



## Medicenna Reports Fiscal Year 2021 Financial Results and Operational Highlights

May 28, 2021

-- Management hosting conference call and webcast today at 8:30 AM ET

TORONTO and HOUSTON, May 28, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced its financial results and operational highlights for the fiscal year ended March 31, 2021. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"The strong momentum we have generated over the past year leaves us poised to achieve key milestones that will lay a solid foundation for expansion of our clinical-stage pipeline," said Fahar Merchant, PhD, President and CEO of Medicenna. "We have recently added significant talent, expertise, and depth to our management team through the appointments of industry veterans and immuno-oncology experts Kevin Moulder, PhD and Mann Muhsin, MD as our CSO and CMO, respectively. Our ability to recruit such ideal candidates to these positions was due in large part to our innovative preclinical assets and robust clinical data set demonstrating the best-in-class potential of our Superkine platform." Dr. Merchant continued, "Looking ahead, we will work towards the advancement of MDNA11 into the clinic in calendar Q3 and the selection of a lead candidate from our BiSKITs™ program by the end of calendar 2021. We are excited for the fiscal year ahead and believe we are well positioned for sustained growth with multiple upcoming catalysts with cash runway into late 2022."

Program highlights for the year ended March 31, 2021, along with recent developments include:

### **MDNA11: IL-2 Superkine Program**

- On May 29, 2020, Medicenna announced the presentation of data at the 2020 American Society of Clinical Oncology (ASCO) virtual meeting related to MDNA11, the Company's long-acting IL-2 super-agonist. Non-human primate data demonstrated that MDNA11 could induce an up to 10-fold expansion in cancer fighting immune cells without: (a) generating anti-drug antibodies, (b) causing hypotension associated with vascular leak syndrome, (c) inducing cytokine release syndrome, or (d) causing other undesirable immune-mediated adverse events. Further, results showed durable tumor control for over 200 days and a strong immune memory response in a murine colon cancer model.
- On October 26, 2020, Medicenna announced a poster presentation at the 32<sup>nd</sup> EORTC-NCI-AACR (ENA) Symposium on Molecular Targets and Cancer Therapeutics. The poster highlighted preclinical studies evaluating MDNA11 that supports its potent therapeutic efficacy as a monotherapy agent in multiple tumor models.
- On November 4, 2020, Medicenna held a Scientific Advice Meeting for MDNA11 (similar to a pre-IND meeting) with the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA). During the meeting, the MHRA confirmed that the Company's CMC, pre-clinical and Phase 1/2a clinical plans were appropriate for submission of an Investigational Medical Product Dossier (IMPd) for a first in human study with MDNA11 in the UK. We are currently in the process of advancing MDNA11 into a Phase 1/2a clinical trial in Australia and the UK. Submission of the Australian regulatory package is expected by the end of June 2021, and initiation of the trial is expected in the third quarter of calendar 2021. Initiating the Phase 1/2a trial outside of the U.S. will allow Medicenna to begin dose escalation studies at doses that are closer to therapeutically effective doses and take advantage of an increased prevalence of checkpoint inhibitor naïve patients. The company plans to expand the trial to the U.S. and Canada after completion of the study's dose escalation portion, subject to discussions with the respective regulatory agencies.
- On March 25, 2021, Medicenna presented new preclinical data on MDNA11 during an oral presentation at the virtual Cytokine-Based Cancer Immunotherapies Summit. Data featured in the presentation showed that treatment with MDNA11 alone or in combination with anti-PD-1 therapy resulted in 100% tumor growth inhibition in a murine MC38 tumor model whereas tumor growth in this model was not effectively controlled by anti-PD-1 monotherapy.

### **MDNA55: Recurrent Glioblastoma Program**

- On October 15, 2020, Medicenna provided an update on the clinical development of MDNA55, an interleukin-4 (IL-4)-guided toxin targeting recurrent glioblastoma (rGBM), the most common and uniformly fatal form of brain cancer. Following an End of Phase 2 Meeting with the United States Food and Drug Administration (FDA), the agency agreed that Medicenna could conduct an innovative open-label hybrid Phase 3 trial that allows use of a substantial number of subjects (two-thirds) from a matched external control arm to support regulatory approval of MDNA55 for rGBM. The FDA also expressed their willingness to consider an interim analysis of the trial if certain criteria are met. Unlike conventional randomized control trials, the hybrid trial design will reduce the overall number of subjects needed in the study to achieve the primary endpoint as well as potentially reduce the cost and timelines associated with completing the trial. Medicenna is

currently pursuing a partnership strategy to facilitate MDNA55's further development and commercialization.

