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Mateon Therapeutics Announces Results from Second Interim Analysis of CA4P Phase 2/3 FOCUS Study in Platinum-resistant Ovarian Cancer

- ***Primary Endpoint - Early Progression Free Survival data favors CA4P***
- ***CA4P continues to be safe and well-tolerated***
- ***Next interim analysis expected in September***

SOUTH SAN FRANCISCO, Calif., Aug. 16, 2017 (GLOBE NEWSWIRE) -- Mateon Therapeutics, Inc. (OTCQX:MATN), a biopharmaceutical company developing vascular disrupting agents (VDAs) for the treatment of orphan oncology indications, today announced results from its second scheduled interim analysis of the ongoing phase 2/3 FOCUS study evaluating CA4P in combination with bevacizumab (Avastin®) and physician's choice chemotherapy in patients with platinum resistant ovarian cancer (prOC).

FOCUS is designed to evaluate whether the addition of CA4P improves progression-free survival (PFS), the primary endpoint of the study, as well as objective response rate (ORR) and other measures. All patients enrolled in the FOCUS study are receiving either CA4P or placebo plus the current standard-of-care for platinum-resistant ovarian cancer, bevacizumab (Avastin®) and chemotherapy. The current interim analysis is based on initial results from the first 40 patients (19 with CA4P, 21 with placebo) in the study who have been treated for at least two months or discontinued from the trial. A total of 91 patients have been enrolled in the phase 2 portion of FOCUS. The next (third) interim analysis will be conducted when approximately ¾ of the enrolled patients (originally targeted at 80) have been treated for at least two months or discontinued from the study.

"We are encouraged that early data on the primary endpoint of the study continue to favor CA4P and that our investigational drug remains well tolerated," said William D. Schwieterman, M.D., President and Chief Executive Officer. "There is a large unmet medical need in the ovarian cancer market as patients with prOC have low survival rates and few treatment options. We look forward to additional and more mature data from the 3rd interim analysis expected just over one month from now - in this upcoming analysis we will have more data on the current patients, who will have had additional time under treatment, as well as initial efficacy and safety information on approximately 25 additional patients."

Efficacy Results

PFS, the primary endpoint of the study, continues to favor the CA4P group, with a 1.68 month increase in median PFS for the patients receiving CA4P compared to control (6.64 months vs. 4.96 months; HR=0.68; p=0.456). Progression events are available from 16 of 40 (40%) patients: six patients (31.6%) in the CA4P arm and ten (47.6%) patients in the control arm progressed or died while in the study.

Partial responses were observed in 4 of 16 (25.0%) patients treated with CA4P and 6 of 19 (31.6%) patients treated with the control regimen. Stable disease was observed in 9 of 16 (56.3%) patients treated with CA4P compared to 11 of 19 (57.9%) patients treated in the control arm.

Safety Results

CA4P continues to show a favorable safety profile. Most patients receiving CA4P experienced transient increases in blood pressure (BP) compared to the control arm (57.9% vs. 9.5%, respectively). BP increases generally peaked two hours following treatment and normalized without clinical sequelae two to three hours later. Rates of grade 3 hypertension were similar between the treatment and control arms (21.1% vs. 23.8%). There was one case of grade 4 hypertensive crisis in the CA4P arm. Adverse events that occurred in > 25% of patients and more frequently in the treatment arm included nausea, fatigue, cough, and hypertension, most of which were mild to moderate in severity. Rates of neutropenia, anemia, and thrombocytopenia were low and similar between treatment arms.

About Mateon

Mateon Therapeutics, Inc. is a biopharmaceutical company seeking to realize the full potential of vascular targeted therapy (VTT) in oncology. VTT includes vascular disrupting agents (VDAs) such as the investigational drugs that Mateon is developing, and anti-angiogenic agents (AAs), a number of which are FDA-approved and widely used in cancer treatment. These two approaches have distinct yet complementary mechanisms of action.

At Mateon, we believe that we can significantly improve cancer therapy by employing these two complementary approaches simultaneously. When utilized this way, VDAs obstruct existing blood vessels in the tumor leading to significant central tumor cell death while AAs prevent the formation of new tumor blood vessels.

Mateon is committed to leveraging our intellectual property and the product development expertise of our highly skilled management team to enable VTT to realize its true potential and to bring much-needed new therapies to cancer patients worldwide.

Safe Harbor Statement
Certain statements in this news release, including, but not limited to, safety and efficacy of CA4P, future clinical trial results, the potential significance of the interim data and the company's need for additional funding in the near term are considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. They can be affected by inaccurate assumptions Mateon might make or by known or unknown risks and uncertainties, including, but not limited to: the sufficiency of the Company's cash resources to conduct and complete future clinical and pre-clinical trials; the uncertainties as to the future success of ongoing and planned clinical trials; and the unproven safety and efficacy of products under development or that may be developed in the future. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in Mateon's reports to the Securities and Exchange Commission, including Mateon's reports on Forms 10-Q, 8-K and 10-K. However, Mateon undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise.

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