

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

February 9, 2022

- -- Phase 1/2 ABILITY study of MDNA11 on track with first set of efficacy results from early dose escalation cohorts expected in mid-calendar 2022
  - -- Preliminary pharmacodynamic data show preferential stimulation of anti-cancer immune cells with MDNA11 treatment in the ABILITY study
    - -- First clinical site in the US open for enrolment
    - -- Management hosting conference call and webcast today at 8:30 am ET

TORONTO and HOUSTON, Feb. 09, 2022 (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 December 31, 2021. All dollar amounts are in Canadian currency unless otherwise noted.

"Our recent progress was highlighted by the ABILITY study's preliminary readout, which, although early, supports our belief that MDNA11 has significant potential," said Fahar Merchant, Ph.D., President and Chief Executive Officer of Medicenna. "Despite the low doses tested, we believe the biological activity observed to date was superior to those reported by other programs in the clinic at equivalent doses of IL-2. Furthermore, MDNA11 was well tolerated while exhibiting preferential stimulation of anti-cancer immune cells and we expect that its biological activity will be further enhanced in subsequent dose escalation cohorts. We are pleased with the trial's progress and results to date and we believe that this will position us to report the first set of efficacy results from early dose escalation cohorts in mid-calendar 2022."

Dr. Merchant continued, "Beyond MDNA11, we will continue to leverage our platforms and the expertise of our recently formed Scientific Advisory Board and Development Advisory Committee, to advance additional candidates towards the clinic. Efforts to date on our Superkine and BiSKITs ™ platforms will be unveiled at a conference in calendar Q2. Looking forward, we believe our robust platforms set a solid foundation for sustained growth with a steady cadence of catalysts expected over the coming months."

Program highlights for the quarter ended December 31, 2021, along with recent developments include:

### MDNA11: IL-2 Superkine Program

- On December 22, 2021, Medicenna announced positive preliminary data from the first two dose escalation cohorts of the Phase 1/2 ABILITY study of MDNA11, the Company's "beta-only" and long-acting IL-2 super-agonist. The results showed an ~2-fold increase in CD8+ T and NK cell levels over baseline with MDNA11 treatment at doses where competing "not-alpha" IL-2 variants have not exhibited any activity. In addition, MDNA11 preferentially increased CD8 + T cells over pro-tumor Treg cells, as the CD8+ T / Treg ratio increased by ~2 fold over baseline. MDNA11 demonstrated an encouraging safety profile, with no dose limiting toxicities and no evidence of cytokine release syndrome or vascular leak syndrome reported to date.
- o Throughout the quarter ended December 31, 2021, Medicenna received regulatory clearances from the United States Food and Drug Administration ("FDA") and Health Canada to expand the Phase 1/2 ABILITY study, which is currently enrolling patients in Australia, in the U.S. and in Canada. Subsequent to the quarter end, we are pleased to report that the Company opened its first U.S. trial site for enrollment.
- o On October 7, 2021, Medicenna announced the presentation of preclinical data from murine and IND-enabling non-human primate (NHP) studies of MDNA11 at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics (Triple Meeting). Data presented at the meeting showed that MDNA11 did not lead to the safety issues typically associated with IL-2 and preferentially induced durable proliferation and expansion of anti-cancer immune cells with limited stimulation of pro-tumor Treg cells. In addition, MDNA11 alone or in combination with anti-PD-1 agents resulted in 100% tumor control and long-term protection against tumor re-challenge by inducing antigen-specific CD8<sup>+</sup> T cells in a murine cancer model.
- Subsequent to the quarter end, Medicenna announced the publication of preclinical data on MDNA11 in the *Journal for ImmunoTherapy of Cancer*. In vitro, murine and non-human primate studies featured in the paper, demonstrated MDNA11s vastly superior selectivity, PK, PD, safety and efficacy profile when compared to other IL-2 programs in development.