- Throughout fiscal year 2021, Medicenna presented updated data from the Phase 2b trial evaluating MDNA55 in rGBM subjects. Data from the most recent presentation at the 2<sup>nd</sup> Annual Glioblastoma Drug Development Summit in December showed that amongst an all-comer population, a single treatment with MDNA55 resulted in a greater than 100% increase in 2-year survival (OS-24 of 22% vs. 10%; calculated from date of relapse) compared to an eligibility matched external control arm. A single MDNA55 treatment also improved 12-month progression free survival by more than 100% compared to what is achieved with approved therapies (PFS-12 of 27% vs. 2 to 10%). Further, a subset of subjects treated with transient (median 3 cycle) low dose bevacizumab (5mg/Kg, Q2W), in order to reduce steroid use, saw improvements in median survival (mOS) and OS-24 compared to the all-comer population of 21.8 months (vs. 11.9 months) and 44% (vs. 20%) respectively, when calculated from time of treatment.
- Subsequent to the fiscal year end, Medicenna announced the peer-reviewed publication of clinical data from the Phase 2b trial evaluating MDNA55 in rGBM. The data, which was published in *Clinical Cancer Research*, indicated that early determination of progression free survival (PFS) with modified RANO (mRANO) criteria may be a strong surrogate for overall survival (OS) in rGBM.

#### **Bifunctional SuperKine ImmunoTherapies (BiSKITs™) Program**

- On October 26, 2020, preclinical data related to MDNA19-MDNA413, a novel and long-acting **DUal CytoKine (DUCK Cancer™)** designed to simultaneously activate cancer killing immune cells while reversing the anti-inflammatory tumor microenvironment (TME), were presented at the 32<sup>nd</sup> ENA Symposium on Molecular Targets and Cancer Therapeutics. Data showed that MDNA19-MDNA413 induced anti-tumor Th1 immune responses and inhibited pro-tumoral IL-4/IL-13 signaling, demonstrating the potential of the molecule to address a critical unmet need by effectively targeting immunologically "cold" tumors that are often resistant to immunotherapeutic agents.
- Subsequent to the fiscal year end, Medicenna presented preliminary preclinical data supporting the potent immune modulating effects of MDNA19-MDNA413 at the 2021 American Association of Cancer Research (AACR) Annual Meeting. We believe the presented data demonstrate the ability of MDNA19-MDNA413 to activate a pro-inflammatory, anti-tumor response due to its highly selective binding and signaling via the intermediate affinity IL-2 receptor (CD122/CD132), while simultaneously inhibiting pro-tumoral immune pathways by blocking IL4/IL13 signaling via the Type 2 IL-4 receptor (IL-4R/IL-13R1).

#### **Operational Highlights**

- On August 24, 2020 Medicenna's common shares began trading on The Nasdaq Capital Market ("Nasdaq"). Medicenna now trades on both the Nasdaq and the Toronto Stock Exchange under the symbol "MDNA".
- On September 30, 2020, Dr. Jack Geltosky, an experienced pharmaceutical licensing executive with a strong research and development background, was elected as an addition to Medicenna's Board of Directors.
- Subsequent to the fiscal year end, Medicenna strengthened its leadership team by appointing Kevin Moulder, PhD and Mann Muhsin, MD, industry veterans with extensive experience developing immuno-oncology drugs, as Chief Scientific Officer (CSO) and Chief Medical Officer (CMO), respectively.

#### **Upcoming Milestones**

Medicenna seeks to achieve the following milestones in the upcoming quarters:

- In June 2021, submit a Clinical Trial Notification to the Australian Human Research Ethics Committee to commence a Phase 1/2a trial evaluating MDNA11.
- Initiate a Phase 1/2a trial with MDNA11 in the third quarter of calendar 2021.
- Report preliminary update on any available safety, PK/PD and biomarker results from the Phase 1/2a MDNA11 monotherapy study late in Q4 of calendar 2021.
- Execute a collaboration or partnership for a registration trial and commercialization of MDNA55 for rGBM.
- Declare a lead candidate from our BiSKITs™ program in late calendar 2021.

#### **Annual Financial Results**

Medicenna had cash, cash equivalents, and marketable securities of \$40.4 million at March 31, 2021. These funds provide the Company with sufficient capital to execute its current planned expenditures through late 2022 based on its current plans and projections.

