Medicenna Announces Promising Single-Agent Response and Durability of MDNA11 in the Phase 1/2 ABILITY Study During Dose Escalation at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC)

November 6, 2023

- *MDNA11 continues to demonstrate encouraging single-agent activity from the dose escalation and evaluation portion of the ABILITY-1 Study including deep ongoing partial responses with 100% reduction of target lesions in one pancreatic and 70% reduction of target lesion in one melanoma cancer patient*

- *MDNA11 also showed durable stable disease in 3 melanoma patients for at least 5 months to 18 months with concomitant shrinkage of tumor size following failure with check-point inhibitor therapies*

- *MDNA11 is generally well tolerated with no dose-limiting toxicities or vascular leak syndrome reported in any of the dose escalation cohorts*

- *Medicenna believes that these data reaffirm the differentiated and promising therapeutic activity, safety, PD and PK profile of the 'beta-enhanced not-alpha' albumin-fused IL-2 superkine in patients with advanced solid tumors who have failed current standard of care*

TORONTO and HOUSTON, Nov. 06, 2023 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA), a clinical-stage immunotherapy company focused on the development of Superkines, today announced that new clinical data from the Phase 1 monotherapy dose escalation/evaluation portion of the Phase 1/2 ABILITY-1 (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study evaluating MDNA11, the only long-acting, 'beta-enhanced not-alpha' interleukin-2 (IL-2) super-agonist in clinical development, in patients with advanced solid tumors, were presented at the 38th Annual Meeting of the Society for Immunotherapy of Cancer (SITC) held in San Diego, CA, on November 4th, 2023.

"We are very encouraged by two partial responses and three durable stable diseases in patients with advanced cancer who had progressed on multiple prior therapies, reinforcing MDNA11's promising single-agent activity," said Fahar Merchant, Ph.D., President and Chief Executive Officer of Medicenna. "These data add to the growing body of evidence demonstrating the clinical effectiveness of MDNA11 with highly favorable underlying immune response characterized by robust expansion and activation of $CD8^+$ T cells with minimal impact on immune-suppressive Tregs. MDNA11 with uniquely differentiating 'beta-enhanced not-alpha' features, continues to be a potential best-in-class next-generation IL-2 super-agonist for treatment of advanced solid tumors. We look forward to reporting results from the monotherapy expansion and combination escalation arms of the Phase 2 study in the first half of 2024."

Key findings from the Phase 1 monotherapy dose escalation portion of the ABILITY-1 study at time of data cut-off (26-Oct-2023) include:

Favorable safety profile: No dose limiting toxicity (DLT) reported and no evidence of vascular leak syndrome (VLS). Vast majority (95.6%) of treatment-related adverse events (TRAEs) were of grade 1-2 severity and resolved within 48 hours; grade 3 TRAEs mainly constituted transient LFT elevations; no grade 4 or 5 events were reported.

Encouraging single-agent anti-tumor activity at doses of ≥ 60 ug/kg (N = 15):

- **Partial response reported in 2 patients with aggressive tumor types**

  - A patient with metastatic pancreatic ductal adenocarcinoma (PDAC; MSI-H), who had previously failed on multiple systemic therapies and exhibited primary resistance to immune checkpoint inhibitors, experienced remarkable response to MDNA11 (60 ug/kg) with baseline target lesions and non-target lesions showing deepening shrinkage on successive imaging scans. Following return from a 7 week vacation, a single new lesion was observed and MDNA11 treatment was resumed. Prior to receiving one cycle of radiotherapy for the new lesion, complete resolution of initial 2 target and 1 non-target lesions was achieved. Patient continues on MDNA11 post radiotherapy.

  - A patient with cutaneous melanoma, who progressed on prior line of dual checkpoint inhibitors, treated with MDNA11 (90 ug/kg dose), showed a 70% reduction of the target lymph node lesion at week 12.

- **Durable stable disease in 3 metastatic melanoma patients with concomitant reduction in tumor burden**: Two patients with SD of >20 (acral melanoma) and >24 weeks (cutaneous melanoma) are continuing MDNA11 treatment in the 120 ug/kg cohort. One patient with cutaneous melanoma had SD for > 1.5 years having started MDNA11 at the 10 ug/kg dose with subsequent intra-patient dose escalations of 30, 60 and 90 ug/kg.

- **Potent proliferation of effector immune populations:** Pharmacodynamic data showed robust and durable activation of effector immune cells, particularly $CD8^+$ T cells ($CD25^+$, $OX40^+$), with minimal impact on the immunosuppressive Treg population.

- **Recommended Dose for Expansion (RDE):** Target dose of 90 ug/kg (following two step-up doses of 30 and 60 ug/kg) Q2W IV infusion was chosen for monotherapy expansion portion of the ABILITY-1 study.

- **Monotherapy expansion part of ABILITY-**1 is enrolling patients with metastatic melanoma, non-melanoma skin cancers (CSCC, MCC, and BCC) and MSI-H/dMMR tumors.

The main objectives of the monotherapy dose escalation part of the Phase 1/2 ABILITY-1 study (Clinicaltrials.gov ID: NCT05086692) were to assess MDNA11's safety, tolerability, PK, PD, and anti-tumor activity to inform on the RDE in an all-comer solid tumor population with advanced cancers refractory to prior systemic therapies. A total of six dose escalation cohorts (MDNA11 dose ranging from 3 ug/kg to 120 ug/kg) were evaluated, with the majority of patients (73%) having also received at least one prior line of immunotherapy with or without primary resistance to immune checkpoint inhibitors.

A copy of the poster and a related slide deck have been posted to the "Events and Presentations" page of Medicenna's website.

About MDNA11

MDNA11 is an intravenously administered, long-acting 'beta-enhanced not-alpha' interleukin-2 (rIL-2) Superkine specifically engineered to overcome the shortcomings of aldesleukin and other next generation IL-2 variants by preferentially activating immune effector cells (CD8+ T and NK cells) responsible for killing cancer cells, with minimal or no stimulation of immunosuppressive Tregs. These unique proprietary features of the IL-2 Superkine have been achieved by incorporating seven specific mutations and genetically fusing it to a recombinant human albumin scaffold to improve the pharmacokinetic (PK) profile and pharmacological activity of MDNA11 due to albumin's natural propensity to accumulate in highly vascularized sites, in particular tumor and tumor draining lymph nodes. MDNA11 is currently being evaluated in the Phase 1/2 ABILITY-1 study as both a monotherapy and in combination with pembrolizumab (Keytruda®).

About Medicenna

Medicenna is a clinical-stage immunotherapy company focused on developing novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first in class class-empowered superkines. Medicenna's long-acting IL-2 Superkine, MDNA11, is a next-generation IL-2 with superior affinity toward CD122 (IL-2 receptor beta) and no CD25 (IL-2 receptor alpha) binding, thereby preferentially stimulating cancer-killing effector T cells and NK cells. Medicenna's IL-4 Empowered Superkine, bizaxofusp (formerly MDNA55), has been studied in 5 clinical trials enrolling over 130 patients, including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. Bizaxofusp has obtained FastTrack and Orphan Drug status from the FDA and FDA/EMA, respectively. Medicenna's early-stage BiSKITs™ program (**Bi**functional **S**uper**K**ine **I**mmuno**T**herapies) is designed to enhance the ability of Superkines to treat immunologically "cold" tumors.

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, without limitation, statements on the clinical development and potential and safety profile of MDNA11, additional data and reporting thereof. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expect", "believe", "seek", "potentially" and similar expressions and 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 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.

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