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Matinas BioPharma Completes Enrollment of ENHANCE-IT Study of MAT9001 Against Vascepa®

Topline data expected first quarter 2021

BEDMINSTER, N.J., Aug. 27, 2020 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), today announced that it has completed enrollment in the ENHANCE-IT Study (Pharmacodynamic Effects of a Free Fatty Acid Formulation of Omega-3 Pentaenoic Acids to ENHANCE Efficacy in Adults with Hypertriglyceridemia), a second head-to-head comparative study of MAT9001 against Vascepa®. The ENHANCE-IT study is assessing MAT9001's effectiveness in reducing triglyceride levels and other important lipid markers, as well as characterizing bioavailability and blood levels of eicosapentaenoic acid (EPA) and other omega-3 fatty acids. The Company expects to have topline data available in the first quarter of 2021.

"Successful completion of ENHANCE-IT enrollment is a key milestone for Matinas, and this study will provide important data for both MAT9001 and Vascepa. We believe the data generated in this clinical trial should further differentiate MAT9001's superior clinical profile over Vascepa. The data from ENHANCE-IT will be an important addition to our understanding of the rapidly-growing omega-3 class and help guide the future treatment of patients with cardiovascular disease and elevated triglycerides," commented James J. Ferguson, M.D., Chief Medical Officer of Matinas. "The dedication and commitment of the clinical trial sites, the investigators, and the study participants allowed us to complete enrollment in less than three months during an otherwise challenging time. We eagerly anticipate completing the trial in 2020 and reporting topline data in early 2021."

ENHANCE-IT is an open-label, randomized, 28-day crossover study assessing the pharmacodynamic effects of MAT9001 vs. Vascepa. The study is now fully enrolled and includes adult men and women with elevated triglycerides (150-499 mg/dL), with at least 50% of study subjects with TGs ≥ 200 mg/dL. The study protocol involves two 28-day treatment periods, with a washout period of at least 28 days in between treatments and is being conducted at eight sites in the United States. MAT9001 and Vascepa are each administered as 2g twice daily with food in accordance with currently approved Vascepa labeling. Lipid parameters (triglycerides, Total-, LDL-, VLDL-, HDL-, and non-HDL cholesterol, apolipoproteins A1, B and C3, and PCSK9) and omega-3 blood levels are being measured at each baseline and at the end of each treatment period. The primary endpoint is the percent change from baseline to end-of-treatment in plasma triglycerides.

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.

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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