## MDNA55: Empowered IL-4 Superkine Program

• On November 18, 2021, Medicenna announced that John H. Sampson, M.D., Ph.D., MHSc, MBA, Robert H. and Gloria Wilkins Distinguished Professor of Neurosurgery at Duke University School of Medicine and member of Medicenna's Board

of Directors, received The Abstract Award for Excellence in Clinical Trials in connection with an oral presentation on MDNA55 at the 26<sup>th</sup> Annual Meeting of the Society for Neuro-Oncology.

o In October 2021, the design of the planned open-label hybrid Phase 3 trial of MDNA55 in recurrent glioblastoma (GBM) was highlighted in a <u>peer-reviewed manuscript</u> published in *The Lancet Oncology*, and in an oral presentation at the Society for Neuro-Oncology and American Society of Clinical Oncology's First Annual Conference on CNS Clinical Trials. Medicenna continues to pursue a partnership to facilitate MDNA55's further development and commercialization and remain in active discussions towards this goal.

## **Operational Highlights**

- Subsequent to the quarter end, Medicenna announced the appointment of industry veterans Dr. Peter Lloyd, Dr. L. Bruce Pearce, and Paul Smith to the Company's Development Advisory Committee and Dr Martin Bexon as the acting Chief Medical Officer.
- Subsequent to the quarter end, Medicenna announced the formation of its Scientific Advisory Board (SAB). The SAB consists of four highly accomplished leaders in cancer immunotherapy and drug development: Sergio Quezada, Ph.D. (Chairman), Burkhard Becher, Ph.D., David Mooney, Ph.D., and William Redmond, Ph.D.

#### **Financial Results**

Medicenna had cash, cash equivalents, and marketable securities of \$23.4 million at December 31, 2021. These funds provide the Company with sufficient capital to execute its current planned expenditures through to the end of calendar 2022 and important upcoming catalysts based on its current plans and projections.

Net loss for the quarter ended December 31, 2021, was \$4.8 million, or \$0.09 per share, compared to a net loss of \$5.3 million, or \$0.11 per share, for the quarter ended December 31, 2020. The decrease in net loss for the quarter ended December 31, 2021, compared with the quarter ended December 31, 2020, was primarily a result of lower research and development expenses.

Research and development (R&D) expenses of \$2.9 million were incurred during the quarter ended December 31, 2021, compared with \$3.2 million incurred in the quarter ended December 31, 2020. The decrease in R&D expenses in the current fiscal year's quarter is primarily attributable to reduced chemistry, manufacturing and controls costs, associated with the first scale-up of good laboratory practices and good manufacturing practices for the manufacturing of MDNA11, which was ongoing in the prior year period and predominantly complete as of September 30, 2021; decreased discovery and pre-clinical expenses associated with the MDNA11 IND-enabling studies ongoing in the prior year period and predominantly complete as of September 30, 2021; decreased spend on licensing and patent legal due to expenses incurred in the prior year period related to market research activities and the timing of patent prosecution; and a decrease in regulatory costs in the current year period due to expenses incurred in the prior year period associated with the End of Phase 2 meeting with the FDA meeting for MDNA55. These decreases were offset by higher clinical costs due to the MDNA11 ABILITY study for which the first subject was treated in September 2021, as well as higher personnel costs associated with increased headcount to support increased activities.

General and administrative expenses remained consistent year over year with \$2.0 million in expenses incurred during the quarter ended December 31, 2021, compared with \$2.1 million during the quarter ended December 31, 2020.

Medicenna's condensed consolidated interim financial statements for the quarter ended December 31, 2021 and the related management's discussion and analysis (MD&A) will be available on SEDAR 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 ET. 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: 13726690. 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 ABILITY Study

The ABILITY (A Beta-only IL-2 ImmunoTherapY) 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.

## **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™ 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 Statement**

This news release contains forward-looking statements within the meaning of applicable securities laws that relate to the future operations of the

Company and other statements that are not historical facts including, but not limited to, statements related to the potential and development of MDNA11 and the Superkine and BiSKITs ™ platforms, including data updates and the reporting of results, the expansion of studies, regulatory submissions and costs and timeline, a strategic partnership for MDNA55 and its development and commercialization, the growth of the Company's pipeline, cash runway, and the unveiling of additional clinical candidates derived from the Company's platforms. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expect", "believe", "seek" and similar expressions. All statements other than statements of historical fact, included in this release, including statements on 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 for the year ended March 31, 2021, which is available on SEDAR at <a href="www.sedar.com">www.sedar.com</a>, and Form 40-F of the Company filed with the United States Securities and Exchange Commission 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. The forward-looking statements contained in this news release are made as of the date hereof and 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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