Net loss for the year ended March 31, 2021 was \$17.3 million, or \$0.35 per share, compared to a loss of \$8.2 million, or \$0.26 per share for the year ended March 31, 2020. The increase in net loss for the year ended March 31, 2021 compared with the year ended March 31, 2020 was primarily a result of increased research and development expenditures related to the MDNA11 program as well as costs associated with the NASDAQ listing, in particular directors and officers insurance premiums as well as no reimbursement under the grant from the Cancer Prevention and Research Institute of Texas ("CPRIT") in the current year.

Research and development expenses of \$10.9 million were incurred during the year ended March 31, 2021, compared with \$5.9 million incurred in the year ended March 31, 2020. The increase in research and development expenses in the current year is primarily attributable to higher CMC costs associated with GMP manufacturing of MDNA11 for the planned Phase 1/2a clinical trial, increased discovery and pre-clinical expenses associated with GLP compliant MDNA11 IND enabling studies as well as discovery work on the BiSKITs™ platform, increased regulatory costs associated with the EOP2 meeting for MDNA55 as well as the Scientific Advice Meeting for MDNA11 with the MHRA and preparation for the initiation of a Phase 1/2a clinical trial and no reimbursement of expenses with respect to the CPRIT grant in the year ended March 31, 2021, compared with \$1.0 million in the year ended March 31, 2020.

General and administrative expenses of \$6.5 million were incurred during the year ended March 31, 2021, compared with \$2.4 million during the year ended March 31, 2020. The increase in expenditures year over year is primary attributable to increased directors and officers liability insurance premiums due to our NASDAQ listing as well as higher board fees, legal fees and listing expenses in the current year due to activities associated with our NASDAQ listing, filing a shelf prospectus in both Canada and the United States, qualifying our common shares with the Depository Trust Company (DTC) and other corporate initiatives.

#### **Conference Call and Webcast**

Medicenna will host a conference call and webcast today at 8:30 AM ET. To access the call, please dial (877) 407-9716 from the United States or (201) 493-6779 internationally, and refer to conference ID: 13719231. To access the live webcast, visit this [link to the event](#). Following the live webcast, an archived version of the call will be available on Medicenna's website.

#### **About Medicenna**

Medicenna is a clinical stage immunotherapy company focused on the development of novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first in class Empowered Superkines for the treatment of a broad range of cancers. Medicenna's long-acting IL-2 Superkine asset, MDNA11, is a next-generation IL-2 with potentially superior CD122 binding without CD25 affinity and therefore preferentially stimulates cancer killing effector T cells and NK cells when compared to competing IL-2 programs, based on the preclinical studies conducted to date. Medicenna's early-stage program on **Bifunctional SuperKine ImmunoTherapies (BiSKITs™)** is designed to further enhance the ability of Superkines to treat immunologically "cold" tumors. Medicenna's lead IL4 Empowered Superkine, MDNA55, has completed a Phase 2b clinical trial for rGBM, the most common and uniformly fatal form of brain cancer. MDNA55 has been studied in five clinical trials involving 132 subjects, including 112 adults with rGBM. MDNA55 has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

#### **Forward-Looking Statement**

This news release contains forward-looking statements within the meaning of applicable securities laws and relate to the future operations of the Company and other statements that are not historical facts including statements related to the achievement of milestones, the expansion and advancement of its clinical pipeline, the clinical potential and development of its BiSKITs™, MDNA11 and MDNA55 programs, and Superkine platform, partnering strategy and activities, cash runway and expected costs and timelines of clinical trials and activities. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects", "believes" and similar expressions. All statements other than statements of historical fact, included in this release, including the future plans and objectives of the Company, are forward-looking statements that are subject to risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. Important factors that could cause actual results to differ materially from the Company's expectations include the risks detailed in the annual information form and Form 40-F of the Company and in other filings made by the Company with the applicable securities regulators from time to time in Canada and the United States.

The reader is cautioned that assumptions used in the preparation of any forward-looking information may prove to be incorrect. Events or circumstances may cause actual results to differ materially from those predicted, as a result of numerous known and unknown risks, uncertainties, and other factors, many of which are beyond the control of the Company. The reader is cautioned not to place undue reliance on any forward-looking information. Such information, although considered reasonable by management, may prove to be incorrect and actual results may differ materially from those anticipated. Forward-looking statements contained in this news release are expressly qualified by this cautionary statement. Except as required by law, we do not intend and do not assume any obligation to update or revise publicly any of the included forward-looking statements.

#### **Further Information**

For further information about the Company please contact:

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#### **Investor Contact**

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