UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
Date of Report (Date of earliest event reported)
September 30, 2020

MATEON THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-21990**	**13-3679168**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

29397 Agoura Road Suite 107
Agoura Hills, CA 91301
(Address of principal executive offices and Zip Code)

Registrant's telephone number, including area code
(650) 635-7000

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of class	Trading Symbols	Name of each exchange on which registered
N/A		

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [ ]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [ ]

Item 8.01 Other Events

OXi4503 Publications

A series of peer-reviewed publications on OXi4503 confirming its anti-tumor activities that can be further enhanced with checkpoint inhibitor and other chemo-agents. Most important is Dr. Uckun's publication on OXi4503 for pediatric AML and FDA granting our request for Rare Pediatric Designation for AML for OXi4503. The data can be summarized as follow:

OXi4503 exhibited single-agent anti-leukemia activity in animal models of AML and in a Phase 1A clinical study for relapsed/refractory (R/R) AML. Notably, the combination of OXi4503 with cytarabine (ARA-C) in xenografted human AML models was more effective than either drug alone. The clinical safety profile of OXi4503 as a single agent has previously been evaluated in Phase 1A clinical trials. In the NCT00977210 Phase 1 dose-finding study in 43 advanced solid tumor patients, OXi4503 doses were escalated from 0.06 to 15.4 mg/m2, and 8.5 mg/m2 was defined as the maximum tolerated dose (MTD). In the NCT01085656 Phase 1A trial designed to evaluate the safety profile, MTD, and recommended Phase 2 dose of OXi4503 in patients with R/RAML and MDS, a total of 18 patients were treated with single-agent OXi4503 and showed a manageable safety profile at single-agent dose levels up to of 7.81 mg/m2 and there was early evidence of possible single-agent anti-AML activity.

More recently, a Phase 1B study was performed to evaluate the safety, tolerability, and clinical activity of a combination of OXi4503 and the standard anti-AML drug ARA-C. The combination therapy exhibited a manageable toxicity and a promising benefit to risk profile in adults relapsed AML. An MTD level of OXi4503 was identified as the recommended dose for further clinical development of this novel two-drug combination. In 26 evaluable AML patients, there were four complete remissions (CR/CRi) and one partial remission. The median overall survival time for the four patients who achieved a CR/CRi was 528 days (95% confidence interval [CI]: 434 – NA), which was significantly longer than the median overall survival time of 113 days (95% CI: 77–172) for the remaining 22 patients who did not achieve a CR (Log rank Chi-square = 11.8, P-value = 0.0006). The safety, feasibility, and clinical activity of OXi4503 + ARA-C combination regimen in R/R AML deserve further clinical validation in a randomized registration study.

Taken together, the preclinical and clinical studies to date demonstrate the potential of OXi4503 as a promising new drug in the treatment of pediatric AML in relapse, an orphan disease with a low survival rate and no established or effective standard of care. OXi4503 has received orphan drug designation for AML in both the US and the European Union. Further, the US FDA has granted fast track designation to OXi4503 for the treatment of R/R AML. OXi4503 may offer renewed hope for salvage therapy of pediatric AML patients in relapse who have this rare and fatal disease.

1) Clinical Potential of Combretastatin A1 Diphosphate for the Treatment of Relapsed Pediatric Acute Myeloid Leukemia. Fatih M. Uckun, Vuong N. Trieu. Clin Res Pediatr 2019;2(2):1-2. https://asclepiusopen.com/clinical-research-in-pediatrics/volume-2-issue-2/2.pdf
2) Tumors Resistant to Checkpoint Inhibitors Can Become Sensitive after Treatment with Vascular Disrupting Agents. Horsman MR, Wittenborn TR, Nielsen PS, Elming PB. Int J Mol Sci. 2020 Jul 6;21(13):4778. doi: 10.3390/ijms21134778. PMID: 32640548

