Medicenna Announces New Clinical Data Providing Preliminary Evidence of MDNA11's Single Agent Anti-Cancer Activity in the Phase 1/2 ABILITY Study

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-- Tumor control was achieved in four of ten evaluable patients with advanced solid tumors unresponsive to other treatments enrolled in the ABILITY Study's low and mid-stage dose escalation cohorts

-- Study's fifth dose-escalation cohort is open for enrollment following a favorable review of safety data from Cohort 4 by the trial's Safety Review Committee

-- Data featured in an oral presentation taking place at 1:00 PM ET today at the Cytokine Based Drug Development Summit

TORONTO and HOUSTON, July 27, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical-stage immunotherapy company, today announced new clinical data on safety, pharmacodynamics and anti-tumor activity from the Phase 1/2 ABILITY study of MDNA11, the Company's long-acting IL-2 super agonist. The data, which provide preliminary evidence of MDNA11's single agent anti-cancer activity in patients with advanced solid tumors who have been unresponsive to other treatments, are being featured in an oral presentation taking place at 1:00 PM ET today at the Cytokine Based Drug Development Summit.

"The ABILITY Study's latest data add to a body of clinical evidence we believe supports our view on MDNA11's potential as a best in class IL-2 agonist," said Dr. Fahar Merchant, President and CEO of Medicenna. "Data from the trial's initial and mid-stage dose escalation cohorts showed signs of tumor control in four of ten evaluable patients with hard to treat cancers such as sarcomas and pancreatic cancer that are also highly resistant to immunotherapies."

Dr. Merchant continued, "Complementing these early anti-tumor results are pharmacodynamic data that are consistent with MDNA11's novel 'beta-only' mechanism of action and pre-clinical evidence of tumor localization. Treatment with MDNA11 leads to multi-fold increases in anti-cancer immune cells without stimulation of cells that cause immunosuppression and toxicity typically associated with native IL-2 and its 'alpha-binding' variants. These early findings continue to fuel our optimism for the outcome of the ABILITY Study based on the evolving data as we escalate from 60 µg/kg to the 90 µg/ dose."

The ABILITY Study's dose escalation cohorts are evaluating MDNA11 monotherapy administered intravenously once every two weeks to patients with advanced solid tumors. The trial's first two cohorts evaluated MDNA11 doses ≤ 10 µg/kg. The trial's third cohort was administered a dose of 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.

Key data from patients enrolled in the trial's four initial dose escalation cohorts include:

Demographics:

- Patients enrolled in the study to date (N=14) have failed up to four lines of prior systemic therapy.
- 11 of 14 patients have relapsed or did not respond to at least one prior immunotherapy with a checkpoint inhibitor.
- To date, 10 of the 14 enrolled patients, including two of six patients in Cohort 4 have received at least one post-baseline scan and are evaluable for response to the investigational treatment.

Safety:

- MDNA11 treatment in Cohort 4 (comprised of two step-up doses of 30 µg/kg followed by fixed doses of 60 µg/kg every 2 weeks) was not associated with any dose-limiting toxicities.
- The Safety Review Committee has approved dose escalation for Cohort 5 to the 90 µg/kg dose every 2 weeks following two priming doses at 30 µg/kg.
- Significant increases in eosinophil count from baseline were not observed with MDNA11 treatment. Extremely high eosinophil count is associated with vascular leak syndrome which is a known side effect of high-dose recombinant human IL-2 (Proleukin®)[1].

Anti-tumor Activity:

- Four of ten evaluable patients have achieved tumor control as defined in the study with MDNA11 monotherapy, including two patients at the 10 µg/kg dose (sarcoma and metastatic melanoma), one sarcoma patient at the 30 µg/kg dose and one pancreatic cancer patient in Cohort 4 receiving the 60 µg/kg dose.
- The first imaging scans in the remaining four patients enrolled at the 60 µg/kg dose are expected in September.

Pharmacodynamics:

- MDNA11 preferentially expanded anti-cancer NK and $CD8^+$ T cells without stimulating proliferation of pro-tumor Treg cells.
- MDNA11 treatment potently activated anti-cancer $CD8^+$ T cells as shown by increases in both $CD25^+$ and $ICOS^+$ $CD8^+$ T cells.
- Unlike IL-2, MDNA11 has not induced increases in $ICOS^+$ Treg cells. $ICOS^+$ Treg cells are highly immunosuppressive and associated with lack of response to high dose IL-2 immunotherapy.[2]

A copy of the Cytokine Based Drug Development Summit presentation, entitled, “Co-Stimulation of Adaptive and Innate Immune Cells to Achieve Clinical Benefit with MDNA11, a Long-Acting ‘Beta-only’ IL-2 Super-Agonist,” will be posted to the “ Events and Presentations” page of Medicenna’s website following its conclusion.

References

1. https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103293s5130lbl.pdf
2. Sim, Geok Choo, et al. "IL-2 therapy promotes suppressive $ICOS^+$ Treg expansion in melanoma patients." *The Journal of clinical investigation* 124.1 (2014): 99-110.

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 a checkpoint inhibitor. Approximately 100 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.

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 ™ (**Bi**functional **S**uper**K**ine **I**mmuno**T**herapie**s**) progam is designed to enhance the ability of Superkines to treat immunologically “cold” tumors. Medicenna's IL-4 Empowered Superkine, MDNA55, has been studied in five 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 under applicable securities laws. 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 statements related to MDNA11’s potential and efficiency, the time of availability of the first imaging scans in the remaining four patients enrolled at the 60 µg/kg dose and the ABILITY Study 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 risk that interim data of clinical studies, including the ABILITY Study, may not be indicative of future results, as well as the risks detailed in the annual information form and 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.

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