Medicenna Reports Second Quarter Fiscal 2025 Financial Results and Corporate Update

November 15, 2024

MDNA11 continues to show best-in-class potential in the ABILITY-1 study with an objective response rate (ORR) of 30% in the monotherapy dose expansion cohort among patients with cancer progression after one or more immune checkpoint inhibitor (ICI) therapy

Two PRs were observed among 3 microsatellite instability high (MSI-H) ICI resistant patients (ORR 66.7%) with both responders having pancreatic cancer including one patient with 100% tumor regression and no progression of target and non-target lesions for at least 26 months

First PR observed in the combination dose escalation arm of the ABILITY-1 study in a microsatellite stable (MSS) colon cancer patient not eligible for ICI therapy, indicating MDNA11's potential to improve outcomes for cancers that do not typically respond to ICIs

Favorable safety profile in the combination dose escalation arm of the Phase 1/2 ABILITY-1 study with Merck's (known as MSD outside of Canada and the US) KEYTRUDA® (pembrolizumab) with no dose limiting toxicities observed at the 60 and 90 µg/kg dose, Q2W with enrolment now proceeding at the 120 µg/kg dose, Q2W and Q3W

Company reported cash and cash equivalent balance of $30 million excluding $1.9M following recent warrant exercises maintaining runway through mid calendar year 2026

Multiple MDNA11 milestones anticipated in Q1 and Q2 of calendar 2025

TORONTO and HOUSTON, Nov. 15, 2024 (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 reported financial results and corporate highlights for the fiscal quarter ended September 30, 2024, including updates on its on-going global Phase 1/2 ABILITY-1 study with MDNA11, a long-acting "non-alpha, enhanced beta" IL-2 Superkine.

"Achieving objective response rates with MDNA11 monotherapy that are comparable to those of block-buster immunotherapies, particularly in patients with advanced solid tumors that are resistant to immunotherapy, is a remarkable testimony to the potential of MDNA11 and our IL-2 superkine platform," said Fahar Merchant, Ph.D., President and CEO of Medicenna. "Further evidence of our confidence in MDNA11 arises from early but encouraging signs of tumor response in the combination setting in cancers that are not approved for checkpoint inhibitors. We are also encouraged with the safety profile observed in combination with KEYTRUDA®, as we explore higher and more convenient dosing schedule of MDNA11. We look forward to sharing additional results from our programs during the next 2 quarters as well as our progress with next generation Superkines for treatment of cancer and autoimmune diseases."

PROGRAM AND BUSINESS UPDATE:

Highlights for the three months ended September 30, 2024, along with recent developments, include:

MDNA11: IL-2 Superkine Program

On November 9th, 2024, at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC), Medicenna reported positive, updated clinical results from the ongoing monotherapy expansion and combination dose escalation portions of the Phase 1/2 ABILITY-1 Study.

ORR of 30% in Expansion Cohort with Single Agent MDNA11 in ICI Resistant Patients

- The updated results at SITC demonstrated that the ORR was 30% in the Phase 2 monotherapy dose expansion cohort (3 of 10) among ICI resistant patients with advanced and/or metastatic solid tumors.
- Including patients from the dose escalation/evaluation cohort (n = 10) that meet the Phase 2 eligibility criteria, the ORR was 25% (5 of 20%), including 1 complete response (CR) and 4 partial responses (PR) and a clinical benefit rate of 40% (8 of 20) including 3 patients with stable disease (SD) for at least 6 months.
- Two PRs were observed among 3 microsatellite instability high (MSI-H) ICI resistant patients (ORR 66.7%) with both responders having pancreatic ductal adenocarcinoma (PDAC) including one patient with 100% tumor regression and no signs of progression of target and non-target lesions for at least 26 months.
- ORR in patients with ICI resistant cutaneous melanoma was 27% (3 of 11), with one patient achieving a complete response at week 52 who remains on treatment as of week 63.
- A new fourth partial response, in a cutaneous melanoma patient in the monotherapy expansion cohort, was reported at SITC. This response has since been confirmed in a subsequent scan which occurred after the data cut-off date.

