

February 1, 2021



## Matinas BioPharma Announces Topline Results from ENHANCE-IT Study of LYPDISO™ Against Vascepa®

- *LYPDISO™ demonstrated a statistically significant 46% relative percent increase in EPA change from baseline over Vascepa® –*
- *LYPDISO™ demonstrated a 39% relative difference in response over Vascepa in TG reduction –*
- *Primary endpoint of percent change from baseline to end of treatment in triglycerides in the pharmacodynamic population did not meet statistical significance over Vascepa® –*
- *Per protocol analysis demonstrated statistical significance and superiority vs. Vascepa® on several key lipid and inflammatory markers –*
- *Management to host conference call today, Monday, February 1, 2021 at 8:00 a.m. ET –*

BEDMINSTER, N.J., Feb. 01, 2021 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today announced topline results from the ENHANCE-IT study (*Pharmacodynamic Effects of a Free-fatty Acid Formulation of Omega-3 Pentaenoic Acids to ENHANCE Efficacy in Adults with Hypertriglyceridemia*), the second head-to-head comparative study of LYPDISO™ vs. Vascepa®.

In ENHANCE-IT, the key parameters evaluated included triglycerides (TGs), other lipoprotein and inflammatory markers, and blood levels of omega-3 fatty acids. The primary endpoint was the percent change from baseline to end-of-treatment in TG and superiority vs. Vascepa®.

Analyses were performed on a Pharmacodynamic (PD) population (n=94; all subjects with evaluable measurements in the two-treatment period, regardless of compliance with study drug treatment), and a Per Protocol (PP) population (n=82; those subjects in the PD population where overall compliance in both treatment periods was at least 80% with no clinically important protocol violations or deviations).

Plasma eicosapentaenoic acid (EPA) concentrations were statistically significantly higher with LYPDISO™, with a 46% relative percentage improvement in EPA blood level concentrations over Vascepa®.

In the PD population there was a greater reduction in TGs with LYPDISO™ (21.9%) as

compared with Vascepa (15.7%); this 39% relative improvement did not achieve statistical significance. In the PP population, there were statistically significant superior reductions in TGs, total cholesterol (TC), VLDL cholesterol (VLDL-C) and high sensitivity C-reactive protein (hsCRP), a well-established inflammatory marker.

“In this ENHANCE-IT study, LYPDISO™ achieved significantly higher EPA levels, and lowered triglycerides as well as hsCRP levels to a greater extent than Vascepa®,” said John J.P. Kastelein, M.D., Ph.D., Matinas Scientific Advisory Board member and Professor of Medicine at the Department of Vascular Medicine at the Academic Medical Center of the University of Amsterdam, The Netherlands. “The REDUCE-IT outcomes trial with Vascepa® has shown that achieved EPA levels drive the cardiovascular protection conferred by omega-3 fatty acids. The impressive biomarker changes in ENHANCE-IT with LYPDISO™ support a potential robust protection against cardiovascular disease in a pivotal Phase 3 outcome program.”

### PLASMA FATTY ACIDS – Pharmacodynamic (PD) Population

PD Population (n=94)							
Fatty Acid	Baseline (Median)		End-of-Treatment (Median)		% Δ from Baseline (Median)		Re
	LYPDISO™	Vascepa®	LYPDISO™	Vascepa®	LYPDISO™	Vascepa®	Inc
							On
							3 le
							Vas
<b>EPA</b> (µg/mL)	<b>13.8</b>	<b>15.5</b>	<b>143</b>	<b>115</b>	<b>1009</b>	<b>690</b>	4
<b>DPA</b> (µg/mL)	<b>20.3</b>	<b>20.7</b>	<b>57.8</b>	<b>50.3</b>	<b>183</b>	<b>145</b>	2
<b>DHA</b> (µg/mL)	<b>48.6</b>	<b>50.2</b>	<b>49.7</b>	<b>48.1</b>	<b>4.5</b>	<b>-1.4</b>	
<b>EPA+DPA+DHA</b> (nmol/mL )	<b>254</b>	<b>263</b>	<b>789</b>	<b>696</b>	<b>221</b>	<b>160</b>	3

The pharmacodynamic (PD) population included all subjects for whom the estimation of PD parameters was possible for 2 treatment periods.

