March 31, 2020

Matinas BioPharma Provides Comment on Impact of Vascepa® Patent Litigation on MAT9001 and Update on COVID-19 Pandemic's Effect on Business Operations and Clinical Programs

BEDMINSTER, N.J., March 31, 2020 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, today commented on the recent United States District Court decision to invalidate patents related to Amarin Corporation's Vascepa and also provided an update on the effect of the rapidly evolving COVID-19 pandemic on its business operations and clinical development programs.

Impact of Invalidity Decision on Amarin Corporation's Vascepa® Patents

Matinas is aware of the United States District Court for the District of Nevada's ruling yesterday in favor of the generic companies in Amarin Corporation's patent litigation against two filers of abbreviated new drug applications, or ANDAs, for Amarin's Vascepa. Amarin issued a statement yesterday indicating that it will appeal and vigorously defend its intellectual property, while seeking an injunction to prevent a potential launch of generic versions of Vascepa. In noting that an ANDA for Vascepa has not been approved, Amarin also commented that this decision has no impact on geographies outside the United States where Vascepa is currently sold and/or under regulatory review.

"We understand that there may be concern from our shareholders about the impact this decision against Amarin may have on MAT9001, our proprietary prescription-only omega-3 free fatty acid based combination of primarily eicosapentaenoic acid (EPA) and docosapentaenoic acid (DPA) for the treatment of hypertriglyceridemia and cardiovascular and metabolic conditions," stated Jerome D. Jabbour, Chief Executive Officer of Matinas. "Without commenting on the substance of Amarin's legal case, we believe there are certain facts and realities which should be highlighted as set forth below," continued Mr. Jabbour.

- The Nevada District Court's ruling on the Vascepa patents has no impact on the validity of the issued or pending patents covering MAT9001, which extend until 2033 or potentially later;

- Matinas continues to believe that MAT9001, if approved, will be eligible for 5-year New Chemical Entity exclusivity and subject to the protections afforded by the Hatch Waxman Amendments, which could prevent generic alternatives to MAT9001 for no less than 7.5 years from the date of approval;

- MAT9001 was designed to be the potential best-in-class prescription-only omega-3 drug with a profile superior to every other approved prescription omega-3 product, including Vascepa and any generic alternative to Vascepa;

- In a previous head to head study with Vascepa, MAT9001 demonstrated superiority versus Vascepa® (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoprotein CIII and PCSK9 levels;

- The Company's ENHANCE-IT study is designed and positioned to further highlight the differentiating characteristics of MAT9001 to Vascepa, including enhanced blood levels of EPA, which we believe could be important for commercialization of MAT9001, if approved;

- Our intended Phase 3 registration study of MAT9001 in patients with severe hypertriglyceridemia (triglycerides (TGs) ≥ 500 mg/dL) is planned to include both a 2g dose arm and a 4g dose arm for approval, whereas Vascepa and any generic competitor will only have a 4g approval.

- MAT9001 is further differentiated from Vascepa in that its dosing is intended to be once or twice daily, without regard to meals.

"We continue to believe that MAT9001 has best in class potential regardless of the final outcome of the Vascepa patent litigation," continued Mr. Jabbour. "Ultimately, MAT9001's potential position as the best-in-class prescription-only omega-3 continues to be contingent on, among other things, the results of the planned ENHANCE-IT study and the outcome of our potential Phase 3 clinical program in severe hypertriglyceridemia. We are excited to have the opportunity to let the data speak for themselves and we look forward to building upon the existing data for MAT9001 which demonstrates superiority to Vascepa, and therefore to any generic alternative to Vascepa."

Update on Effect of COVID-19 Pandemic on Operations and Clinical Programs

Based on the concerns for the safety and health of patients and their caregivers, and risks of disruption to the integrity of trials from COVID-19, very few of the planned clinical trials in the U.S. and globally are commencing and the vast majority that are in progress are being suspended. After conducting our own analyses, the Company has determined to pause enrollment in each of its ongoing clinical trials as set forth below. In taking these decisions, the Company relied on guidance from the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration's (FDA) guidance document, entitled "Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic." These decisions will be re-evaluated on an ongoing basis as the COVID-19 situation evolves globally.

