



## Medicenna Reports First Quarter Fiscal 2022 Financial Results and Operational Highlights

August 13, 2021

-- Phase 1/2 ABILITY Study of MDNA11 in patients with advanced solid tumors remains on track for initiation in the third quarter of calendar 2021

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

TORONTO and HOUSTON, Aug. 13, 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 quarter ended June 30, 2021. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"We are off to a strong start in fiscal 2022 and well positioned for continued success with a steady frequency of value creating milestones expected over the coming year," said Fahar Merchant, PhD, President and CEO of Medicenna. "We are on track to initiate our Phase 1/2 ABILITY Study of MDNA11 in calendar Q3. We believe MDNA11's 'beta-only' IL-2 receptor selectivity provides clear differentiation compared to the 'pegylated not-alpha' IL-2 agents currently in the clinic. We aim to clinically demonstrate MDNA11's best-in-class potential through the ABILITY Study and look forward to providing a preliminary update on safety, PK/PD, and biomarker data by calendar year-end with preliminary efficacy readouts expected over the course of calendar 2022."

Dr. Merchant continued, "Beyond MDNA11, we remain in active discussions in pursuit of a partnership for MDNA55 and continue to leverage the power of our Superkine and BiSKITs™ platforms to advance the development of additional cytokine-based immunotherapies. With funding through the end of 2022, we are well positioned to ensure the continued advancement of these programs and our ABILITY Study, which in turn should allow us to generate value for patients and shareholders."

Program highlights for the quarter ended June 30, 2021, along with recent developments include:

### MDNA11: IL-2 Superkine Program

- On June 23, 2021, Medicenna announced the submission of a clinical trial application to a Human Research Ethics Committee (HREC) in Australia to initiate the Phase 1/2 ABILITY Study of MDNA11, the Company's selective, long-acting and novel IL-2 super-agonist. The study is designed to assess the safety, pharmacokinetics (PK), pharmacodynamics (PD), and anti-tumor activity of MDNA11 in patients with advanced solid tumors. It will begin with a monotherapy dose escalation phase followed by an expansion phase for both the MDNA11 monotherapy arm at the recommended phase 2 dose (RP2D), and a combination arm designed to evaluate MDNA11 with a checkpoint inhibitor.

Medicenna remains on track to start enrollment in the ABILITY Study in Australia in the third quarter of calendar 2021, with expansion to additional sites in the US, UK, and Canada to occur thereafter. The remaining regulatory submissions and approvals for these jurisdictions remain on track for completion in calendar 2021.

- Subsequent to the quarter end, Medicenna announced the peer-reviewed publication of preclinical data on MDNA109, the Company's IL-2 Superkine platform that forms the basis for MDNA11. The data, which were published in *Frontiers in Immunology*, highlight the ability of an MDNA109-armed oncolytic virus to reverse immunosuppressive tumor microenvironments (TME) and its potential to treat immunologically "cold" tumors such as pancreatic cancer. Collectively, these findings provide external validation for the broad clinical utilization of the MDNA109 platform.

### MDNA55: Recurrent Glioblastoma (rGBM) Program

- On May 7, 2021, Medicenna announced the peer-reviewed publication of clinical data from the Phase 2b trial evaluating MDNA55, an interleukin-4 (IL-4)-guided toxin 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. This data supplements previously presented findings observed in Medicenna's proposed patient population showing an 81% tumor control rate (26/32) based on mRANO and a median overall survival (OS) of 15.7 months, which represents a doubling in survival when compared to an external control arm (median OS of 7.2 months). Medicenna remains in active discussions in pursuit of a partnership to facilitate MDNA55's further development and commercialization.

### Bifunctional SuperKine ImmunoTherapies (BiSKITs™) Program

- On April 12, 2021, Medicenna presented preliminary preclinical data at the 2021 American Association of Cancer Research (AACR) Annual Meeting supporting the immune modulating effects of MDNA19-MDNA413, a novel and long-acting **DUal CytoKine** (DUCK Cancer™) designed to simultaneously activate cancer killing immune cells while

reversing the immunosuppressive TME. The Company believes 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-13Ralpha1).

#### **Operational Highlights**

- During the fiscal first quarter 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.
- During and subsequent to the quarter end, Medicenna received USD \$1.4 million for reimbursement of past expenses through its non-dilutive grant from the Cancer Prevention and Research Institute of Texas (CPRIT).

#### **Upcoming Milestones**

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

- Start enrollment in the Phase 1/2 ABILITY Study of MDNA11 in Australia in the third quarter of calendar 2021
- Receive regulatory approval to expand the ABILITY study to additional sites in the US, UK, and Canada by the end of calendar 2021
- Provide a preliminary update on any available safety, PK/PD and biomarker results from the monotherapy portion of the ABILITY study late in the fourth quarter of calendar 2021
- Report preliminary efficacy data from the ABILITY study in the first half of calendar 2022
- Execute a collaboration or partnership for a registration trial and commercialization of MDNA55 in rGBM.
- Declare a lead candidate from the BiSKITs™ program in late calendar 2021.

#### **Financial Results**

Medicenna had cash, cash equivalents, and marketable securities of \$35.9 million at June 30, 2021. These funds provide the Company with sufficient capital to execute its current planned expenditures through the end of calendar 2022 based on its current plans and projections.

Net loss for the quarter ended June 30, 2021 was \$6.4 million, or \$0.12 per share, compared to a loss of \$2.4 million, or \$0.05 per share, for the quarter ended June 30, 2020. The increase in net loss for the quarter ended June 30, 2021 compared with the prior year 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 in the current period.

Research and development expenses of \$4.3 million were incurred during the quarter ended June 30, 2021, compared with \$1.8 million in the prior year. The increase in expenses in the current year quarter is primarily attributable to higher CMC costs associated with GLP and GMP manufacturing of MDNA11 for the ABILITY Study, increased pre-clinical expenses associated with GLP compliant MDNA11 IND enabling studies as well as discovery work on the BiSKITs™ platform, increased clinical costs due to activities in preparation for initiation of ABILITY study and higher salary and benefits costs associated with increased headcount necessary to support increased activities. The increase in expense was partially offset by reimbursement of expenses with respect to the CPRIT grant of \$1.8 million in the quarter ended June 30, 2021 (June 30, 2020 - \$nil).

General and administrative expenses of \$1.9 million were incurred during the quarter ended June 30, 2021, compared with \$0.7 million in the quarter ended June 30, 2020. The increase in expenses in the current quarter is primarily attributable to increased directors and officers liability insurance premiums due to our NASDAQ listing.

Medicenna's condensed consolidated interim financial statements for the quarter ended June 30, 2021 and the related management's discussion and analysis (MD&A) will be available on SEDAR at [www.sedar.com](http://www.sedar.com) and EDGAR at [www.sec.gov](http://www.sec.gov).

#### **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: 13721841. 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 thereby preferentially stimulating cancer killing effector T cells and NK cells unlike competing IL-2 programs. Medicenna's early-stage BiSKITs™ program, **(Bi)functional SuperKine ImmunoTherapies**) 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 enrollment, expansion and timing of results for its Phase 1/2 ABILITY Study and its timeline, design and expansion, the clinical potential of MDNA11, the clinical potential and development of the BiSKITs™ program and its timeline, partnering discussions around MDNA55 and timeline for a potential transaction, the Company's current cash position and additional potential funding needs and the timing of such needs and the Company's general growth opportunities and potential. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects", "believes", "seeks" 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

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Source: Medicenna Therapeutics Corp.