Blood fatty acids levels increased with both LYPDISO™ and Vascepa®, with similar findings in both the PD and the PP populations. In the PD population the change in fatty acid level with LYPDISO™ was 46% greater for EPA, 26% greater for DPA, and 38% greater for total omega-3 levels than with Vascepa® – all highly statistically significant. DHA levels did not change meaningfully with either therapy but increased slightly with LYPDISO™.

These findings highlight and further confirm the greater bioavailability of LYPDISO's free fatty acid formulation in delivering substantially higher blood levels of EPA.

## LIPOPROTEINS AND INFLAMMATORY MARKERS – Pharmacodynamic (PD) Population

Variable*	PD Population (N = 94)		P-value
	Median % Δ		
	LYPDISO™	Vascepa®	
TG	-21.9	-15.7	0.27
TC	-5.2	-2.9	0.17
LDL-C	-5.4	-2.5	0.24
VLDL-C	-16.3	-12.9	0.26
HDL-C	-1.3	-1.5	0.69
Non-HDL-C	-7.5	-3.8	0.19
Apo A1	-5.0	-3.5	0.46
Apo B	-4.7	-1.9	0.54
Apo C3	-12.5	-10.5	0.53
PCSK9	-7.7	-6.1	0.80
hs-CRP	-5.7	9.4	0.03

\*Units of mg/dL for lipoprotein lipids, units of ng/mL for PCSK9, and units of mg/L for hs-CRP

In the PD population LYPDISO™ reduced TGs by 21.9%, compared to a 15.7% reduction with Vascepa®; this difference (a relative improvement of 39%) did not achieve statistical significance.

There were similar numerical trends for all other lipid parameters. Of note, LYPDISO™ did not raise LDL cholesterol, as has been noted with other omega-3 formulations containing DHA.

With regard to changes in hs-CRP, there were statistically significant and superior differences between groups – LYPDISO™ was associated with reductions in hs-CRP, while Vascepa was associated with increases in hs-CRP.

## LIPOPROTEINS AND INFLAMMATORY MARKERS – Per Protocol (PP) Population

Variable	*PP Population (N = 82)		P-value
	Median % Δ		
	LYPDISO™	Vascepa®	
TG	- 20.9*	-13.8	0.04
TC	- 5.5*	-2.3	0.04
LDL-C	-5.6	-2.1	0.17
VLDL-C	- 16.0*	-10.9	0.03
HDL-C	-1.6	-2.0	0.52

Non-HDL-C	-7.6	-3.2	0.07
Apo A1	-5.0	-2.9	0.44
Apo B	-4.1	-1.8	0.60
Apo C3	-11.1	-8.7	0.10
PCSK9	-6.7	-5.5	0.68
hs-CRP	<b>- 6.1*</b>	<b>9.9</b>	<b>0.01</b>

\*The per protocol population (**PP**) included all subjects in the **PD** population for whom compliance for both study periods was at least 80% and for whom no clinically important protocol violations or deviations occurred during the trial.

\*Statistically significant (superiority) vs. Vascepa

In the prespecified PP population, there were similar numerical trends as seen within the PD population; however, given the more stringent compliance requirements for this population, with less inter-individual variability, some of the differences between groups now emerged as statistically significant.

In the PP population, LYPDISO™ reduced TGs by 20.9%, compared to a 13.8% reduction with Vascepa®; this difference was significant with a P-value of 0.04 (a relative improvement of 51%).

There were additional statistically significant superior reductions with LYPDISO™ in total cholesterol (5.5% vs 2.3%) and VLDL-C (16.0% vs 10.9%), with similar non-significant numerical trends for the other lipid parameters.

In the PP population, there were again significant differences between groups in hs-CRP response.

