Medicenna Reports Third Quarter Fiscal 2021 Financial Results and Operational Highlights

February 12, 2021

TORONTO and HOUSTON, Feb. 12, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "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, 2020. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"Last quarter we achieved key regulatory milestones across our pipeline that position us for what we expect to be a catalyst rich calendar year," said Dr. Fahar Merchant, Chairman, President and Chief Executive Officer of Medicenna. "The FDA's acceptance of our precedent-setting registration trial design for MDNA55 in recurrent glioblastoma we believe has bolstered our pursuit of a partnership for this due to the strength of our clinical data set and the high unmet need that exists for this uniformly fatal brain cancer. We also received positive feedback from the UK's MHRA on our plans for a Phase 1/2 clinical trial of MDNA11, which is supported by preclinical data demonstrating the long-acting IL-2 Superkine's best-in-class potential."

Dr. Merchant continued, "Each of these accomplishments was enabled by the scientific and clinical progress we made throughout the past calendar year, which was facilitated by our team's ability to successfully navigate the challenges of the pandemic and execute on our goals. Moving forward, we will seek to continue to strategically adapt to these challenges as we work to bring MDNA11 to the clinic in mid-calendar 2021, pursue a partnership strategy for MDNA55, and position the Company for continued growth."

Program highlights for the quarter ended December 31, 2020, along with recent developments, include:

MDNA55: Recurrent Glioblastoma Program:

- On December 11, 2020 Medicenna hosted a key opinion leader (KOL) call and 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. The call featured a discussion by KOLs on the design and advantages of the planned Phase 3 registrational trial of MDNA55 in rGBM. The U.S. Food and Drug Administration (FDA) has agreed that the trial can have an innovative open label hybrid design that allows use of a substantial number of subjects (2/3) from a matched external control arm and has also expressed a willingness to consider an interim analysis if certain criteria are met. Compared to conventional randomized control trials, the hybrid trial design will reduce costs, timelines, and the number of subjects needed to achieve the primary endpoint. KOLs also discussed the keys to the FDA's acceptance of this precedent-setting trial design, which include the significant unmet medical need in rGBM and the large effect size exhibited in the MDNA55 Phase 2b study. A replay of the call, which featured Dr. David Reardon (Harvard Medical School), Dr. John Sampson (Duke School of Medicine), Dr. Ruthie Davi (Acorn AI), and Dr. Amy McKee (Parexel) can be found here.

- On October 15, 2020 Medicenna announced the completion of a positive End of Phase 2 meeting with the FDA regarding the regulatory pathway for MDNA55. Following the meeting, the Company was authorized by the FDA to proceed with the hybrid trial design highlighted during the KOL call discussed above. Medicenna is currently pursuing a partnership strategy to facilitate MDNA55's further development.

- On December 9, 2020 Medicenna presented updated data from the Phase 2b trial evaluating MDNA55 in rGBM patients at the 2nd Annual Glioblastoma Drug Development Summit. 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 patients treated with low dose bevacizumab to reduce steroid use saw improvements in median survival (mOS) and OS-24 compared to the all-comer population (mOS of 21.8 months vs. 11.9 months; OS-24 of 44% vs. 20%; calculated from time of MDNA55 treatment).

MDNA11: IL-2 Superkine Program

- 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 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. Submission of the IMPD and initiation of the trial is expected in mid-calendar 2021. Initiating the Phase 1/2a trial outside of the U.S. will allow Medicenna to begin dose escalation studies at a higher dose and take advantage of an increased prevalence of checkpoint inhibitor naive patients. The company plans to expand the trial to the U.S. after completion of the study's dose escalation portion.

- On October 26, 2020 Medicenna announced a poster presentation at the 32nd ENA Symposium on Molecular Targets and Cancer Therapeutics. The poster highlighted preclinical studies evaluating MDNA11 and a long-acting bispecific IL-2/IL-13 Superkine designed to simultaneously activate cancer killing immune cells while reversing anti-inflammatory tumor micro-environments. MDNA11 data substantiated its potent therapeutic efficacy as a monotherapy agent in multiple tumor models. Studies evaluating Medicenna's novel bispecific IL-2/IL-13 Superkine demonstrated the potential of the platform to address a critical unmet need by effectively targeting immunologically "cold" tumors that are often resistant to immunotherapeutic agents.

Operational Highlights

- Medicenna had cash, cash equivalents and marketable securities of $33.2 million at December 31, 2020. Subsequent to the quarter end the Company received additional proceeds of approximately $7.8 million related to its at-the-market (ATM) facility and warrant exercises. These funds provide the Company with sufficient capital through to late-calendar 2022 based on its current plans and projections.

Upcoming Milestones

Medicenna will seek to achieve the following milestones in the upcoming quarters:

- Submit to the MHRA an IMPD for a Phase 1/2 trial evaluating MDNA11 in mid-calendar 2021.
- Initiate a Phase 1/2 trial with MDNA11 in mid-calendar 2021.
- Report results from the safety portion of a Phase 1/2 MDNA11 monotherapy study late in the second half of calendar 2021.
- Execute a partnership for a registration trial and commercialization of MDNA55 for rGBM.
- Declare a lead candidate for its bispecific Superkine program in calendar 2021.

Financial Results

Net loss for the quarter ended December 31, 2020 was $5.3 million, or $0.11 per share, compared to a loss of $2.4 million, or $0.07 per share, for the quarter ended December 31, 2019. The increase in net loss for the quarter ended December 31, 2020 compared with the quarter ended December 31, 2019 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 D&O insurance premiums.

Research and development expenses of $3.2 million were incurred during the quarter ended December 31, 2020, compared with $1.7 million in the quarter ended December 31, 2019. The increase in expenses in the current quarter is primarily attributable to :

- higher chemistry, manufacturing and controls activities;
- discovery and pre-clinical expenses associated with GLP and GMP manufacturing work and IND enabling studies;
- regulatory costs associated with preparation for the Phase 1/2a clinical trial; and
- increased licensing and patent legal fees related to outsourced business development activities, market research studies and the timing of patent prosecution.

The above increases were partially offset by lower clinical trial costs due to completion of the Phase 2b rGBM clinical study.

General and administrative expenses of $2.1 million were incurred during the quarter ended December 31, 2020, compared with $0.7 million during the quarter ended December 31, 2019. This increase in expenditures is primarily attributed to increased D&O liability insurance premiums due to the Company's NASDAQ listing as well as higher board fees, personnel costs and legal fees associated with the listing and other corporate initiatives.

Medicenna's condensed consolidated interim financial statements for the quarter ended December 31, 2020 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.

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 IL2 Superkine asset, MDNA11, is a next-generation IL-2 with 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. 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 Statements
This news release contains forward-looking statements under applicable securities laws and relate to the future operations of the Company and other statements that are not historical facts. 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 statements related to upcoming developments and milestones, the clinical potential of MDNA11 and its development timeline and expected milestones, the potential partnership for MDNA55, the expected benefits of the hybrid trial design of MDNA55 and the identification of a lead candidate for the Superkine

program and the future plans and objectives of the Company, are forward-looking statements that involve 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 of the Company dated May 14, 2020 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 and that study results could change over time as the study is continuing to follow up all subjects and new data are continually being received which could materially change study results. 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 at the time of preparation, 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 of this news release and the Company will update or revise publicly any of the included forward-looking statements only as expressly required by Canadian and United States securities law.

Further Information

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