September 15, 2020

Matinas BioPharma Announces Positive End of Phase 2 Meeting with the FDA for MAT9001 in Severe Hypertriglyceridemia (SHTG)

- FDA Agreement to Move Directly into Phase 3 -

- FDA to Require a Single Phase 3 Trial of 12 Weeks Duration to Support Efficacy for an NDA filing in SHTG -

BEDMINSTER, N.J., Sept. 15, 2020 (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 the result of its End of Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) concerning the development and registration pathway for MAT9001, a potential best-in-class prescription omega-3 therapy. The official minutes of the meeting confirmed that the FDA and Matinas are aligned on key next steps for MAT9001's Phase 3 development program and registration pathway for an initial indication to treat severe hypertriglyceridemia (SHTG), a clinical disorder associated with major complications such as pancreatitis and atherosclerotic cardiovascular disease. The Company remains on track to initiate its Phase 3 program in the first half of 2021.

"We are extremely pleased with the outcome of our meeting with FDA and are encouraged by the highly collaborative and strategic input we received for our program. I am very proud of what we have accomplished as a team and look forward to initiating the Phase 3 trial in SHTG and maximize the clinical opportunities for MAT9001," said Theresa Matkovits, Ph.D., Chief Development Officer of Matinas BioPharma.

The Company and the FDA agreed on key elements of the Phase 3 program to support a New Drug Application (NDA) filing, including the requirement for a single 12-week study to support efficacy in SHTG. Moreover, FDA provided flexibility to Matinas in the totality of patient safety data needed to meet regulatory requirements for NDA submission. The Company is evaluating several ways to both meet these requirements and to potentially provide additional data differentiating MAT9001 from other prescription omega-3 drugs.

"Alignment with the FDA on our Phase 3 development program provides clarity about our development pathway for MAT9001 in SHTG," said Jerome D. Jabbour, CEO of Matinas BioPharma. "With this important feedback from FDA, we can confidently move forward with our streamlined 505(b)2 registration for MAT9001. Our level of enthusiasm for this potential best-in-class omega-3 therapy remains high, and we look forward to forthcoming near-term data from our ongoing ENHANCE-IT head to head trial of MAT9001 vs. Vascepa to once

again highlight the differentiation between these two products and the potential significant clinical benefits of MAT9001 for patients with hypertriglyceridemia and cardiovascular disease."

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.

MAT9001, 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. MAT9001 is currently in a second head-to-head comparative study against Vascepa® (ENHANCE-IT), with topline data expected in the first quarter of 2021.

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

MAT2203, the Company's lead product candidate utilizing its LNC platform, is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, 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, with potential cohort progression anticipated in the fourth quarter of 2020.

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.

Investor and Media Contacts

Peter Vozzo
Westwicke
443-213-0505
peter.vozzo@westwicke.com

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

Source: Matinas BioPharma Holdings, Inc.