Medicenna Announces EMA Approval of its Clinical Trial Application to Expand its Phase 1/2 ABILITY-1 Study to Europe

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- ABILITY-1 study is currently enrolling patients for the treatment of advanced solid tumors with MDNA11, a novel long-acting IL-2 super-agonist, as a monotherapy or in combination with KEYTRUDA®, at clinical trial sites in U.S.A., Canada, Australia, and Korea

- Monotherapy expansion and combination escalation data of the ABILITY-1 study are expected in H2 2024

TORONTO and HOUSTON, June 26, 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 that the European Medicines Agency ("EMA") has approved the Clinical Trial Application ("CTA") for the conduct of the Phase 1/2 ABILITY-1 (A Beta-only IL-2 ImmunoTherapY) Study with MDNA11 either alone or in combination with pembrolizumab (KEYTRUDA®) thereby expanding the clinical trial in the European Union ("EU"). MDNA11 is the Company's long-acting, "beta-enhanced not-alpha" IL-2 super-agonist and is currently enrolling patients with advanced solid tumors in the ABILITY-1 trial at clinical trial sites in U.S.A., Canada, Australia, and Korea.

"We are excited to build on the early success and promising efficacy and safety of our ongoing ABILITY-1 study that is demonstrating MDNA11's best-in-class potential," said Fahar Merchant, PhD, President & CEO of Medicenna. "Expanding the clinical trial to various centers in the EU is an important milestone and adds to the positive momentum behind our MDNA11 program. We anticipate that the expansion to Europe will expedite enrolment in the trial and advance the study towards key updates in the monotherapy expansion and combination escalation portions of the ABILITY-1 study which will be presented at medical conferences during H2 2024."

The ABILITY-1 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 and includes an MDNA11 monotherapy arm, as well as a combination arm designed to evaluate MDNA11 in combination with pembrolizumab (KEYTRUDA®).

About MDNA11

MDNA11 is a long-acting 'beta-enhanced not-alpha' interleukin-2 (IL-2) Superkine specifically engineered to overcome the shortcomings of aldesleukin and other next generation IL-2 variants by preferentially activating immune effector cells ($CD4^+$ T, $CD8^+$ 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 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 12 patients are expected to be enrolled and administered ascending doses of MDNA11 intravenously once every two weeks in combination with pembrolizumab. 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 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 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.

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

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to, express or implied statements regarding the future operations of the Company, estimates, plans, strategic ambitions, partnership activities and opportunities, objectives, expectations, opinions, forecasts, projections, guidance, outlook or other statements that are not historical facts, such as statements on the Company's clinical potential, of MDNA11 and the ABILITY-1 study and its, safety, enrollment and the reporting of data therefrom. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs

result in commercialization of a product. Results in early-stage clinical studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented. Forward-looking statements are often identified by terms such as “will”, “may”, “should”, “anticipate”, “expect”, “believe”, “seek”, “potentially” and similar expressions. Forward-looking statements are based on a number of assumptions believed by the Company to be reasonable at the date of this news release. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such statements will prove to be accurate. These statements are subject to certain risks and uncertainties and may be based on assumptions that could cause actual results and future events to differ materially from those anticipated or implied 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.

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 or implied in forward-looking statements. 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.

This news release contains hyperlinks to information that is not deemed to be incorporated by reference in this news release.

Investor and Media Contact:

Christina Cameron
Investor Relations, Medicenna Therapeutics
ir@medicenna.com
(647) 953-0673

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