3) Safety, feasibility and preliminary efficacy of single agent combretastatin A1 diphosphate (OXi4503) in patients with relapsed or refractory acute myeloid leukemia or myelodysplastic syndromes. Cogle CR, Collins B, Turner D, Pettiford LC, Bossé R, Hawkins KE, Beachamp Z, Wise E, Cline C, May WS, Moreb JS, Hsu J, Hiemenz J, Brown R, Norkin M, Wingard JR, Uckun F. Br J Haematol. 2020 Jun;189(5):e211-e213. doi: 10.1111/bjh.16629. Epub 2020 Apr 1. PMID: 32236943
4) A Phase 1B Clinical Study of Combretastatin A1 Diphosphate (OXi4503) and Cytarabine (ARA-C) in Combination (OXA) for Patients with Relapsed or Refractory Acute Myeloid Leukemia. Uckun FM, Cogle CR, Lin TL, Qazi S, Trieu VN, Schiller G, Watts JM. Cancers (Basel). 2019 Dec 26;12(1):74. doi: 10.3390/cancers12010074. PMID: 31888052

Press release

September 16, 2020, we announced that the US Food and Drug Administration (FDA) granted our request and designate OXi4503 (combretastatin A1-diphosphate; CA1P) for treatment of acute myeloid leukemia (AML) due to genetic mutations that disproportionately affect pediatric patients as a drug for a “rare pediatric disease,” as defined in section 529(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ff(a)(3)).

The FDA grants rare pediatric disease designation for diseases with serious or life-threatening manifestations that primarily affect people aged from birth to 18 years, and that affect fewer than 200,000 people in the U.S. Under the FDA’s Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application or biologics license application for a product for the prevention or treatment of a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application, and may be sold or transferred. In August 2019, AstraZeneca has reportedly paid approximately $95 million to buy a priority review voucher from Swedish Orphan Biovitrum (Sobi) (https://www.astrazeneca.com/media-centre/press-releases/2019/astrazeneca-agrees-to-buy-us-fda-priority-review-voucher-from-sobi-22082019.html). Likewise, Biohaven Pharmaceutical Holding Company Ltd. reportedly paid approximately $105 million for a priority review voucher in March 2019 (https://www.biohavenpharma.com/investors/news-events/press-releases/03-18-2019).

Item 9.01 Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description	Incorporation by reference
99.1	Rare Pediatric Designation OXi4503 press release	Filed herewith.
99.2	Uckun & Trieu Publication of Pediatric AML	Filed herewith.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Mateon Therapeutics, Inc.

Date: September 30, 2020

/s/ Vuong Trieu

By: Vuong Trieu
Chief Executive Officer

Exhibit 99.1

FDA Granted Pediatric Disease Designation for OXi-4503

-Treatment of acute myeloid leukemia (AML) due to genetic mutations that disproportionately affect pediatric patients

AGOURA HILLS, Calif., September 16, 2020 (GLOBE NEWSWIRE) — Mateon Therapeutics “Mateon” (OTCQB: MATN), a leading developer of TGF-β therapeutics for oncology and COVID-19, announced today that the US Food and Drug Administration (FDA) granted our request and designate OXi4503 (combretastatin A1-diphosphate; CA1P) for treatment of acute myeloid leukemia (AML) due to genetic mutations that disproportionately affect pediatric patients as a drug for a “rare pediatric disease,” as defined in section 529(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ff(a)(3)).

“We are excited about this Rare Pediatric Disease designation for AML.”, said Dr. Vuong Trieu, Chief Executive Officer of Mateon. “This builds on our previous Rare Pediatric Disease designations for OT-101 and CA4P. It also completed our refocusing of the company to rare pediatric diseases. We are looking forward to initiate clinical programs among these indications post-COVID-19. In the meantime, we are focusing on deploying OT-101 against severe COVID-19 and Artemisinin against COVID-19 in general among various clinical trials globally.”.

