Medicenna Presents MDNA11 Data from IND-Enabling Studies at the AACR-NCI-EORTC Conference

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-- MDNA11 preferentially induced durable proliferation and expansion of anti-cancer immune cells with limited stimulation of pro-tumor Treg cells in non-human primates (NHP)

-- MDNA11 administration in NHPs did not lead to safety issues typically associated with IL-2

-- MDNA11 alone or in combination with anti-PD1 checkpoint inhibitor resulted in 100% tumor control and long-term protection against tumor re-challenge by inducing antigen-specific CD8 T cells in murine cancer model

TORONTO and HOUSTON, Oct. 07, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. (“Medicenna” or “the Company”) (NASDAQ/TSX: MDNA), a clinical stage immuno-oncology company, today announced the presentation of new preclinical data from its MDNA11 program in a virtual poster session at the AACR-NCI-EORTC Virtual International Conference On Molecular Targets and Cancer Therapeutics.

Data presented in the poster and corresponding abstract are from murine and IND-enabling non-human primate (NHP) studies of MDNA11, Medicenna’s selective, long-acting and novel IL-2 super-agonist. Murine studies evaluated the anti-tumor activity of MDNA11 as monotherapy and in combination with anti-PD1 checkpoint inhibition in MC38 tumor model. NHP studies evaluated the safety, pharmacokinetics (PK), and pharmacodynamics (PD) of three repeated doses of 0.15 mg/kg, 0.3 mg/kg, or 0.6 mg/kg MDNA11, with each dose intravenously administered 14 days apart.

“These preclinical studies reinforce the potential of MDNA11 and the advantages of its differentiated ‘beta only’ approach to targeting the IL-2 receptor,” said Fahar Merchant, PhD, President and CEO of Medicenna. “We believe that the results from NHPs showed that MDNA11 induced durable proliferation and expansion of anti-cancer immune cells, while demonstrating safety, PK, and PD profiles that indicate it can overcome the shortcomings of native IL-2 and competing variants. In mice, treatment with MDNA11 alone or in combination with anti-PD-1 agents led to complete responses and a strong immune memory effect that protected against tumor re-challenge. Collectively, these results support, in our view, the continued clinical evaluation of MDNA11 as monotherapy and in combination with checkpoint inhibition through our ongoing Phase 1/2 ABILITY study.”

Key data and conclusions presented in the poster and corresponding abstract include:

NHP studies:

- Dose proportional increases in exposure as measured by both C_{max} and area under the curve (AUC) were observed with increasing doses of MDNA11.
- Serum levels of MDNA11 generally were near or reached the lower limit of quantification within 4-5 days after dosing, with PD effects lasting more than 7 days after dosing.
- MDNA11 preferentially induced durable proliferation and expansion of anti-cancer immune effector cells (non-Treg $CD4^+$ T-cells, $CD8^+$ T-cells and NK cells), with limited stimulation of pro-tumor Treg cells.
- MDNA11 exhibited a favorable safety profile. No signs of cytokine release syndrome or anti-drug antibodies were observed at any dose level. No clinical or histological evidence of pulmonary edema or vascular leak syndrome was observed at any dose level.
- The main safety observations were loss of appetite, reduced activity, and diarrhea, which was observed at the highest dose level and were also transient in nature.

Murine studies

- Treatment with MDNA11 alone or in combination with anti-PD-1 therapy led to tumor growth inhibition and durable complete responses in a murine MC38 tumor model even though tumor growth was not inhibited by anti-PD-1 monotherapy.
- Initial treatment with MDNA11 alone or in combination with anti-PD-1 protected against subsequent tumor re-challenge by inducing long-term, antigen-specific CD8+ T-cells.

The virtual poster presentation titled, “*MDNA11 is a Long-Acting ‘Beta-Only’ IL-2 Agonist that Demonstrates a Safe and Durable Anti-tumor Immune Response*” is available for on-demand viewing on the AACR-NCI-EORTC conference website will be available on the “ Events and Presentations” page of Medicenna’s website.

MDNA11 is currently being evaluated in patients with advanced solid tumors in the Phase 1/2 ABILITY (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study. A

preliminary update on safety, PK/PD, and biomarker data from early cohorts of patients enrolled in the dose escalation phase of the study this year is expected by the end of calendar 2021. A preliminary efficacy update from the study is expected in the first half of calendar 2022.

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 selective, long-acting and novel 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 and relate to the future operations of the Company and other statements that are not historical facts including statements related to the clinical potential and development of MDNA11 and the anticipated timing for various results from studies related to MDNA11. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects", "believes", "seeks" and similar expressions. All statements other than statements of historical fact, included in this release, including 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 and Form 40-F of the Company 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. 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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