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Matinas BioPharma Demonstrates in vivo Biological Activity and Disease Improvement in Two Inflammatory Disease Models with Oral LNC-Delivered Small Oligonucleotides

In an acute colitis model, data show statistically significant knockdown of elevated levels of serum TNFα, reductions in tissue TNFα mRNA and improvement in disease activity scores

In an acute psoriasis model, data show reductions in tissue IL-17A mRNA and improvement in clinical disease markers including skin lesions

BEDMINSTER, N.J, Dec. 27, 2023 (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 technology, announces results from a series of *in vivo* studies demonstrating successful oral delivery of two LNC-formulated small single-strand oligonucleotides that specifically target key inflammatory cytokines TNFα and IL-17A in well-established and validated animal models that mimic acute inflammatory responses seen in human diseases.

“These studies demonstrate successful oral delivery and biological activity of two different LNC-formulated small oligonucleotides targeting inflammatory cytokines with reductions in tissue cytokine mRNA in both colitis and psoriasis, along with significant reductions in serum TNFα levels in colitis. Commensurate improvements in clinical disease markers and scores were also documented in both models,” said James Ferguson, M.D., Matinas’ Chief Medical Officer.

“While additional study is warranted, the successful oral delivery of small oligonucleotides is very exciting and we believe these data demonstrate how Matinas’ LNC platform could be used for the oral delivery of functional small oligonucleotides with potential therapeutic applications,” Dr. Ferguson added. “Importantly, the unique nature of the particular oligonucleotides evaluated in these studies, which interfere with cytokine synthesis rather than simply targeting the cytokine itself, creates additional opportunities for potential future applications of LNC-delivered therapeutics, either alone or in combination with other therapeutics with different mechanisms of action.”

Earlier this year, Matinas established the *in vitro* potency of these proprietary oligonucleotides and their LNC formulations in knocking down their respective cytokine targets in cultured cells. Both were advanced to *in vivo* studies to evaluate meaningful biological activity in relevant disease models.

Acute Colitis Study (TNFα)

A dextran sulfate sodium (DSS)-induced murine colitis model was used to evaluate an orally administered LNC-delivered small oligonucleotide that specifically targets TNFα mRNA synthesis. Colon tissue TNFα mRNA levels, as assessed by quantitative real-time PCR analysis, were lower following orally administered active LNCs, resulting in statistically significant reductions of serum TNFα levels by 37% compared with diseased, but untreated animals. Importantly, clinical disease activity scores at key time points in the studies were also significantly improved with an active LNC formulation.

Acute Psoriasis Study (IL-17A)

An imiquimod (IMQ)-induced murine psoriasis model was used to evaluate an orally administered, LNC-delivered small oligonucleotide designed to inhibit IL-17A mRNA synthesis, which contributes significantly to the progression of psoriatic skin lesions. Similar to the DSS colitis model, skin tissue levels of IL-17A mRNA in the IMQ psoriasis model were lower with orally administered active LNCs compared with IMQ alone. In this model, while IL-17A serum levels were not expected to change, improvement was demonstrated in clinical disease markers of skin redness and scaling, further validating the biological activity of these small oligonucleotides.

Additional tissue and histologic analyses from both studies are ongoing and the Company plans to present these data at future scientific meetings.

“We believe that our proprietary encapsulation and oral delivery methods could be applied to other small oligonucleotides, including RNAi therapeutics such as siRNA and antisense oligonucleotides,” said Jerome D. Jabbour, Chief Executive Officer of Matinas “While a variety of methods for administering small oligonucleotides exist, most are primarily directed to the liver, and none provide oral administration and delivery capabilities. The opportunity to orally deliver small oligonucleotides with extra-hepatic targeting could be key differentiating features in rapidly advancing anti-inflammatory therapy.

“We plan to further review the data from these inflammatory disease models to determine the best path forward for this program,” he added. “Further study and optimization of these LNC-delivered small oligonucleotides will be required to assess the most appropriate therapeutic targets and the associated magnitude of benefit.”

About Matinas BioPharma

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

Matinas’ lead LNC-based therapy is MAT2203, an oral formulation of the broad-spectrum antifungal drug amphotericin B, which although highly potent, can be associated with significant toxicity. Matinas’ LNC platform provides oral delivery of amphotericin B without the significant nephrotoxicity otherwise associated with IV-delivered formulations. MAT2203 also allows for safe, longer-term use outside of a hospital setting, which could have substantial favorable pharmacoeconomic impact. MAT2203 was successfully evaluated in the completed Phase 2 EnACT study in cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 will be further evaluated as an oral step-down monotherapy treatment following IV amphotericin B in a single pivotal Phase 3 study in

the treatment of aspergillosis in persons with limited treatment options who are unable to be treated with azoles for reasons related to drug-drug interactions, resistance or for whom these antifungal agents are unable to be used for other clinical reasons.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can potentially provide solutions to many of the challenges standing in the way of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos such as 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 potential of our LNC platform technology, and 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 technologies 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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