“We are very grateful for all the hard work and dedication on the part of the study team, the investigators, and most importantly, the study subjects, especially during a pandemic,” commented James J. Ferguson, M.D, FACC, FAHA, Chief Medical Officer of Matinas. “These results have advanced our understanding of the potential role of LYPDISO™ in the management of patients with elevated triglycerides and cardiovascular disease. Bioavailability is clearly an important consideration in achieving higher EPA levels. Even when Vascepa is given the advantage of being dosed with meals, LYPDISO™ provides TG lowering that is better than with Vascepa®, with no increase in LDL-C, and with the added advantage of substantially higher blood levels of EPA, total omega-3 and significant impact on hs-CRP.”

“We are very pleased with the topline data from ENHANCE-IT,” said Jerome D. Jabbour, Chief Executive Officer of Matinas. “The statistically significant superior EPA levels achieved with LYPDISO are an important differentiator vs. Vascepa®. Although we did not achieve statistical significance on the primary endpoint of triglycerides in the prespecified population, these data point to the potential for robust cardiovascular risk reduction with LYPDISO™. We further believe that these data could position LYPDISO™ to potentially become the best-in-class prescription omega-3 for the reduction of cardiovascular risk and we will begin a process to identify a partner with which to collaborate on a cardiovascular outcomes study.”

ENHANCE-IT was an open-label, randomized, 28-day crossover study assessing the pharmacodynamic effects of LYPDISO vs. Vascepa. The study enrolled 100 adult men and women with elevated triglycerides (150-499 mg/dL), with approximately 58% of study subjects with TGs  $\geq$  200 mg/dL. The study protocol involved two 28-day treatment periods, with a washout period of at least 28 days in between treatments and was conducted at eight sites in the U.S. LYPDISO and Vascepa were 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), a key inflammatory marker (hs-CRP), and omega-3 blood levels were measured at each baseline and at the end of each treatment period. The primary endpoint measured the percent change from baseline to end-of-treatment in plasma triglycerides.

Analysis of the safety database for ENHANCE-IT remains ongoing. There were no serious adverse events reported for this study and no dropouts related to study drug adverse events.

Further analyses of additional clinical data from the study are continuing and the Company expects to present the full data from this study at upcoming scientific congresses and in peer-reviewed journals over the course of the year.

### **Conference Call and Webcast Information**

Matinas will host a live conference call and webcast today, February 1, 2021, at 8:00 a.m. Eastern Time to discuss the results from ENHANCE-IT. A slide presentation will accompany the call and webcast and will be available on the Company's website.

Participating on the conference call will be members of the Matinas management team as well as Dr. Kastelein.

The conference call can be accessed by dialing 877-407-5976 for participants in the U.S. or Canada and 412-902-0031 for international callers (reference passcode 13715418).

The conference call will also be webcast live on Matinas' website, [www.matinasbiopharma.com](http://www.matinasbiopharma.com), under the 'Investors' section and will be archived there for 90 days.

### **About Matinas BioPharma**

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care for patients in areas of significant unmet medical need. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

LYPDISO, the Company's lead product candidate for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia.

In addition, Matinas is developing a portfolio of products based upon its proprietary lipid nanocrystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them orally bioavailable, less toxic, and targeted to cells and tissues.

MAT2203 is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, primarily used to treat serious invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT is currently enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

MAT2501 is an oral, encochleated formulation of the broad-spectrum aminoglycoside antibiotic medicine amikacin, primarily used to treat chronic and acute bacterial infections. The Company recently announced that it has been awarded up to \$3.75 million from the Cystic Fibrosis Foundation (CFF) to support development of MAT2501 toward an indication to treat nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

### **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 ENHANCE-IT study, the Company's strategic focus and the future development of its product candidates, including MAT9001, 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.

## Investor and Media Contacts

Peter Vozzo  
Westwicke  
443-213-0505  
[peter.vozzo@westwicke.com](mailto:peter.vozzo@westwicke.com)

Ian Cooney  
Director – Investor Relations & Corporate Development  
Matinas Biopharma, Inc.  
(415) 722-4563  
[icooney@matinasbiopharma.com](mailto:icooney@matinasbiopharma.com)



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