OXi4503 in combination with standard chemotherapy drug cytarabine was generally well tolerated by adult AML patients and a maximum tolerated dose level of OXi4503 was identified as the recommended dose for further clinical development of this novel two-drug combination. In 26 evaluable AML patients, there were 4 complete remissions (CR/CRi) and one partial remission (PR). The CR responses were associated with >1-year overall survival times. The combination therapy exhibited a manageable toxicity and a promising benefit to risk profile in older adults with relapsed AML. Four of the 5 objective responders were in the ≥65-years poor prognosis age category with adverse cytogenetic features.

Acute leukemia is the most common cancer in children accounting for one-third of all childhood cancers. Acute lymphoblastic leukemia (ALL) accounts for 80% and acute myeloid leukemia (AML) accounts for 15% of all acute leukemia cases in children. Children with AML have a worse prognosis with a 5-year survival rate of 64% than children with ALL who have a 5-year survival rate of ~90% on contemporary risk-adjusted treatment programs. Children with AML who have unfavorable risk factors, such as adverse cytogenetics, have a particularly poor survival outcome even after intensive multimodality therapy and hematopoietic stem cell transplantation. Approximately one-third of children with AML relapse after induction chemotherapy and only one-third of these patients become long-term survivors. Relapsed disease is the greatest challenge to a better survival outcome in AML. Although new drugs have recently been developed against several molecular targets in AML blast cells, the vast majority of relapsed pediatric AML patients still die of leukemia. Therefore, novel therapies are urgently needed for pediatric AML.

About Oxi4503

OXi4503 exhibited single-agent anti-leukemia activity in animal models of AML and in a Phase 1A clinical study for relapsed/refractory (R/R) AML. Notably, the combination of OXi4503 with cytarabine (ARA-C) in xenografted human AML models was more effective than either drug alone. The clinical safety profile of OXi4503 as a single agent has previously been evaluated in Phase 1A clinical trials. In the NCT00977210 Phase 1 dose-finding study in 43 advanced solid tumor patients, OXi4503 doses were escalated from 0.06 to 15.4 mg/m2, and 8.5 mg/m2 was defined as the maximum tolerated dose (MTD). In the NCT01085656 Phase 1A trial designed to evaluate the safety profile, MTD, and recommended Phase 2 dose of OXi4503 in patients with R/RAML and MDS, a total of 18 patients were treated with single-agent OXi4503 and showed a manageable safety profile at single-agent dose levels up to of 7.81 mg/m2 and there was early evidence of possible single-agent anti-AML activity. More recently, a Phase 1B study was performed to evaluate the safety, tolerability, and clinical activity of a combination of OXi4503 and the standard anti-AML drug ARA-C. The combination therapy exhibited a manageable toxicity and a promising benefit to risk profile in adults with relapsed AML. An MTD level of OXi4503 was identified as the recommended dose for further clinical development of this novel two-drug combination. In 26 evaluable AML patients, there were four complete remissions (CR/CRi) and one partial remission. The median overall survival time for the four patients who achieved a CR/CRi was 528 days (95% confidence interval [CI]: 434 – NA), which was significantly longer than the median overall survival time of 113 days (95% CI: 77–172) for the remaining 22 patients who did not achieve a CR (Log rank Chi-square = 11.8, P-value = 0.0006).

About rare pediatric disease voucher program

The FDA grants rare pediatric disease designation for diseases with serious or life-threatening manifestations that primarily affect people aged from birth to 18 years, and that affect fewer than 200,000 people in the U.S. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, a sponsor who receives an approval of a new drug application or biologics license application for a product for the prevention or treatment of a rare pediatric disease may be eligible for a voucher, which can be redeemed to obtain priority review for any subsequent marketing application, and may be sold or transferred. In August 2019, AstraZeneca has reportedly paid approximately $95 million to buy a priority review voucher from Swedish Orphan Biovitrum (Sobi) (https://www.astrazeneca.com/media-centre/press-releases/2019/astrazeneca-agrees-to-buy-us-fda-priority-review-voucher-from-sobi-22082019.html).
Likewise, Biohaven Pharmaceutical Holding Company Ltd. reportedly paid approximately $105 million for a priority review voucher in March 2019 (https://www.biohavenpharma.com/investors/news-events/press-releases/03-18-2019).

