

# Medicenna Reports First Quarter Fiscal 2025 Financial Results and Announces First Complete Responder with MDNA11 Monotherapy

August 1, 2024

Patient with melanoma, having failed dual check-point inhibitor therapy, achieved a complete response following treatment with MDNA11 at week 52 with 100% regression of all target and non-target lesions reinforcing its best-in-class potential

Updated scans from pancreatic cancer patient continues to show sustained 100% regression of target and non-target lesions at 115 weeks and remains in remission 6 months after ending MDNA11 treatment

All other previously announced patients with partial responses remain on treatment and the combination dose escalation with pembrolizumab (KEYTRUDA®) continues to enroll patients at the MDNA11 monotherapy expansion dose (90 µg/kg, Q2W)

Company reported cash and cash equivalent balance of \$36 million, following a \$20 million investment by RA Capital, extending runway to mid-2026

Updated MDNA11 monotherapy and combination data and other program updates anticipated at multiple conferences throughout H2 2024

TORONTO and HOUSTON, Aug. 01, 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 reported financial results and corporate highlights for the fiscal quarter ended June 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.

"We are delighted to announce the first complete response in a melanoma patient, refractory to dual checkpoint inhibitors, in the monotherapy dose-escalation arm of the ABILITY-1 study, reinforcing MDNA11s deep and durable single-agent activity and differentiation from competing IL-2 programs," said Fahar Merchant, Ph.D., President and CEO of Medicenna. "Notably, the melanoma complete responder remains on treatment after 12 months and the pancreatic cancer patient has shown durable tumor control for over 115 weeks while maintaining complete regression of target and non-target lesions for the past 6 months without any further treatment. These data underscore MDNA11s best-in-class attributes including its favorable safety, pharmacokinetic, and pharmacodynamic profile. The recent \$20 million financial backing from RA Capital Management extends our cash runway to mid-2026 and allows us to expedite the study by expanding the clinical trial in the EU following regulatory clearance by EMA in June. We look forward to presenting updated data on MDNA11 and other programs at medical conferences throughout the second half of 2024."

#### **PROGRAM AND BUSINESS UPDATE:**

Highlights for the three months ended June 30, 2024, along with recent developments, include: MDNA11: IL-2 Superkine Program

- A cutaneous melanoma patient, who had progressed on prior line of dual checkpoint inhibitors, had a partial response at week 12 followed by a complete response at week 52. The patient is continuing with MDNA11 (Q2W; 90 μg/kg), showing durability for at least 12 months.
- A pancreatic cancer patient with primary resistance to checkpoint inhibitor therapy has shown durable tumor control for over 115 weeks and maintains complete regression of target and non-target lesions for the past 6 months without any further treatment.
- Previously reported patients with partial responses continue on the study further supporting the durability of MDNA11.
- Dose escalation in combination with KEYTRUDA® continues to enroll at the higher dose of MDNA11 90  $\mu$ g/kg Q2W and 400 mg pembrolizumab Q6W (priming MDNA11 30 & 60  $\mu$ g/kg) following absence of any dose limiting toxicities (DLTs) at 60  $\mu$ g/kg.

Recent updates on MDNA11 presented at various conferences this quarter included the following key highlights:

- An overall response rate of 29% and a clinical benefit rate of 50% (1 complete response, 3 partial responses, and 3 stable diseases > 24 weeks) in 14 efficacy evaluable high-dose phase 2 eligible patients who all failed checkpoint inhibitor therapy.
- MDNA11 demonstrated an acceptable safety profile with no DLTs and no evidence of vascular leak syndrome in monotherapy dose escalation at all dose levels. The vast majority (95%) of treatment-related adverse events (TRAEs) were grade 1-2 and resolved within 48 hours; grade 3 TRAEs mainly constituted asymptomatic transient LFT elevations; no grade 4 or 5 events were reported.
- Pharmacodynamic analysis showed potent and durable systemic immune activation with significant increases in stemness,
   central and effector memory CD8<sup>+</sup> T cells and markers of enhanced effector function in circulating CD8<sup>+</sup> T and NK cells, all

of which are critical for achieving meaningful and durable anti-cancer response.

Analysis of gene expression signatures from pre-treatment and on-treatment paired biopsies show that cancer promoting
pathways were degraded while immune-related pathways against cancer cells were enhanced during MDNA11 treatment.

# Bizaxofusp (formerly MDNA55): Empowered IL-4 Superkine Program

• On June 1, 2024, the Company presented survival follow-up and updated final Phase 2b study results for bizaxofusp at the 2024 American Society of Clinical Oncology Annual Meeting, demonstrating significant survival benefit with bizaxofusp in recurrent glioblastoma, versus a propensity matched external control arm.

# **Operational Highlights**

- On June 26, 2024, the Company announced that the EMA approved its Clinical Trial Application to expand the Phase 1/2
  ABILITY-1 study to Europe, marking an important milestone for the Company and adding positive momentum behind the
  MDNA11 program.
- On April 30, 2024, the Company closed a \$20 million financing through a non-brokered private placement with RA Capital Management.

#### **Financial Results**

As at June 30, 2024, the Company had a cash and cash equivalents balance of \$35.6 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 ABILITY-1 study and through mid-calendar year 2026.

For the three months ended June 30, 2024, the Company reported total operating costs of \$4.0 million compared to total operating costs of \$4.5 million for the three months ended June 30, 2023. The decrease is primarily related to a decrease in general and administrative expenses (\$0.4 million).

R&D expenses of \$2.8 million were incurred during the three months ended June 30, 2024, compared with \$2.8 million incurred in the three months ended June 30, 2023. Steady R&D expenses year over year is related to decreased chemistry, manufacturing, and controls cost due to a significant one-time expenditure in the previous period and increased clinical costs during the current period relative to the prior comparable period.

G&A expenses of \$1.3 million were incurred during the period ended June 30, 2024, compared with \$1.6 million during the prior comparable period. The decrease relative to the prior comparative period is primarily due to the decrease in public company expenses from \$1.1 million for the three months ended June 30, 2023, to \$0.6 million for the three months ended June 30, 2024. The decrease is primarily related to a reduction in D&O insurance premiums, reduced professional services including legal and audit fees, and a reduction in US-based investor and public relations expenses.

For the three months ended June 30, 2024, the Company reported a net loss of \$3.6 million (\$0.05 per share) compared to a net loss of \$2.8 million (\$0.04 per share) for the three months ended June 30, 2023. The increase in net loss for the three months ended June 30, 2024, compared with the three months ended June 30, 2023, is primarily due to the \$1.7 million non-cash gain in the fair value of the warrant derivative for the three months ended June 30, 2023. The value of the warrant derivative fluctuates with the Company's share price which increased slightly in the current period versus a 30% decline in the prior comparative period. This was partially offset by a \$0.4 million decrease in general and administration expenditures for the three months ended June 30, 2024, compared to June 30, 2023.

Medicenna's financial statements for the three months ended June 30, 2024, and the related management's discussion and analysis (MD&A) will be available on SEDAR+ at <a href="https://www.sedarplus.ca">www.sedarplus.ca</a>.

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

For more information, please visit <a href="www.medicenna.com">www.medicenna.com</a>, and follow us on <a href="Twitter">Twitter</a> and <a href="LinkedIn">LinkedIn</a>.

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 and bizaxofusp, the reporting of additional results, anticipated corporate milestones, partnership efforts and the securing by Medicenna of the alignment with the EMA for the proposed Phase 3 trial design and obtaining breakthrough therapy designation for bizaxofusp from the FDA. 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 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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