

# Medicenna Reports First Quarter Fiscal 2023 Financial Results and Operational Highlights

August 15, 2022

- -- Extended Cash Runway Into 2024 With US\$20 Million Raise To Complete Phase 1/2 ABILITY Study And Advance Pipeline
- -- New MDNA11 Data From Dose Escalation in ABILITY Study Shows Tumor Control In Four Of Ten Evaluable Patients Including Unconfirmed Partial Response In Pancreatic Cancer Patient
  - -- ABILITY Study Commences Enrolling In Its Fifth Dose Escalation Cohort With No Dose-Limiting Toxicities Reported To Date
  - -- Additional Clinical Results Including Tumor Control Data From Fourth And Fifth Dose Escalation Cohorts Expected During The Second Half Of Calendar 2022
    - -- Management Hosting Conference Call And Webcast Today At 8:30 am EDT

TORONTO and HOUSTON, Aug. 15, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA, TSX: MDNA), a clinical stage immunotherapy company, today announced its financial results and operational highlights for the quarter ended June 30, 2022. Dollar amounts are in Canadian currency unless otherwise noted.

"We are off to a solid start in fiscal 2023 with a stronger balance sheet and promising anti-tumor activity of MDNA11 monotherapy in the ABILITY study," said Dr. Fahar Merchant, President and CEO of Medicenna. "Whereas single agent activity with next-generation IL-2s has been elusive, we are encouraged with early signs of tumor control in patients with "immunologically cold" tumors including an unconfirmed partial response in a patient with advanced pancreatic cancer. These findings have accompanied desirable pharmacokinetic and pharmacodynamic characteristics, suggesting that MDNA11's rational design and 'beta-only' binding profile are facilitating selective stimulation of anti-cancer immune cells while avoiding the liabilities associated with native IL-2 and competing IL-2 programs. We look forward to building on these preliminary data as we continue to evaluate higher doses of MDNA11 as a single agent and plan to report new data from the ABILITY study during the coming weeks and months."

#### **Recent Clinical Highlights**

In July 2022, Medicenna presented clinical data at the Cytokine Based Drug Development Summit in Boston ("Cytokine Summit") on safety, pharmacodynamics, and anti-tumor activity from the first four (low and mid) dose escalation cohorts of the Phase 1/2 ABILITY study of MDNA11, the Company's long-acting IL-2 superagonist. Treatment was administered via intravenous (IV) infusion every two weeks in all dose cohorts. These data provide preliminary evidence of MDNA11's single agent anti-tumor activity, as tumor control was achieved in four of ten evaluable patients with advanced solid tumors unresponsive to other treatments. Patients achieving tumor control included one sarcoma patient and one metastatic melanoma patient from the second dose escalation cohort (10 µg/kg dose), one sarcoma patient from the third dose escalation cohort (30 µg/kg dose), and one pancreatic cancer patient from the fourth dose escalation cohort (two 30 µg/kg "priming" doses followed by step-up to a fixed 60 µg/kg dose). An additional four patients from the fourth dose escalation cohort are awaiting their first post-baseline scan and are not yet evaluable for response to MDNA11. All fourteen patients enrolled in the ABILITY study to date failed between one to four lines of prior systemic therapy, including eleven who relapsed on, could not tolerate, or did not respond to at least one prior immunotherapy with a checkpoint inhibitor.

Following the presentation at the Cytokine Summit, a patient with pancreatic cancer had further tumor shrinkage consistent with an unconfirmed partial response (uPR). The uPR is preliminary and subject to further review. As per protocol and RECIST 1.1, a second scan at 28 days after the most recent scan is required to confirm a partial response in this patient. As a result, the preliminary data from this scan are subject to change and not predictive of the final results. There can be no assurance that, upon completion of the confirmatory scan, that the patient will have a partial response.

Pharmacodynamic data from the ABIILTY study show MDNA11 treatment leading to the preferential activation and expansion of anti-cancer immune cells (CD8<sup>+</sup> T cells and natural killer cells) with limited proliferation of regulatory T cells (cause of immunosuppression) and eosinophils (cause of toxicity) typically associated with native IL-2 and "alpha-binding" IL-2 variants. In addition, MDNA11 continues to exhibit an acceptable safety profile, with no dose-limiting toxicities reported in the ABILITY study to date. The trial is currently enrolling into its fifth dose escalation cohort, which evaluates patients receiving two 30 µg/kg priming doses of MDNA11 followed by step up to a fixed dose of 90 µg/kg with each dose administered at 2 week intervals.

#### **Expected Upcoming Milestones**

Additional anti-tumor activity data from the ABILITY study's fourth dose escalation cohort are expected in late September 2022.

Initial safety, PK, PD and anti-tumor activity data from the ABILITY study's fifth dose escalation cohort are expected in the fourth quarter of calendar 2022.