"Matinas has been monitoring developments domestically and abroad and is committed to ensuring the health of its employees, the safety of participants in ongoing clinical trials, and the safety and health of the larger caregiver and patient communities," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "Equally important, we are taking prudent steps to ensure the integrity of our clinical trials in which continuity and avoidance of disruption are critical elements for successfully answering the important underlying scientific

questions. Given the importance of the ENHANCE-IT and EnACT studies to our overall business, we need to do everything we can to ensure patient safety while at the same time preserving the best opportunity to ensure the successful delivery of clinically meaningful data. Despite the current circumstances, the fundamentals of our business, as well as our balance sheet, remain strong and we are collectively committed to navigating this pandemic as best as reasonably possible."

Clinical Trial Impact of COVID-19

- ***ENHANCE-IT***

Following consultation with the study director, Dr. Kevin Maki, as well as feedback from the various clinical trial sites involved, the Company has temporarily paused enrollment in the ENHANCE-IT (*Pharmacodynamic Effects of a Free-fatty Acid Formulation of Omega-3 Pentaenoic Acids to ENHANCE Efficacy in Adults with Hypertriglyceridemia*) trial, a head-to-head comparative study of MAT9001 vs. Vascepa. The Company previously announced initiation of this study on March 5, 2020, with expected topline data in the fourth quarter of 2020. Presently, there is not enough available information to determine whether an adjustment to this guidance is required. The Company will work to resume enrollment as soon as clinically appropriate and has taken steps to potentially increase the speed of enrollment, including adding additional strategic clinical sites in the United States.

- **EnACT**

On March 26, 2020, the Uganda National Drug Authority (NDA) informed all affected sponsors and clinical investigators that recruitment of new clinical trial participants in Uganda was to be immediately suspended as a result of the global COVID-19 Pandemic. As a result, and in consultation with the principal investigator, Dr. David Boulware, enrollment of new patients into the EnACT (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) study has been temporarily paused. Additionally, the two patients who had been enrolled and dosed in the clinical study were discontinued and transitioned onto standard of care therapy consistent with established guidelines. These actions were taken to mitigate any potential risk to the integrity of clinical data. The Company is in discussions with the Uganda NDA and the clinical site and will resume enrollment as soon as clinically appropriate. The Company should be in position to provide an update on enrollment during its first quarter 2020 conference call, but continues to expect potential progression from the first patient cohort to the second patient cohort during 2020 given the significant unmet medical need in the treatment of crypotococcal meningitis in Uganda.

Regulatory Impact of COVID-19

The Company's ongoing preparations for an End-of-Phase 2 meeting for MAT9001 with the FDA to date have not been impacted by the COVID-19 pandemic. Those studies necessary to support a planned 505(b)(2) registration pathway have been completed and final study reports are in the process of being prepared. The Company continues to expect to request a meeting with FDA to be held in the third quarter of 2020 to discuss these data, as well as the protocol for a Phase 3 registration study of MAT9001 in patients with severe hypertriglyceridemia (TGs≥ 500 mg/dL).

Supply Chain Update

We continue to work closely with our third-party manufacturers and other trusted partners to manage our supply chain activities and mitigate any potential disruptions to our clinical trial product supply as a result of COVID-19. We are pleased to report that we currently do not expect any supply-related delays to our ongoing clinical programs. Sufficient quantities of both MAT9001 and MAT2203 are currently available to complete ENHANCE-IT and the first cohort of patients in EnACT.

Employees and Communities

Matinas has instituted a mandatory work-from-home policy for its employees at each location to stem the spread of the coronavirus and enable the continued health and safety of its work force. The duration of this remote working arrangement will be guided by the direction of the governor of New Jersey and the actions and guidelines issued by the federal government, including the CDC.

As we, along with the rest of the world, navigate these unprecedented circumstances, we are committed to continuing to implement measures intended to minimize any potential business impact from COVID-19 and will continue to closely monitor, assess and respond to the situation as it evolves.

Financial Outlook

Matinas continues to evaluate the impact of COVID-19 on its business operations and cash runway. The Company ended 2019 in a strong financial position. During the first quarter of 2020, the Company raised approximately $50 million in gross proceeds from a common stock offering. As of February 29, 2020, Matinas had cash, cash equivalents and marketable securities totaling approximately $70 million. While it is possible that certain business disruptions related to COVID-19 are likely to lead to lower spending in 2020, the Company continues to believe that cash on hand is sufficient to fund operations into the second half of 2022. The Company will provide an update to its 2020 financial guidance, if necessary, on its first quarter 2020 results conference call.

*VASCEPA® is a registered trademark of the Amarin group of companies.

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 the Company's proprietary lipid nano-crystal (LNC) platform delivery 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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Source: Matinas BioPharma Holdings, Inc.