About Mateon Therapeutics

Mateon was created by the recent reverse merger with Oncotelic which became a wholly owned subsidiary of Mateon Therapeutics Inc. (OTCQB:MATN) creating an immuno-oncology company dedicated to the development of first in class RNA therapeutics as well as small molecule drugs against cancer. OT-101, the lead immuno-oncology drug candidate of Mateon/Oncotelic, is a first-in-class anti-TGF-βRNA therapeutic that exhibited single agent activity in some relapsed/refractory cancer patients in clinical trial settings. Mateon/Oncotelic is seeking to leverage its deep expertise in oncology drug development to improve treatment outcomes and survival of cancer patients with a special emphasis on pediatric cancer patients. Mateon has rare pediatric designation for DIPG (CA4P) and melanoma (CA4P). For more information, please visit www.oncotelic.com and www.mateon.com.

Mateon's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Words such as "may", "expect", "anticipate" "hope", "vision", "optimism", "design", "exciting", "promising", "will", "conviction", "estimate," "intend," "believe", "quest for a cure of cancer", "innovation-driven", "paradigm-shift", "high scientific merit", "impact potential" and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about future plans, the progress, timing, clinical development, scope and success of future clinical trials, the reporting of clinical data for the company's product candidates and the potential use of the company's product candidates to treat various cancer indications. Each of these forward-looking statements involves risks and uncertainties and actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. These risks are not exhaustive, the company faces known and unknown risks, including the risk factors described in the company's annual report on Form 10-K filed with the SEC on April 10, 2019 and in the company's other periodic filings. Forward-looking statements are based on expectations and assumptions as of the date of this press release. Except as required by law, the company does not assume any obligation to update forward-looking statements contained herein to reflect any change in expectations, whether as a result of new information future events, or otherwise.

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EDITORIAL

Asclepius

Clinical Potential of Combretastatin A1 Diphosphate for the Treatment of Relapsed Pediatric Acute Myeloid Leukemia

Fatih M. Uckun, Vuong N. Trieu

Immuno-Oncology Program, Mateon Therapeutics, Agoura Hills, CA 91301, United States

Acute leukemia is the most common cancer in children accounting for one-third of all childhood cancers. Acute lymphoblastic leukemia (ALL) accounts for 80% and acute myeloid leukemia (AML) accounts for 15% of all acute leukemia cases in children.[1-3] Children with AML have a worse prognosis with a 5-year survival rate of 64% than children with ALL who have a 5-year survival rate of ~90% on contemporary risk-adjusted treatment programs. Children with AML who have unfavorable risk factors, such as adverse cytogenetics, have a particularly poor survival outcome even after intensive multimodality therapy and hematopoietic stem cell transplantation.[1-3] Approximately one-third of children with AML relapse after induction chemotherapy and only one-third of these patients become long-term survivors. Relapsed disease is the greatest challenge to a better survival outcome in AML.[1-7] Although new drugs have recently been developed against several molecular targets in AML blast cells, the vast majority of relapsed pediatric AML patients still die of leukemia.[1-3] Therefore, novel therapies are urgently needed for pediatric AML.

