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Matinas BioPharma Reports Successful Treatment of Patient with Limb-Threatening Mucor Infection in its Oral MAT2203 Compassionate/Expanded Use Access Program

BEDMINSTER, N.J., June 24, 2024 (GLOBE NEWSWIRE) -- [Matinas BioPharma](#) Holdings, Inc. (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, announces the recent successful treatment of a 22-year-old male with polymicrobial necrotizing fasciitis (flesh-eating disease) that involved drug-resistant *Lichtheimia*, an angio-invasive species of the fungus *Mucorales*. This patient was treated at New York Presbyterian/Weill Cornell Medical Center and was discharged after just six weeks of treatment with MAT2203, Matinas' oral formulation of the potent antifungal amphotericin B. The patient was treated under Matinas' Compassionate/ Expanded Use Access Program by Sharan Yadav, MD, Infectious Disease Fellow.

"Our team faced the challenge of an extremely aggressive fungal soft tissue infection in a young patient at high risk for amputation. Treatment with AmBisome[®] was initially helpful but, as frequently seen with intravenous amphotericin, was complicated by increasingly severe adverse effects, including significant renal toxicity that required ICU care. Switching to oral MAT2203 allowed us to effectively treat his infection and allow his kidney function to return to baseline," said Dr. Yadav. "We were very pleased to see the patient improve on this medication, leave the ICU, and eventually be discharged to rehab and later to home, where he can now bear weight on his leg and walk with assistance."

A total of 24 patients are currently receiving or have completed treatment with MAT2203 under the Compassionate/Expanded Use Access Program, and four additional cases are awaiting submission and/or FDA approval. In each instance, the patient was not responding to azole therapy, was unable to receive azole therapy due to drug/drug interactions or was unable to tolerate IV-amphotericin B for an appropriate treatment duration due to toxicity. In all patients who experienced serious renal toxicity while receiving IV-amphotericin B who were subsequently treated with MAT2203, renal toxicity was reversed, and renal function returned to baseline.

"We remain very excited by the consistently positive clinical impact of broad-spectrum, oral MAT2203," said [Theresa Matkovits, PhD, Chief Development Officer at Matinas](#) "Our Compassionate/Expanded Use Access Program continues to attract the attention of infectious disease doctors across the country who are treating patients with a wide variety of

invasive fungal infections. Our ORALTO Phase 3 registration trial will provide the opportunity to further validate these results and position MAT2203 for a New Drug Application (NDA) filing with an initial indication for the early step-down therapy for invasive aspergillosis in patients with limited treatment options. We continue to work diligently toward securing the ideal global development and commercialization partnership to advance MAT2203 into Phase 3 later this year.”

MAT2203 is not yet licensed or approved anywhere globally.

About MAT2203

Matinas BioPharma is developing MAT2203 as a potential oral broad-spectrum treatment for invasive deadly fungal infections. Although amphotericin B is a fungicidal agent, it is currently only available through an intravenous route of administration, which is known to be associated with several significant safety issues such as renal toxicity and anemia due to very high circulating levels of amphotericin B. MAT2203 has the potential to overcome the significant limitations of the currently available amphotericin B products due to its targeted oral delivery. Combining comparable fungicidal activity with targeted delivery results in a lower risk of toxicity and potentially creates the ideal antifungal agent for the treatment of invasive fungal infections. MAT2203 was successfully evaluated in the completed Phase 2 EnACT study in HIV patients suffering from cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 will be further evaluated in a single Phase 3 registration trial (the “ORALTO” trial) as an oral step-down monotherapy following treatment with AmBisome (liposomal amphotericin B) compared with the standard of care in patients with invasive aspergillosis who have limited treatment options.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can potentially provide solutions to many challenges of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos including small oligonucleotides such as ASOs and siRNA. The combination of its unique mechanism of action and flexibility with routes of administration (including oral) positions Matinas’ LNC technology to potentially become a preferred next-generation orally available intracellular drug delivery platform. 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, the future development of its product candidates, including MAT2203, the Company’s ability to identify and pursue development, licensing and partnership opportunities for its products, including MAT2203, 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 continue as a going concern, 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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