Medicenna Presents Phase 1/2 ABILITY Study Data Highlighting MDNA11's Favorable Clinical Profile at the 2022 Frontiers in Cancer Immunotherapy Meeting

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-- New data show that MDNA11 boosted the lymphocyte population by 2-fold without inducing significant increases in eosinophils (associated with toxicity)

-- MDNA11 selectively increased a sub-population of anti-tumor ICOS$^+$ CD8 T cells without enhancing proliferation of highly immune-suppressive pro-tumor ICOS$^+$ Treg cells

-- Dose-dependent and 3-fold increase in immune cells expressing Granulysin, a peptide known to target tumor cell killing.

TORONTO and HOUSTON, May 11, 2022 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced that clinical data from the Phase 1/2 ABILITY (**A B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study of MDNA11, the Company's long-acting IL-2 super-agonist, have been featured in a poster presentation at the 9th Annual Frontiers in Cancer Immunotherapy Meeting. The meeting, organized by the New York Academy of Sciences, is taking place both virtually and in-person from May 9 – 11, 2022.

"Developing a best-in-class IL-2 Superkine is our top priority and we are pleased to disclose additional promising clinical data which are consistent with our expectations based on the novel "beta-only" mechanism of MDNA11," said Dr. Fahar Merchant, President and CEO of Medicenna. "The cadence of our early clinical data demonstrates that MDNA11 is a unique long-acting IL-2 with favorable pharmacokinetic and pharmacodynamic effects boosting cancer-fighting CD8$^+$T cells and natural killer cells without stimulating immunosuppressive regulatory T cells or eosinophils known to cause toxicity".

The presentation featured both, previously announced data from the ABILITY study's initial dose escalation cohorts showing dose-dependent stimulation of anti-cancer immune cells with MDNA11 treatment (doses ranging from 3 µg/kg to 30 µg/kg administered every 2 weeks), as well as new pharmacokinetic (PK) and pharmacodynamic (PD) analyses from the first 8 patients with treatment refractory solid tumors. Key findings from the new analyses include:

- MDNA11 treatment led to a dose-dependent expansion of cancer fighting lymphocytes (>200% increase at 30 µg/kg) and no significant increases in eosinophil count when compared to baseline. Extremely high eosinophil count is associated with severe toxicity and is a known side effect of high-dose recombinant human IL-2 (Proleukin®)[1].
- MDNA11 treatment potently activated anti-cancer CD8$^+$ T cells by increasing (a) their population by >3-fold, and (b) boosting their activation as shown by increase in both, CD25$^+$ and ICOS$^+$ CD8$^+$ T cells.
- Unlike IL-2, MDNA11 did not induce an increase in ICOS$^+$ Treg cells. ICOS$^+$ Treg cells are highly immunosuppressive and associated with lack of response to high dose IL-2 immunotherapy.[2]
- MDNA11 has shown a favorable and consistent pharmacokinetic profile following multiple doses suggesting that it may not be generating anti-drug antibodies associated with immunogenicity.
- Granulysin expressing immune cells also increased by 3-fold in a dose-dependent manner. Granulysin is a potent agent causing cancer specific cell death and is associated with better patient outcomes.[3,4]

Enrollment into the study's fourth dose escalation cohort is ongoing. An initial update on efficacy data from the ABILITY study is expected in mid-2022.

A copy of the presentation, entitled, "MDNA11 is a Long-Acting 'Beta-Only' IL-2 Agonist Exhibiting Potent Tumor Growth Control in Preclinical Models and Preferential Expansion of NK and CD8$^+$ T Cells in Patients with Advanced Solid Tumors," will be posted to the " Events and Presentations" page of Medicenna's website.

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.
3. Kishi, Atsuko, et al. "Differential expression of granulysin and perforin by NK cells in cancer patients and correlation of impaired granulysin expression with progression of cancer." *Cancer Immunology Immunotherapy* 50.11 (2002):604-614.
4. Pages, Franck, et al. "Effector memory T cells, early metastasis, and survival in colorectal cancer." *New England Journal of Medicine* 353.25 (2005): 2654-2666.

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 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.

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 under applicable securities laws and relate to the future operations of the Company and other statements that are not historical facts. 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 the clinical potential and development of MDNA11 and the timing of updates on 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 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. 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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