Medicenna Reports Confirmed Partial Response in Pancreatic Cancer and Clinical Update on MDNA11's Monotherapy Dose Escalation Portion of the Ongoing Phase 1/2 ABILITY Study

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- *Confirmed partial response in fourth-line metastatic pancreatic cancer patient, who had previously failed chemotherapy and checkpoint inhibitor therapy, supports MDNA11's single-agent potential in advanced solid tumors unresponsive to established treatments*

- *The observed tumor control rate of 36% in the low and mid-dose cohorts (n=14) in patients with advanced metastatic cancer further enhances our confidence in MDNA11's monotherapy activity, consistent with our belief in its potential to selectively bolster cancer-fighting immune cells*

- *Fifth dose-escalation cohort is currently enrolling patients with no dose-limiting toxicities observed in the trial to-date*

TORONTO and HOUSTON, Sept. 28, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced new clinical data on anti-tumor activity from the Phase 1/2 ABILITY study of MDNA11, the Company's "beta-only" long-acting IL-2 super-agonist. These data include a confirmed partial response (PR) in a fourth-line metastatic pancreatic ductal adenocarcinoma (PDAC) patient that had previously failed chemo and checkpoint inhibitor therapies. The confirmatory scan for this patient continues to show further tumor reduction compared to prior scans, suggesting durable anti-cancer activity following MDNA11 monotherapy. Overall, five of fourteen evaluable patients in the ABILITY study's low and mid-stage dose escalation cohorts have achieved tumor control (PR or stable disease (SD)) with MDNA11 monotherapy.

"We are excited to report confirmation of a partial response in a patient with late-stage pancreatic cancer, one of the most aggressive tumors that rarely responds to single agent immunotherapy," said Fahar Merchant, PhD, President and CEO of Medicenna. "Furthermore, four additional patients have experienced tumor control despite the advanced stage of cancer in all patients enrolled in ABILITY's dose escalation cohorts. This outcome provides early evidence supporting our belief in MDNA11's single-agent anti-tumor activity and underscores its therapeutic potential as a best-in-class IL-2 agonist. Given that the dose-escalation portion of the trial is designed primarily to evaluate the safety and pharmacokinetics and determine the phase 2 dose, these early signs of potential clinical benefit are particularly impressive as we continue to dose escalate and advance towards the trial's dose expansion phases early next year."

The ABILITY study's dose escalation cohorts are evaluating MDNA11 monotherapy administered intravenously once every two weeks to patients with advanced solid tumors, with the primary objective of evaluating the safety and pharmacokinetics and determining the recommended Phase 2 dose (RP2D). Once the RP2D has been established, a key secondary objective of the trial will be to evaluate the anti-tumor activity of MDNA11 alone and in combination with the checkpoint inhibitor KEYTRUDA® (pembrolizumab) in the trial's dose expansion phases.

The ABILITY study's first three dose escalation cohorts evaluated MDNA11 at doses of 3,10 and 30 µg/kg. Patients in the fourth and fifth dose escalation cohorts receive two 30 µg/kg "priming" doses of MDNA11 before stepping up to receive fixed doses of 60 and 90 µg/kg, respectively. The trial is currently enrolling patients in the fifth dose-escalation cohort, with no dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues observed to-date. A summary of demographic and therapeutic activity data from all evaluable patients in the first four dose escalation cohorts is provided below.

Patient Demographics

Prior to enrolment in the ABILITY Study, patients in Cohorts 1 to 4 (n=14) had failed up to four lines of systemic therapy.

Prior to enrolment in the ABILITY Study, eleven of fourteen patients (89%) in Cohorts 1 to 4 had relapsed on, could not tolerate, or did not respond to at least one immunotherapy with a checkpoint inhibitor.

Therapeutic Activity

Five of fourteen evaluable patients (36%) have achieved tumor control as defined in the study

- One fourth-line (4L) metastatic PDAC patient that had previously failed chemo and checkpoint inhibitor therapies achieved a confirmed PR at the 60 µg/kg dose
- One 3L non-clear cell renal cell carcinoma patient at the 60 µg/kg dose achieved SD
- One 4L sarcoma patient receiving the 30 µg/kg dose achieved SD
- Two patients (3L sarcoma and 3L metastatic melanoma) achieved SD at the 10 µg/kg dose, with the metastatic melanoma patient maintaining SD for more than a year while escalating to the 60 µg/kg dose.

To date, MDNA11 has demonstrated a favorable tolerability profile in the monotherapy dose escalation segment of the ABILITY study. New data on MDNA11's safety, pharmacokinetic and pharmacodynamic profiles are expected to be presented at a major medical meeting in the fourth quarter of the calendar year.

About the Phase 1/2 ABILITY Study
The ABILITY (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study is designed to assess the safety, pharmacokinetics, pharmacodynamics, and anti-tumor activity of various doses of intravenously administered MDNA11 in patients with advanced, relapsed, or refractory solid tumors. The trial includes an MDNA11 monotherapy arm, as well as a combination arm designed to evaluate MDNA11 with KEYTRUDA® (pembrolizumab). Approximately 80 patients are expected to be enrolled into the ABILITY Study. Following establishment of the recommended Phase 2 dose (RP2D) and optimal 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. For more information, see ClinicalTrials.gov Identifier: NCT05086692.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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 Statements
This news release contains forward-looking statements within the meaning of applicable securities laws that relate to the future operations of the Company and other statements that are not historical facts including, but not limited to, statements related to the clinical potential, development and tolerability profile of MDNA11 and the expected timing for the presentation of new data related thereto. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expect", "believe", "seek", "potentially" and similar expressions. All statements other than statements of historical fact, included in this release, including, but not limited to, MDNA11's ultimate treatment potential and statements on 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 latest Annual Information Form and Annual Report on Form 20-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. 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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