Medicenna Reports Second Quarter Fiscal 2022 Financial Results and Operational Highlights

November 12, 2021

-- Phase 1/2 ABILITY Study of MDNA11 on track for preliminary data updates in calendar 2021 and mid-calendar 2022

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

TORONTO and HOUSTON, Nov. 12, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today provided a business update and announced its financial results and operational highlights for the quarter ended September 30, 2021. All dollar amounts are in Canadian currency unless otherwise noted.

"Our accomplishments over the past few months have laid the foundation towards achieving key milestones that intend to provide the first set of human data of MDNA11 with the aim to show differentiated and potentially superior clinical activity of our lead IL-2 Superkine asset," said Fahar Merchant, PhD, President and CEO of Medicenna. "We recently began dosing patients in the ABILITY study of MDNA11 in Australia and received IND clearance to expand to sites in the United States. We believe that this will position us to present a key safety and biomarker data update late in calendar 2021 and initial efficacy data in mid-calendar 2022. Through these updates, we hope to provide clinical validation of the non-human primate data which demonstrated the advantages of MDNA11's 'beta-only' approach of stimulating cancer fighting T-cells without the toxic side effects of native IL-2."

Dr. Merchant continued, "Alongside our progress with MDNA11, the MDNA55 Phase 3 clinical trial hybrid design was highlighted in a peer-reviewed manuscript published in *The Lancet Oncology* and we continue to engage in active discussions in pursuit of a strategic partnership for this asset. We are particularly enthusiastic about advancing our preclinical assets derived from our BiSKITs and Superkine platforms, and expect to declare a lead candidate by calendar year end. In concert with the progress of our Phase 1/2 MDNA11 ABILITY study, our programs are designed to fuel sustained growth of our pipeline as we endeavor to advance innovative cytokine-based therapies for patients with unmet medical needs."

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

MDNA11: IL-2 Superkine Program

- On September 14, 2021, Medicenna announced the initiation of subject dosing in the Phase 1/2 ABILITY Study of MDNA11, the Company's "beta-only" and long-acting 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 includes a monotherapy dose escalation phase, which will be 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 continues to advance the ABILITY study at trial sites in Australia and, subsequent to the quarter end, received IND clearance from the U.S. Food and Drug Administration to expand the trial to sites in the United States. The Company also intends to expand the ABILITY study to additional sites in the UK and Canada and expects to complete the remaining regulatory submissions for these jurisdictions in calendar 2021.

- Subsequent to the quarter end, Medicenna announced the presentation of new 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 from NHP studies 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 a murine cancer model, MDNA11 alone or in combination with a PD-1 checkpoint inhibitor resulted in 100% tumor control and long-term protection against tumor re-challenge by inducing antigen-specific $CD8^+$ T cells.

- Results based on independent research were published in a peer-reviewed publication in *Frontiers in Immunology* featuring data on MDNA109, the Company's IL-2 Superkine platform that forms the basis for MDNA11. The data 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, we believe these findings provide external validation of the versatility of our Superkine platform.

MDNA55: Empowered IL-4 Superkine Program

- In October 2021, the design of the planned open-label hybrid Phase 3 trial of MDNA55 in recurrent glioblastoma (rGBM) was highlighted in a peer-reviewed manuscript 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.

Unlike conventional randomized control trials, the hybrid trial design will reduce the overall number of patients 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 in active discussions in pursuit of a partnership to facilitate MDNA55's further development and commercialization.

Operational Highlights

- On September 20, 2021, Medicenna announced the issuance of a U.S. patent providing added intellectual property protection for its MDNA11 program. Claims in the patent cover methods of treating a variety of specified cancers with IL-2 variants such as MDNA11. The patent's term extends into at least 2032, without accounting for potential extensions.

- On September 23, 2021, Medicenna announced the appointment of John H. Sampson, MD, PhD, MBA, to its Board of Directors. Dr. Sampson is the Robert H. and Gloria Wilkins Distinguished Professor of Neurosurgery at Duke University School of Medicine, President of Private Diagnostic Clinic, Duke's physician practice with revenue of over $1 billion, and a member of the prestigious National Academy of Medicine.

Expected Upcoming Milestones

- Complete regulatory submissions to expand the ABILITY study to additional sites in the UK and Canada by the end of calendar 2021

- Provide preliminary update on safety, PK/PD, and biomarker data from early cohorts of patients enrolled in the dose escalation portion of the ABILITY study by the end of calendar 2021

- Report preliminary safety and efficacy data update from the ABILITY study in mid-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 by the end of calendar 2021.

Financial Results

Medicenna had cash, cash equivalents, and marketable securities of $26.7 million at September 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. Cash used in operating activities increased in the quarter ended September 30, 2021 due to one-time cash outflows associated with completing GMP manufacturing and IND enabling studies for MDNA11 during the quarter as well as paying our annual Directors & Officers liability insurance premiums. We have projected a lower quarterly cash burn in the next few quarters as these one-time high-cost activities are now complete.

Net loss for the quarter ended September 30, 2021, was $8.2 million, or $0.15 per share, compared to a loss of $3.8 million, or $0.08 per share, for the quarter ended September 30, 2020. The increase in net loss for the quarter ended September 30, 2021 compared with the quarter ended September 30, 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 costs in the current period.

Research and development expenses of $6.3 million were incurred during the quarter ended September 30, 2021, compared with $2.2 million incurred in the quarter ended September 30, 2020. The increase in R&D expenses in the current year's quarter is primarily attributable to higher CMC costs associated with GLP and GMP manufacturing of MDNA11 which is now predominantly complete, increased pre-clinical expenses associated with GLP compliant MDNA11 IND enabling studies, which are also now predominantly complete, as well as discovery work on the BiSKITs platform and higher salary and benefits costs associated with a larger headcount necessary to support increased activities.

General and administrative expenses of $2.0 million were incurred during the quarter ended September 30, 2021, compared with $1.7 million during the quarter ended September 30, 2020. The increase in expenditures in the current year quarter is primary attributable to increased directors' and officers' liability insurance premiums due to 3 months of amortization in the current year vs. 2 months in the prior year, increased stock based compensation expense due to timing and value of option grants and an increase in salaries and benefit expenses due to a higher headcount to support ongoing operations.

Medicenna's condensed consolidated interim financial statements for the quarter ended September 30, 2021 and the related management's discussion and analysis (MD&A) will be available on SEDAR at www.sedar.com and EDGAR at 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: 13723601. 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

Medicenna's Phase 1/2 ABILITY (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y** Study) study of MDNA11, the Company's "beta-only" and long-acting IL-2 super-agonist, is designed to assess the safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced solid tumors. The study includes a monotherapy dose escalation phase followed by an expansion phase for both the MDNA11 monotherapy arm at the recommended phase 2 dose, and a combination arm designed to evaluate MDNA11 with a checkpoint inhibitor.

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, (**Bi**functional **S**uper**K**ine **I**mmuno**T**herapie**s**) 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 various expected milestones and their timeline including data updates and the reporting of results, the clinical potential and development of MDNA11, MDNA109 and MDNA55, including the expansion of studies, regulatory submissions and costs and timeline, a strategic partnership for MDNA55 and its development and commercialization, the expect patent terms of the Company's patents, the growth of the Company's pipeline and cash runway. 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 www.sedar.com, 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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