Medicenna Commences Enrollment in the ABILITY-1 Study Combining MDNA11 with Pembrolizumab

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- *The ABILITY-1* Study *will evaluate MDNA11, a highly selective long-acting IL-2 Superkine, in combination with KEYTRUDA® (pembrolizumab) for treatment of patients with advanced solid tumors*
- *MDNA11 continues to demonstrate encouraging single-agent activity from the dose escalation portion of the ABILITY-1 Study*
- *MDNA11 is generally well tolerated with no dose-limiting toxicities or vascular leak syndrome reported in any of the dose escalation cohorts*
- *Company expects to report initial results from both the monotherapy expansion and combination escalation arms of the Phase 2 study in H1 2024*

TORONTO and HOUSTON, Jan. 09, 2024 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA, OTCQB: MDNAF), a clinical-stage immunotherapy company focused on the development of Superkines, today announced initiation of enrollment in the combination arm of the Phase 1/2 ABILITY (**A** **B**eta-only **IL**-2 **I**mmuno**T**herap**Y**) study evaluating MDNA11, a long-acting, "beta-enhanced not-alpha" interleukin-2 (IL-2) super-agonist, with Merck's pembrolizumab (KEYTRUDA ®). The combination portion of the study is being conducted as part of the previously announced Clinical Trial Supply and Collaboration Agreement[1] between Medicenna and Merck (known as MSD outside the United States and Canada) and is designed to evaluate the potential for a synergistic effect of MDNA11 with KEYTRUDA® in patients with advanced solid tumors.

"We are very pleased to announce initiation of the combination study of MDNA11 and the PD-1 inhibitor, pembrolizumab, the leading checkpoint inhibitor therapy," said Fahar Merchant, Ph.D., President and CEO of Medicenna. "Having established an appropriate dose for monotherapy as well as demonstrating its early clinical validation we believe MDNA11 may further enhance anti-tumor activity when combined with pembrolizumab in patients that do not respond or develop resistance to checkpoint therapy. We look forward to reporting preliminary results from both the monotherapy expansion and combination escalation arms of the Phase 2 study in the first half of 2024."

In the Phase 1 monotherapy dose escalation and dose evaluation portions of the study, MDNA11 was well tolerated with promising single-agent activity. As of the data cutoff date of October 26, 2023, responses included:

- one confirmed durable (> 1.5 years) and deep (100% resolution of target lesions) partial response in a heavily pretreated patient with metastatic pancreatic cancer and primary resistance to checkpoint inhibitor (CPI) therapy,
- one deep (70% resolution of target lesion) unconfirmed partial response in a patient with cutaneous melanoma with secondary resistance to CPI, both of whom continue on therapy and,
- multiple patients with extended stable disease and/or target lesion reductions.

Solid tumors represent 90% of all cancers and although CPI therapies have shown promising advances in some types of immunosensitive cancers, more than 70% of patients do not respond to or become resistant to such therapies. MDNA11, with its 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. Pre-clinical data published in JITC in 2023 demonstrated that mice receiving both, MDNA11 and checkpoint inhibitors achieved complete tumor control even after multiple rechallenges when compared to either treatment alone, demonstrating the capacity for MDNA11 to sensitize solid tumors to checkpoint blockade[2].

The ABILITY-1 Study is actively recruiting patients with different types of recurrent or metastatic solid tumors at multiple sites in the USA and Australia and is expected to initiate patient enrolment in Canada and South Korea.

[1] https://ir.medicenna.com/news-releases/news-release-details/medicenna-announces-clinical-collaboration-merck-evaluate-mdna11

[2] https://pubmed.ncbi.nlm.nih.gov/35058325/

About the ABILITY-1 Study

The ABILITY-1 study (NCT05086692) is a global, multi-center, open-label study that assesses the safety, tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity of MDNA11 as monotherapy or in combination with pembrolizumab (Keytruda®). In the combination dose escalation of the Phase 2 study, approximately 6-12 patients are expected to be enrolled and administered ascending doses of MDNA11 intravenously once every two weeks in combination with pembrolizumab 400mg every six weeks. This portion of the study includes patients with a wide range of solid tumors with the potential for susceptibility to immune modulating therapeutics. Upon identification of an appropriate dose regimen for combination, the study will proceed to a combination dose expansion cohort.

About MDNA11

MDNA11 is an extensively engineered long-acting recombinant IL-2 "Superkine" with complete abrogation of IL-2 receptor alpha binding, enhanced

IL-2 receptor beta binding, and fusion to recombinant human albumin. These changes enable effective expansion and activation of anti-tumor $CD8^+$ effector and NK cells while avoiding excessive stimulation of immunoinhibitory Treg cells or side effect inducing endothelial cells, as well as ensuring retention in the tumor and tumor draining lymph nodes. These changes vastly increase efficacy and therapeutic index over the predecessor drug aldesleukin. MDNA11 is currently being evaluated in the Phase 1/2 ABILITY-1 study as both a monotherapy and in combination with the PD-1 blocking antibody pembrolizumab (Keytruda®).

About Medicenna Therapeutics

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 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™ (Bifunctional SuperKine ImmunoTherapies) and the T-MASK™ (Targeted Metalloprotease Activated SuperKine) programs are designed to enhance the ability of Superkines to treat immunologically "cold" tumors.

For more information, please visit www.medicenna.com and follow us on Twitter and LinkedIn.

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 of MDNA11, the ABILITY-1 Study and its enrolment and the timeline for reporting results and additional data. 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 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.

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

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