Anti-tumor activity data from the ABILITY study's single agent expansion phase are expected in the middle of calendar 2023.

Top-line anti-tumor activity data from the ABILITY study's combination arm are expected in the second half of calendar 2023.

### **Financial Results**

"We are pleased to start fiscal 2023 with a newly strengthened balance sheet from our raise of US\$20 million, attracting new healthcare focused institutional investors despite the challenging capital markets, which allows us to extend our cash runway into 2024. Our increased cash position will help us to complete the Phase 1/2 ABILITY Study including the combination arm of the clinical trial and advance at least one BiSKIT candidate to IND

readiness," said Elizabeth Williams, Chief Financial Officer of Medicenna.

Medicenna had cash, cash equivalents, and marketable securities of \$19.3 million at June 30, 2022, compared to \$20.5 million at March 31, 2022. Subsequent to the quarter end Medicenna raised US\$20 million by way of a public offering. Funds on hand as of June 30, 2022 plus those raised in the recent offering, we believe, are sufficient capital to execute the Company's operations into calendar 2024 and through important upcoming catalysts described above.

Net loss for the quarter ended June 30 2022, was \$4.2 million, or (\$0.07) per share, compared to a net loss of \$6.4 million, or (\$0.12) per share, for the quarter ended June 30, 2021. The decrease in net loss for the quarter ended June 30, 2022, compared with the quarter ended June 30, 2021, was primarily a result of reduced research and development spending.

Research and development (R&D) expenses of \$2.4 million were incurred during the quarter ended June 30, 2022, compared with \$4.3 million incurred in the quarter ended June 30, 2021. The decrease in R&D expenses in the current fiscal year's quarter is primarily attributed to costs associated with the development of MDNA11 incurred in the prior year period including, IND enabling studies and manufacturing of GMP materials for the ongoing Phase 1/2 ABILITY Study, for which no comparable expenses exist in the current year period. We expect R&D expenses to increase as we continue to advance in our product pipeline.

General and administrative (G&A) expenses of \$1.9 million were incurred during the quarter ended June 30, 2022, compared with \$1.9 million incurred in the quarter ended June 30, 2021. G&A expenses were consistent quarter over quarter.

Medicenna's condensed consolidated interim financial statements for the quarter ended June 30, 2022, and the related management's discussion and analysis (MD&A) will be available on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a> and EDGAR at <a href="https://www.sec.gov">www.sec.gov</a>.

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

Medicenna will host a conference call and webcast today at 8:30 am EDT. To access the call please dial 1-877-407-9716 from the United States or 1-201-493-6779 internationally and refer to conference ID: 13731985. 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 the Phase 1/2 ABILITY Study

The ABILITY (**A** Beta-only **IL-2** ImmunoTherap**Y**) study is designed to assess the safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced, relapsed, or refractory solid tumors. The trial includes an MDNA11 monotherapy arm, as well as a combination arm designed to evaluate MDNA11 with a checkpoint inhibitor. Approximately 80 patients are expected to be enrolled into the ABILITY study. Following establishment of the recommended Phase 2 dose (RP2D) and optimal treatment schedule in the study's dose escalation phase, Medicenna plans to conduct a dose expansion phase that will enroll patients with renal cell carcinoma, melanoma, and other solid tumors in monotherapy and combination settings. For more information, see ClinicalTrials.gov Identifier: NCT05086692.

#### **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. Medicenna's long-acting IL-2 Superkine, MDNA11, is a next-generation IL-2 with superior CD122 (IL-2 receptor beta) binding without CD25 (IL-2 receptor alpha) affinity thereby preferentially stimulating cancer killing effector T cells and NK cells. Medicenna's early-stage BiSKITs<sup>TM</sup> program, (Bifunctional SuperKine ImmunoTherapies) is designed to enhance the ability of Superkines to treat immunologically "cold" tumors. Medicenna's IL-4 Empowered Superkine, MDNA55, has been studied in 5 clinical trials including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. MDNA55 has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

## **Forward-Looking Statements**

This news release contains forward-looking statements under applicable securities laws. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects", "believes", "seeks", "plan" and similar expressions. All statements other than statements of historical fact, included in this release, including statements related to cash runway, the clinical potential and development and safety profile of MDNA11 and the Superkine and BISKITs platform, the ability to enroll patients in clinical trials or complete clinical trials on a timely basis, including for the ABILITY study, upcoming milestones and the sharing of additional data and out-licensing efforts for MDNA55 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 may differ materially from those contemplated 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 20-F of the Company and in other filings (including the prospectus supplement dated August 9, 2022) made by the Company with the applicable securities regulators from time to time in Canada and the United States.

Readers are 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. Readers are cautioned not to place undue reliance on any forward-looking statements. 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. The forward-looking statements contained in this news release are made as of the date hereof and except as required by law, we undertake no obligation to update or revise any forward-looking statements.

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Source: Medicenna Therapeutics Corp.