

## Medicenna Announces Submission of Clinical Trial Application in Australia for a Phase 1/2 Study of MDNA11

June 23, 2021

- -- Initiation of the ABILITY Study, a first-in-human trial, is expected in the third quarter of 2021
- -- Trial is designed to assess the 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

TORONTO and HOUSTON, June 23, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced that it has submitted a clinical trial application to a Human Research Ethics Committee (HREC) in Australia to initiate a Phase 1/2 clinical study of MDNA11, the Company's selective, long-acting and novel IL-2 super-agonist. Subject to approval by the HREC and acceptance of the Clinical Trial Notification (CTN) by Australia's Therapeutics Goods Administration (TGA), Medicenna expects to initiate this study in the third quarter of 2021. Additionally, pending successful patient recruitment, the Company intends to provide a preliminary update on safety, pharmacokinetic (PK), pharmacodynamic (PD), and biomarker data by year end.

"Submission of this dossier for HREC approval is an important milestone that keeps us on track to execute our broader clinical and corporate strategy," said Fahar Merchant, PhD, President and Chief Executive Officer of Medicenna. "We look forward to the initiation of this trial and reporting results that could support MDNA11's best-in-class potential as a "beta-only IL-2" instead of "not-alpha IL-2" agents currently in the clinic. In addition to MDNA11's first ABILITY Study (A Beta-only IL-2 ImmunoTherapY Study), we are advancing our BiSKITs<sup>TM</sup> program to identify a new a lead candidate to add to our pipeline while we advance partnering discussions around MDNA55. We are encouraged with recent progress we have made on multiple fronts and are also hopeful that a partnership for MDNA55 will be completed in the coming months. Collectively, our pipeline of opportunities leave us well positioned to achieve a steady cadence of value creating milestones as we work to address the unmet needs of patients."

The planned Phase 1/2 ABILITY 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. It includes both, an MDNA11 monotherapy arm as well as a combination arm designed to evaluate MDNA11 with a checkpoint inhibitor. Following its progress in Australia, Medicenna intends to expand the study to the United Kingdom, the United States and Canada.

Mann Muhsin, MD, Chief Medical Officer of Medicenna, commented, "MDNA11 has the attributes to overcome the limitations of competing IL-2 therapies and the filing of this application represents a crucial step in exploring the pan-tumor potential of MDNA11 and its ability to treat multiple tumor types spanning a wide immunogenicity spectrum. Preclinical data demonstrate MDNA11's ability to selectively stimulate durable expansion of cancer-killing immune cells without the unwanted adverse events typically seen with IL-2. Our Phase 1/2 study is designed to clinically validate these results, as it will include safety and PK/PD assessments as well as collection of biomarker data from paired pre- and on-treatment tumor biopsies. The preliminary efficacy readout from the monotherapy arm is expected in 2022 and most notably will evaluate MDNA11's anti-tumor activity in expansion cohorts comprised of subjects with metastatic melanoma and advanced renal cell carcinoma, tumor types that are known to respond to IL-2 therapy but have yet to show comparable responses with the not-alpha IL-2s."

## **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 and therefore preferentially stimulates cancer killing effector T cells and NK cells when compared to competing IL-2 programs. Medicenna's early-stage BiSKITs ™ program (Bifunctional SuperKine ImmunoTherapies) is designed to further enhance the ability of Superkines to treat immunologically "cold" tumors. 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 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 Phase 1/2 clinical trial of MDNA11 and its timeline, design and expansion, the clinical potential of MDNA11, the clinical potential and development of the BiSKITs™ program and its timeline, partnering discussions around MDNA55 and timeline for a potential transaction and the Company's growth. 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 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

For further information about the Company please contact:

Elizabeth Williams, Chief Financial Officer, 416-648-5555, ewilliams@medicenna.com

Investor Contact

For more investor information, please contact:

Dan Ferry, Managing Director, LifeSci Advisors, 617-430-7576, daniel@lifesciadvisors.com



Source: Medicenna Therapeutics Corp.