Medicenna Announces FDA Clearance of IND to Expand the Phase 1/2 ABILITY Study of MDNA11 to the United States

October 27, 2021

-- ABILITY Study is currently ongoing at clinical trial sites in Australia

-- Preliminary update on safety, PK/PD, and biomarker data expected by year-end 2021

-- Initial efficacy data update expected in mid-2022

TORONTO and HOUSTON, Oct. 27, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. (“Medicenna” or “the Company”) (NASDAQ/TSX: MDNA), a clinical stage immuno-oncology company, today announced that the U.S. Food and Drug Administration (FDA) has cleared Medicenna’s investigational new drug (IND) application to expand the Phase 1/2 ABILITY (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study of MDNA11 (the “ABILITY Study”), the Company’s long-acting, “beta-only” IL-2 super-agonist, to clinical trial sites in the United States. The ABILITY Study is currently enrolling patients at clinical trial sites in Australia and regulatory submissions to further expand the trial to sites in Canada and the United Kingdom are expected to be completed this calendar year.

“Clearance of this IND application is an important accomplishment that adds to the positive momentum behind our MDNA11 program,” said Dr. Fahar Merchant, President and CEO of Medicenna. “We anticipate that the expansion of the ABILITY Study to the United States will expedite enrolment in the trial and advance the study towards key updates at the end of 2021 and mid-2022. We believe MDNA11’s differentiated ‘beta-only’ approach to targeting the IL-2 receptor gives it the potential to overcome the shortcomings of other ‘not-alpha’ IL-2 agents, and look forward to reporting the potential benefits of our approach as the study advances towards dose expansion and combination phases of the trial.”

The ABILITY Study is designed to assess the safety, pharmacokinetics (PK), pharmacodynamics (PD), and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced, relapsed, or refractory solid tumors and 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 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.

A preliminary update on safety, PK/PD, and biomarker data from early cohorts of patients enrolled in the dose escalation phase of the ABILITY Study this year is expected at the end of calendar 2021 with initial efficacy data update expected in mid-2022.

About the ABILITY Study
Medicenna’s Phase 1/2 ABILITY 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 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 but not limited to, the impact of the expansion of the ABILITY Study on the tumor types that may be explored with MDNA11, the rate of subject enrollment in the Company’s trial and the ABILITY Study and the timing of results from the Company’s trial and ABILITY Study, the anticipated timing and results of the Company’s trials and studies generally and 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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