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Mateon Therapeutics Receives Notice of Partial Clinical Hold for OX1222 Study

SOUTH SAN FRANCISCO, Calif., Aug. 17, 2018 (GLOBE NEWSWIRE) -- Mateon Therapeutics, Inc. (OTCQB:MATN), a biopharmaceutical company developing investigational drugs for the treatment of orphan oncology indications, today announced that the U.S. Food and Drug Administration (FDA) placed a partial clinical hold on Study OX1222 during a telephone conversation held with the Company on August 16, 2018. OX1222 is the Company's clinical trial of OXi4503 in combination with cytarabine for the treatment of relapsed/refractory acute myeloid leukemia and myelodysplastic syndromes. The partial clinical hold applies to the 12.2 mg/m^2 dose of OXi4503. The FDA is allowing the study to continue to treat and enroll patients using a dose of 9.76 mg/m^2 of OXi4503, which the Company previously tested in cohort 5 of Study OX1222.

The partial clinical hold follows two potential dose-limiting toxicities (DLTs) observed at the 12.2 mg/m^2 dose level that was being evaluated in cohort 6 of Study OX1222. These DLTs consist of one patient experiencing hypotension shortly following initial treatment with OXi4503, and another patient experiencing acute hypoxic respiratory failure approximately two weeks after receiving OXi4503 and cytarabine. Both events were deemed "possibly-related" to OXi4503, and both patients recovered following treatment. The protocol for Study OX1222 generally defines a DLT as any grade 3 serious adverse event (SAE) where a relationship to OXi4503 cannot be ruled out. The FDA has indicated that additional data on patients receiving 9.76 mg/m^2 of OXi4503 must be evaluated before the Company resumes dosing at 12.2 mg/m^2.

"Although it is disappointing that we are not currently continuing with the higher dose of OXi4503, we look forward to gathering more safety and efficacy data at the previous dose level, where we observed two complete remissions in the four patients that we treated," said William D. Schwieterman, M.D., Chief Executive Officer of Mateon.

About Mateon

Mateon Therapeutics, Inc. is a biopharmaceutical company developing investigational drugs for the treatment of orphan oncology indications, with programs in acute myeloid leukemia and immuno-oncology. Mateon is committed to leveraging its product development expertise and intellectual property to bring improved and medically necessary new therapies to cancer patients worldwide.

Safe Harbor Statement

Certain statements in this news release, including, but not limited to, those concerning additional data for OXi4503 and the safety and efficacy of OXi4503 as a treatment for acute myeloid leukemia and myelodysplastic syndromes 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 continue in business and 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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