopharma.com.

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 our business activities, our strategy and plans, our collaboration with BioNTech, the potential of our LNC platform delivery technology, and the future development of its product candidates, the Company's ability to identify and pursue development, licensing 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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Source: Matinas BioPharma Holdings, Inc.