Medicenna Doses First Patient in MDNA11 Phase 1/2 ABILITY Study

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-- Trial designed to assess safety, pharmacokinetics (PK), pharmacodynamics (PD), and anti-tumor activity of MDNA11 in patients with advanced solid tumors

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

-- Preliminary efficacy readouts from study expected over the course of 2022

TORONTO and HOUSTON, Sept. 14, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. (“Medicenna” or “the Company”) (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced the initiation of dosing of patients in the Phase 1/2 ABILITY (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study of MDNA11, the Company’s selective, long-acting and novel IL-2 super-agonist. The study is designed to assess the safety, PK, PD, and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced solid tumors and includes an MDNA11 monotherapy arm, as well as a combination arm designed to evaluate MDNA11 with a checkpoint inhibitor.

“Dosing the first patient with MDNA11 in the ABILITY study is a major step towards demonstrating MDNA11’s potential in the clinic as a differentiated and selective IL-2 agonist,” said Dr. Mann Muhsin, Chief Medical Officer of Medicenna. “That we were able to accomplish this milestone in line with our prior guidance amid the global pandemic speaks to the talent and commitment of our team, advisors, investigators and vendors. We look forward to the continued advancement of this study in other regions of the world and to generating data that we believe will highlight the therapeutic potential of MDNA11 when compared with other IL-2 agents currently in the clinic.”

The ABILITY study is currently enrolling patients at clinical trial sites in Australia with expansion to additional sites planned in the United States, Canada, and the United Kingdom. Medicenna expects the remaining regulatory submissions for these jurisdictions to be completed this calendar year.

"MDNA11 is an engineered IL-2 designed to overcome the safety and PK challenges of native IL-2, while substantially enhancing its selectivity and affinity for the IL-2 beta receptor expressed by cancer-fighting immune cells, which further bolsters its therapeutic profile. Unlike “not-alpha” versions of IL-2 in the clinic, MDNA11 is the first “beta-only” IL-2 Superkine developed by directed evolution to enter clinical development,” said Fahar Merchant, PhD., President and CEO of Medicenna. “Our preclinical studies suggest preferential proliferation of CD8 T cells and NK cells while hindering undesirable stimulation of immunosuppressive Tregs, vascular leak or cytokine release syndrome. We look forward to establishing the optimal dosing regimen for MDNA11 and demonstrating its potential for cancer patients with refractory solid tumors.”

The ABILITY study plans to enroll at least 80 patients with advanced, relapsed, or refractory solid tumors. Patients will receive MDNA11 via intravenous administration in an out-patient setting. Following establishment of the recommended dose and treatment schedule, Medicenna plans to enroll expansion cohorts of patients with renal cell carcinoma and melanoma along with a cohort of patients with 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 by the end of calendar 2021. Preliminary efficacy updates from the study are expected at various times during 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 safety, pharmacokinetics (PK), pharmacodynamics (PD), and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced solid tumors. The study, MDNA11-01, includes a monotherapy dose escalation phase followed by 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.

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 IL-2 Superkine asset, MDNA11, is a next-generation IL-2 with potentially superior CD122 binding without CD25 affinity thereby preferentially stimulating cancer killing effector T cells and NK cells unlike competing IL-2 programs. Medicenna’s early-stage BiSKITs ™ program, (**Bi**functional **S**uper**K**ine **I**mmuno**T**herapie**s**) is designed to further enhance the ability of Superkines to treat immunologically “cold” tumors. Medicenna's 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 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 enrollment, expansion, prospects and timing of regulatory submissions and results for its Phase 1/2 ABILITY study and its timeline, design and expansion, the clinical potential of MDNA11 and the Company's general growth opportunities and potential. 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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