MDNA11 Combination Escalation with KEYTRUDA®: Encouraging Safety Profile with No New Safety Signals and Early Signs of Anti-tumor Activity

- In the combination portion of the study with KEYTRUDA®, no dose limiting toxicities were observed at the 90 µg/kg dose level, and the next 2 cohorts have started enrollment at the higher dose of 120 µg/kg administered either once every 2 weeks or once every 3 weeks, with 400 mg KEYTRUDA® administered once every 6 weeks.
- Early pharmacodynamic analyses demonstrated robust lymphocyte expansion which was sustained with repeat dosing at both 60 µg/kg and 90 µg/kg Q2W MDNA11 in combination with 400 mg Q6W KEYTRUDA®.
- Among 5 heavily pre-treated efficacy-evaluable patients in the combination dose escalation arm, tumor control (PR or SD) was observed in 4 patients (80%), including a PR in a microsatellite-stable (MSS) colon cancer patient and 2 SDs in ovarian squamous cell carcinoma and triple negative breast cancer patients, tumor-types which have failed to demonstrate sufficient anti-tumor activity in response to checkpoint inhibitor therapy in previous clinical trials.

OPERATIONAL UPDATES

On November 13th, 2024, Medicenna announced that it will present pre-clinical data at the 29th Annual Meeting of the Society of Neuro-Oncology taking place in Houston, Texas from November 21 – 24, 2024, and at the 2024 San Antonio Breast Cancer Symposium (SABCS), the world's largest breast cancer conference, taking place in San Antonio, Texas from December 10 – 13, 2024.

In Q1 and Q2 of calendar 2025, Medicenna anticipates achieving several milestones in the MDNA11 program. These include completing monotherapy expansion and combination dose-escalation enrollment, initiating the combination expansion phase of the Phase 1/2 ABILITY-1 study, and providing further clinical updates at medical conferences.

FINANCIAL RESULTS

As at September 30, 2024, the Company had a cash and cash equivalents balance of $30.4 million, compared to $17.0 million at March 31, 2024. The Company also received an additional $1.9 million subsequent to the end of the quarter from the exercise of 1.1 million warrants with a strike price of $1.75 per warrant. These funds are expected to provide the Company with sufficient capital to execute planned expenditures through the completion of the ABILITY-1 study and through mid-calendar year 2026.

For the three months ended September 30, 2024, the Company reported total operating costs of $5.5 million compared to total operating costs of $5.4 million for the three months ended September 30, 2023. Steady operating costs year over year is primarily related to a decrease in general and administrative expenses in the current period which offset an increase in R&D expenditures.

R&D expenses of $3.7 million were incurred during the three months ended September 30, 2024, compared with $3.1 million incurred in the three months ended September 30, 2023. The increase is primarily related to increased clinical costs from the expansion of the MDNA11 ABILITY-1 Study to new clinical sites, the inclusion of more patients in the study 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 $1.8 million were incurred during the three months ended September 30, 2024, compared with $2.3 million during the three months ending September 30, 2023. The decrease is due to a significant reduction in public company expenses in the current period relative to the prior comparative period related due to lower D&O insurance premiums, reduced professional services including legal and audit fees, a reduction in US-based investor and public relations expenses, and non-recurring recruitment fees incurred during the comparative period. The above decreases were partially offset by an increase in stock-based compensation expense in the current period relative to the prior comparative periods due to the grant of options during the current period and a stock-based compensation expense recovery realized in the prior period related to employee departures.

For the three months ended September 30, 2024, the Company reported a net loss of $4.2 million ($0.05 per share) compared to a net loss of $3.7 million ($0.05 per share) for the three months ended September 30, 2023. Net loss was relatively unchanged in the current period relative to the three months ended September 30, 2023 due to offsetting variances in G&A and R&D expenditures.

Medicenna's financial statements for the three and six months ended September 30, 2024, and the related management's discussion and analysis (MD&A) will be available on SEDAR+ at www.sedarplus.ca.

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 X 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 cash runway and planned expenditures, the clinical performance and potential, safety profile of MDNA11, as well as MDNA11's treatment potential, the reporting of additional results, and anticipated corporate milestones. 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 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 news release.

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