Medicenna Reports Third Quarter Fiscal 2025 Financial and Operational Results and Provides Anticipated Milestones

February 13, 2025

- Disease control rate (DCR) of 78% (7 of 9) in combination escalation arm of MDNA11 with Merck's (known as MSD outside of Canada and the US) KEYTRUDA® (pembrolizumab) in ongoing Phase 1/2 ABILITY-1 trial including one complete response, one partial response and five stable disease (as reported on Dec. 5, 2024)

- MDNA11 continued to demonstrate deep and durable single agent activity, with a 30% (3 of 10) objective response rate (ORR) in the monotherapy dose expansion cohort in checkpoint-resistant patients (as reported on Dec. 5, 2024)

- Anticipated H1/2025 milestones related to the ABILITY-1 trial includes completion of enrolment in MDNA11 monotherapy dose expansion arm and MDNA11 + KEYTRUDA® combination dose escalation arm and initiation of combination dose expansion arm

- MDNA113 advancing towards IND-enabling studies as a first-in-class, targeted and conditionally activated bispecific anti-PD1-IL2 immunotherapy

- Ended quarter unchanged relative to previous quarter with $30 million in cash and equivalents (includes warrant exercises), expected to fund operations through mid-2026

TORONTO and HOUSTON, Feb. 13, 2025 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA, OTCQX: MDNAF), a clinical-stage immunotherapy company focused on the development of Superkines, today announced its FY Q3 2025 financial results and provided its 2025 strategic outlook with anticipated milestones.

"We are thrilled about the year ahead as we build on the significant progress we achieved last year," said Dr. Fahar Merchant, President and CEO of Medicenna. "Our excitement is driven by the impressive response rates seen in the ABILITY-1 trial, particularly in the monotherapy arm where 5 patients responded to MDNA11 out of 20 patients with heavily pre-treated advanced solid tumors, including one complete response, despite all of them having failed prior checkpoint inhibitor therapies. Additionally, we are encouraged by early results from the combination dose-escalation arm, where two confirmed objective responses including a complete response have been observed in patients with treatment refractory tumors with historically low response rates to immune checkpoint inhibition. We look forward to presenting PK/PD data from the ABILITY-1 trial at the AACR-Immuno-Oncology Conference later this month and updated efficacy data at other medical conferences in Q2."

Dr. Merchant added, "Equally motivating is the strong financial support we received from RA Capital last year, which validates and reinforces confidence in our innovative approach and positions us well to execute on a robust clinical development program for MDNA11 to support its use across a range of tumor types. As we approach critical value inflecting milestones in the ABILITY-1 trial, we remain committed to advancing our programs and our mission to deliver life-changing therapies for patients with cancer."

CLINICAL PROGRESS DURING FY Q3 2025

- Provided clinical update to the ABILITY-1 study and announced the first complete responder in MDNA11 in combination with KEYTRUDA® (pembrolizumab) in dose escalation arm at an oral presentation at the Immunotherapy Bridge conference. A 70-year-old patient with advanced chemo-refractory anal cancer achieved a complete response in 8 weeks when treated with MDNA11 in combination with KEYTRUDA®. A partial response was seen in a chemo-refractory patient with microsatellite-stable colorectal cancer in the combination escalation arm. Five patients showed stable disease, delivering a 78% disease control rate.
- Presented data from the ongoing Phase 1/2 ABILITY-1 study at the 39th Annual Meeting of the Society for Immunotherapy of Cancer, demonstrating positive single-agent activity of MDNA11 from the dose expansion cohorts and an encouraging safety profile and early anti-tumor activity in combination with KEYTRUDA®. MDNA11 continued to demonstrate promising deep and durable single agent activity, with a 30% (3 of 10) objective response rate ("ORR") in the monotherapy dose expansion cohort (in checkpoint-resistant patients).

