Medicenna Reports Second Quarter Fiscal 2021 Financial Results and Operational Highlights

November 13, 2020

TORONTO and HOUSTON, Nov. 13, 2020 (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 September 30, 2020. All dollar amounts are expressed in Canadian currency unless otherwise noted.

"Over the last several months, we have achieved key clinical, regulatory, and corporate milestones that have left us well positioned for continued growth," said Dr. Fahar Merchant, Chairman, President and Chief Executive Officer of Medicenna. "We believe that the clinical data presented at the ENA Meeting strongly supports MDNA55's ability to improve long-term survival and tumor control in recurrent glioblastoma ("rGBM"), a common and uniformly fatal from of brain cancer. This data is complemented by preclinical results from our IL-2 and IL-13 Superkine platform programs that further demonstrates the potential of MDNA11 and highlights the platform's ability to generate cytokine-based treatments that may have the potential to overcome the shortcomings of currently available immunotherapies."

Dr. Merchant continued, "Moving forward, we aim to build on these achievements as we work to advance and expand our clinical pipeline. We continue to assess potential partnership strategies to facilitate the progression of our MDNA55 program, and have been bolstered by our positive data and the FDA's pioneering recommendation to conduct a hybrid registration trial with a comparator arm that utilizes both traditional and matched external controls. Meaningful progress is also being made toward the advancement of MDNA11 to the clinic, as we recently completed a Scientific Advice Meeting with UK's MHRA and are on track to submit the IMPD, for a Phase 1/2 clinical study, in the middle of the next calendar year. We believe that the continued progression of these programs, together with our recent Nasdaq listing, will enable Medicenna to deliver short- and long-term value to its stakeholders."

Program highlights for the quarter ended September 30, 2020, along with recent developments, include:

MDNA55: Recurrent Glioblastoma Program:

- On October 15, 2020 Medicenna 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 FDA agreed that we could conduct an innovative open-label hybrid Phase 3 trial that allows use of a substantial number of subjects (two-thirds) from a matched external control arm to support regulatory approval of MDNA55 for rGBM. The FDA also expressed their willingness to consider interim analysis of the trial if certain criteria are met. Unlike conventional randomized control trials, the hybrid trial design will reduce the overall number of subjects needed in the study to achieve the primary endpoint as well as reduce the cost and timelines associated with completing the trial.

- On October 26, 2020, Medicenna announced a Late Breaking Abstract poster presentation at the 32nd ENA Symposium on Molecular Targets and Cancer Therapeutics. Amongst an all-comer population, a single treatment with MDNA55 resulted in at least 100% increase in both 12-month progression free survival (PFS-12 of 27% versus 2 to 10%) and 2-year survival (OS-24 of 20% vs 5 to10%) when compared to what is achieved with approved therapies. In a subset of all-comer patients treated with transient low dose bevacizumab, to reduce steroid use, median survival (mOS) was 21.8 months and OS-24 was 44%.

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). It confirmed that our plans for CMC, pre-clinical and Phase 1/2 clinical trial were appropriate for submission of an Investigational Medical Product Dossier (IMPD) in mid-calendar 2021 in order to commence first in human studies with MDNA11 in the UK.

- On October 26, 2020, Medicenna announced a poster presentation at the 32nd ENA Symposium on Molecular Targets and Cancer Therapeutics. The preclinical data, featured results with MDNA11 as well as data related to a long acting bispecific IL-2/IL-13 Superkine designed to simultaneously activate cancer killing immune cells while reversing anti-inflammatory tumor micro-environment (TME). The results substantiated the potent therapeutic efficacy of MDNA11 as a monotherapy agent in multiple tumor models. Medicenna's novel bispecific IL-2/IL-13 Superkines 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

- On August 24, 2020 Medicenna's common shares began trading on The Nasdaq Capital Market ("Nasdaq"). Medicenna now trades on both the Nasdaq and the Toronto Stock Exchange under the symbol "MDNA".

- On September 30, 2020, Dr. Jack Geltosky, an experienced pharmaceutical licensing executive with a strong research and development background, was elected to Medicenna's Board of Directors.

Upcoming Milestones

Medicenna will focus on achieving the following milestones in the upcoming quarters:

- Submit an IMPD to MHRA in support of initiating a Phase 1/2 study for 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 recurrent GBM.
- Declare a lead candidate for its bispecific Superkine program in calendar 2021.

Financial Results

Net loss for the quarter ended September 30, 2020 was $3.8 million, or $0.08 per share, compared to a loss of $1.9 million, or $0.07 per share, for the quarter ended September 30, 2019. The increase in net loss for the quarter ended September 30, 2020 compared with the quarter ended September 30, 2019 was primarily a result of no reimbursement under the CPRIT grant in the current year period, increased research and development expenditures related to the MDNA11 program as well as costs associated with the Nasdaq listing.

Research and development expenses of $2.2 million were incurred during the quarter ended September 30, 2020, compared with $1.2 million incurred in the quarter ended September 30, 2019. The increase in expenses in the current quarter is primarily attributable to no reimbursement of expenditures under the CPRIT grant in the current year period and increased manufacturing and development expenditures related to the MDNA11 program.

General and administration expenses of $1.7 million were incurred during the quarter ended September 30, 2020, compared with $0.6 million during the quarter ended September 30, 2019. This increase in expenditures is primarily attributed to public company expenses in the current periods due to activities associated with our Nasdaq listing and related directors and officers liability insurance premiums.

Medicenna had cash, cash equivalents and marketable securities of $34.2 million as at September 30, 2020. These funds provide the Company with sufficient capital to mid-2022 based on its current plans and projections.

Medicenna's condensed consolidated interim financial statements for the quarter ended September 30, 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 stimulating cancer killing effector T cells and NK cells when compared to competing IL-2 programs. It is anticipated that MDNA11 will be ready for the clinic in 2021. 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. For more information, please visit www.medicenna.com.

Forward-Looking Statement
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 MDNA55's ability to ability to improve long-term survival and tumor control in rGBM, the expansion of our clinical pipeline, the anticipated timing as to when MDNA11 will be ready for the clinic and when clinical trial results will be available, the Phase 3 trial for MDNA55 and a potential interim analysis by the FDA, the submission of an IMPD in order to commence human studies with MDNA11, the timing on declaring a lead candidate from the bi-specifics platform, that we are well positioned for continued growth, that our MDNA11 Superkine platform has the ability to generate cytokine-based treatments that overcome the shortcomings of currently available immunotherapies, partnership plans for MDNA55, that Medicenna is enabled to deliver short- and long-term value to its stakeholders, timing to report results from the safety portion of the MDNA11 Phase 1/2, the period of time that the Company's cash on hand will fund its current plans and operations 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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