Combretastatins are phenolic-stilbene natural products that bind to the colchicine binding site of tubulin and exhibit antimitotic as well as antiangiogenic/vascular disrupting activity and cytotoxicity. The vascular disrupting agent OXi4503 is a synthetic, diphosphorylated prodrug of *cis*-combretastatin A1 (OXi4500), a naturally occurring derivative of the South African bush willow tree, *Combretum caffrum*, that reversibly binds tubulin at the colchicine binding site to inhibit microtubule assembly. OXi4503 is a compound with a dual mechanism of action involving both anti-vascular effects and direct cytotoxicity toward tumor cells [Figure 1].[8-10] OXi4503 has potent nanomolar cytotoxicity/antiproliferative activity against leukemia cells and it has been shown to disrupt the bone marrow endothelial cell support for AML clones.[11,12] The phosphate prodrug, OXi4503, is activated to OXi4500 by endogenous phosphatases and OXi4500 has direct vascular disrupting activity. Evidence suggests that OXi4500 is also metabolized to a reactive orthoquinone species that is also directly cytotoxic to tumor cells. Non-clinical studies have also shown that OXi4503 enhances the efficacy of conventional cytotoxic agents, as well as radiotherapy and anti-angiogenic therapy including monoclonal antibodies and tyrosine kinase inhibitors.[8-13]

OXi4503 exhibited single-agent anti-leukemia activity in animal models of AML and in a Phase 1A clinical study for relapsed/refractory (R/R) AML. Notably, the combination of OXi4503 with cytarabine (ARA-C) in xenografted human AML models was more effective than either drug alone. The clinical safety profile of OXi4503 as a single agent has previously been evaluated in Phase 1A clinical trials. In the NCT00977210 Phase 1 dose-finding study in 43 advanced solid tumor patients, OXi4503 doses were escalated from 0.06 to 15.4 mg/m^2, and 8.5 mg/m^2 was defined as the maximum tolerated dose (MTD). In the NCT01085656 Phase 1A trial designed to evaluate the safety profile, MTD, and recommended Phase 2 dose of OXi4503 in patients with R/RAML and MDS, a total of 18 patients were treated with single-agent OXi4503 and showed a manageable safety profile at single-agent dose levels up to of 7.81 mg/m^2 and there was early evidence of possible single-agent anti-AML activity.[14,15] More recently, a Phase 1B study was performed to evaluate the safety, tolerability, and clinical activity of a combination of OXi4503 and the standard anti-AML drug ARA-C.[16,17] The combination therapy exhibited a manageable toxicity and a promising benefit to risk profile in adults with

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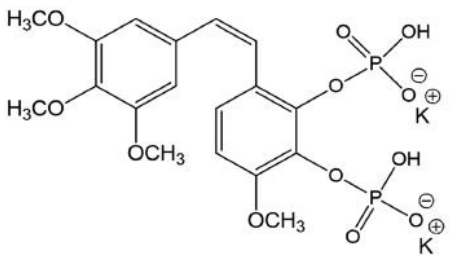

Figure 1: Molecular structure of OXi4503

relapsed AML.[16,17] An MTD level of OXi4503 was identified as the recommended dose for further clinical development of this novel two-drug combination. In 26 evaluable AML patients, there were four complete remissions (CR/CRi) and one partial remission. The median overall survival time for the four patients who achieved a CR/CRi was 528 days (95% confidence interval [CI]: 434 – NA), which was significantly longer than the median overall survival time of 113 days (95% CI: 77–172) for the remaining 22 patients who did not achieve a CR (Log rank Chi-square = 11.8, *P*-value = 0.0006). The safety, feasibility, and clinical activity of OXi4503 + ARA-C combination regimen in R/R AML deserve further clinical validation in a randomized registration study.[16,17]

Taken together, the preclinical and clinical studies to date demonstrate the potential of OXi4503 as a promising new drug in the treatment of pediatric AML in relapse, an orphan disease with a low survival rate and no established or effective standard of care. OXi4503 has received orphan drug designation for AML in both the US and the European Union. Further, the US FDA has granted fast track designation to OXi4503 for the treatment of R/R AML. OXi4503 may offer renewed hope for salvage therapy of pediatric AML patients in relapse who have this rare and fatal disease.

CONFLICTS OF INTEREST

F.M.U. and V.N.T. are employees and shareholders of Mateon Therapeutics, the sponsor for clinical development of OXi4503.

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