ANTICIPATED MILESTONES FOR 2025

MILESTONE	ANTICIPATED CALENDAR DATE
MDNA11 – a long-acting superkine with best-in-class potential for solid tumors (90% of all cancers)	
• **Present** PK/PD data from ongoing ABILITY-1 trial at AACR-Immuno-Oncology Conference with additional efficacy and safety data to be presented in calendar Q2 and remainder of 2025	Feb. 2025

• **Complete** enrollment for the MDNA11 monotherapy dose expansion arm of ABILITY-1 trial	mid 2025
• **Present** results from combination dose escalation arm of the ABILITY-1 trial at a major medical conference (with further updates anticipated in H2/25)	Q2 2025
• **Complete** enrollment for combination dose escalation arm of the ABILITY-1 trial (MDNA11 + KEYTRUDA®)	mid 2025
• **Initiate** combination dose expansion arm of the ABILITY-1 trial to assess efficacy of MDNA11 with KEYTRUDA® in specific tumor types	Q2 2025

Preclinical programs

• **Advance** MDNA113 toward IND-enabling studies as an immunotherapy (MDNA113 is the only 'β-enhanced' anti-PD1-IL2 bi-specific molecule in development)	H2/2025
• **Identify** lead candidate for an immunology and/or inflammation indication	H2/2025

FINANCIAL RESULTS

As at December 31, 2024, the Company reported cash and equivalents of $30.0 million, compared to $17.0 million at March 31, 2024. These funds are expected to provide the Company with sufficient capital to execute planned expenditures through the completion of the MDNA11 ABILITY-1 study, and through mid-calendar year 2026. During the nine months ended December 31, 2024, there were 2,495,917 warrants exercised for proceeds of $3.8 million; 156,135 warrants expired unexercised.

For the three months ended December 31, 2024, the Company reported total operating costs of $5.1 million compared to total operating costs of $4.8 million for the three months ended December 31, 2023. The slight increase in operating costs during the current quarter relative to a year ago is net of an increase in R&D expenditures which was slightly offset by a decrease in G&A expenditures.

R&D expenses of $3.4 million were incurred during the three months ended December 31, 2024, compared with $3.0 million incurred in the three months ended December 31, 2023. The increase is primarily related to increased clinical costs related to the MDNA11 ABILITY-1 Study which has expanded to new clinical sites and enrolled more patients in the current period relative to the prior period, and the inclusion of the combination portion of the MDNA11 study with KEYTRUDA® during the current period which had not commenced in the prior period.

G&A expenses of $1.7 million were incurred during the three months ended December 31, 2024, compared with $1.8 million during the three months ending December 31, 2023. The slight decrease is due to a reduction in public company expenses in the current period relative to the prior comparative period related to lower D&O insurance premiums, reduced professional services including legal and audit fees, and a reduction in US-based investor and public relations expenses. The above decreases were partially offset by an increase in stock-based compensation expense in the current period relative to the prior comparative periods primarily due a stock-based compensation expense recovery realized in the prior period related to employee departures. Excluding stock-based compensation expense (non-cash), G&A expenses decreased $0.4 million in the quarter relative to the comparable quarter in the prior year.

For the three months ended December 31, 2024, the Company reported a net loss of $5.2 million ($0.07 per share) compared to a net loss of $5.0 million ($0.07 per share) for the three months ended December 31, 2023. Net loss was relatively unchanged in the current period relative to the three months ended December 31, 2023 due to offsetting variances in G&A and R&D expenditures, combined with finance income (gain), foreign exchange (gain) and change in fair value of warrant derivative (loss) largely offsetting each other. The Company experienced a relatively large foreign exchange gain during the quarter ($1.2 million) due to the significant balance of US cash held by the Company. Approximately 65% of the Company's cash at December 31, 2024 is held in US funds.

Medicenna's financial statements for the three and nine months ended December 31, 2024, and the related management's discussion and analysis (MD&A) will be available on SEDAR+ at sedarplus.ca.

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. MDNA11 is being evaluated in the Phase 1/2 ABILITY-1 Study (NCT05086692) as monotherapy and in combination with pembrolizumab. 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 high-affinity IL-2β biased IL-2/IL-15 Super-antagonists, from its MDNA209 platform, are being evaluated as potential therapies for autoimmune and graft-versus host diseases. 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 medicenna.com, and follow us on Twitter and LinkedIn.

Forward-Looking Statements

This news release may contain 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 therapeutic treatment potential and safety profile of MDNA11 (both as monotherapy and in combination with pembrolizumab) and MDNA113, expected future milestones, cash runway, strategic outlook and the timing and/or release of any additional clinical updates. 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 pre-clinical or 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. and are subject to risks and uncertainties. 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 information form 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 new release.

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Source: Medicenna Therapeutics Corp.