



Medicenna Presents Updated Clinical Data from Dose Escalation Portion of Phase 1/2 ABILITY Study of MDNA11 at the SITC Annual Meeting

November 10, 2022

- MDNA11's selectivity and dose-dependent stimulation of anti-cancer immune cells indicates potential for increased anti-tumor activity with continued dose escalation

- New data reaffirm MDNA11's potential to overcome the major safety, pharmacokinetic, and pharmacodynamic shortcomings of IL-2 therapies

TORONTO and HOUSTON, Nov. 10, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immunotherapy company, today announced new safety, pharmacokinetic (PK), and pharmacodynamic (PD) data from the first four dose escalation cohorts of the Phase 1/2 ABILITY study of MDNA11, the Company's "beta-only" long-acting IL-2 super-agonist. The data are featured in two posters being presented at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting, which is taking place both virtually and in-person at the Boston Convention and Exhibition Center in Boston, MA, from November 8 – 12, 2022.

"The clinical data being presented at SITC are encouraging and reassert MDNA11's potential as a best-in-class IL-2 super-agonist by virtue of its desirable PK, PD, and safety features, along with the promising signs of anti-tumor activity it has displayed in heavily pre-treated, end-stage patients," said Fahar Merchant, PhD, President and CEO of Medicenna. "We were particularly pleased to see MDNA11's PK profile remaining consistent with repeat dosing, which suggests the absence of an anti-drug antibody response. Moreover, we have continued to see MDNA11 selectively and dose-dependently stimulating anti-cancer immune cells through ABILITY's low and mid-dose cohorts, suggesting potential for further increases in anti-tumor activity as we enroll patients in higher dose cohorts that employ the optimized dosing schedule that will be implemented in the trial's dose expansion phase."

As previously reported, data from the first four (low and mid) dose escalation cohorts of the ABILITY study show tumor control in five of fourteen evaluable patients treated with MDNA11 monotherapy administered intravenously once every two weeks. These results included a confirmed partial response (PR) in a fourth-line (4L) metastatic pancreatic cancer patient who previously failed chemo- and checkpoint inhibitor therapies. The confirmatory scan for this patient showed further tumor reduction compared to prior scans, suggesting durable anti-cancer activity following MDNA11 monotherapy. Collectively, these data support MDNA11's single-agent potential in advanced solid tumors unresponsive to prior treatments.

Newly announced data in the posters include detailed safety and demographic results from ABILITY's first four dose escalation cohorts as well as PK/PD data from the complete set of patients in cohort four. Highlights from the posters (N=14) include:

Demographics: Patients with advanced solid tumors unresponsive to established treatments

- 64% of participants failed 1-2 lines of prior systemic therapy, 36% failed 3-4 lines of prior systemic therapy
- 79% of participants failed prior immunotherapy, 50% failed prior chemotherapy, and 28% failed prior targeted therapy

Safety: MDNA11 has been well tolerated with no dose limiting toxicities

- The majority (92%) of MDNA11 related adverse events (AEs) were Grade 1-2
- All MDNA11 related AEs were transient; majority resolved within 1-2 days
- Most common AEs: infusion related reactions (78.6%), nausea (57.1%), and fever (50%)
- There have been no dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues observed to-date.

Pharmacodynamics: Dose-dependent stimulation of anti-cancer immunity observed

- MDNA11 preferentially stimulated proliferation and expansion of anti-cancer CD8+ T and NK cells but not Tregs (associated with pro-tumor immune pathways) or eosinophils (associated with vascular leak syndrome, a known side effect of the only approved IL-2 therapy)
- MDNA11's effects on anti-cancer immune cells were sustained beyond serum exposure (>11 days), indicating a prolonged PD profile

Pharmacokinetics: Dose-dependent increases in exposure observed

- Dose-dependent increases in C_{max} and AUC were sustained with repeat dosing
- Results suggest there is no clinically meaningful anti-drug-antibody response to MDNA11

The ABILITY study is currently enrolling patients in its fifth dose-escalation cohort (two 30 µg/kg "priming" doses of MDNA11 followed by fixed doses of 90 µg/kg). Initial anti-tumor activity from the fifth dose escalation cohort, alongside a broader update from all of the trial's dose escalation cohorts, is expected in the first quarter of 2023.

Copies of the two posters are available on the SITC Annual Meeting virtual platform. They will also be posted to the "[Events and Presentations](#)" page

of Medicenna's website following the conclusion of the meeting. Details on the in-person poster presentations are shown below.

Title: Pharmacokinetic and Pharmacodynamic Profile of a First-in-Human Study with MDNA11, an Engineered Long-Acting 'Beta-only' IL2 Agonist

Abstract Number: 743

Poster Presentation Date and Time: November 10, 2022, from 9:00 a.m. – 9:00 p.m. ET

Poster Session Location: Boston Convention and Exhibition Center, Hall C

Title: Interim Single-agent Safety and Anti-tumor Activity from Dose Escalation Phase of ABILITY Study on MDNA11, a Long-acting Beta-only IL-2 Agonist

Abstract Number: 744

Poster Presentation Date and Time: November 11, 2022, from 9:00 a.m. – 8:30 p.m. ET

Poster Session Location: Boston Convention and Exhibition Center, Hall C

About the Phase 1/2 ABILITY Study

The ABILITY (**A** Beta-only **IL-2** Immuno**TherapY**) 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 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](https://clinicaltrials.gov/ct2/show/study/NCT05086692) Identifier: [NCT05086692](https://clinicaltrials.gov/ct2/show/study/NCT05086692).

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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, (**B**ifunctional **S**uper**K**ine Immuno**T**herapies) 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, plans and projections and other statements that are not historical facts including, but not limited to, statements related to the clinical potential, safety profile and development of MDNA11 and the expected timing and milestones 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, enrolling patients for ABILITY study 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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Source: Medicenna Therapeutics Corp.