



Medicenna Therapeutics Reports Third Quarter Fiscal 2024 Financial Results and Corporate Update

February 14, 2024

With the Response Rate increasing to 23%, MDNA11 continues to show compelling single-agent activity in the ABILITY-1 study amongst high-dose phase-2 eligible patients (N=13) that failed checkpoint inhibitor therapies, while maintaining an acceptable safety profile

Tumor shrinkage was also observed in all high-dose phase-2 eligible patients with stable disease (SD). In addition to a new PR, the clinical benefit rate (PR plus SD for over 24 weeks) and tumor control rate (PR plus all SD) increased to 46% and 69%, respectively

First patient was dosed in Phase 1 combination escalation portion of the ABILITY Study evaluating MDNA11 with KEYTRUDA® (pembrolizumab)

Additional monotherapy data updates and preliminary combination escalation and expansion data to be shared in H1 and H2 of 2024

Cash runway extended through multiple data readouts and into Q2 of calendar 2025

TORONTO and HOUSTON, Feb. 14, 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 financial results and corporate highlights for the third quarter of fiscal 2024, ended December 31, 2023, and outlined its strategic outlook for 2024.

"We are off to a solid start in 2024 with further validation of single-agent anti-tumor activity of our IL-2 super-agonist, MDNA11, in the ABILITY-1 study," said Dr. Fahar Merchant, President and CEO of Medicenna. "We are encouraged by another PR, increasing the total number of PRs to 3 in patients with prior failure from immune checkpoint therapy. With response rates above 20% at this early stage of the trial in high-dose phase-2 eligible patients, we believe that MDNA11's differentiated mechanism demonstrates its clinical superiority to competing IL-2 programs. This is especially gratifying in view of the desirable safety, pharmacokinetic and pharmacodynamic characteristics observed to date. We look forward to reporting additional monotherapy dose expansion and combination escalation and expansion data from the ABILITY-1 study during H1 and H2 2024."

Dr. Merchant continued, "We believe 2024 will be a transformational year for Medicenna as we continue advancing our mid- and late-stage MDNA11 and bizaxofusp assets for patients battling difficult to treat cancers. The global multi-arm Phase 1/2 ABILITY-1 study is expanding to various cancer centers in the US, Canada, Australia, South Korea and Europe evaluating MDNA11 as a single-agent and in combination with KEYTRUDA® in patients with advanced solid tumors. For bizaxofusp, we plan to seek Breakthrough Therapy Designation from the FDA, in addition to securing alignment with the EMA for the Phase 3 trial design supported by the FDA. These endeavors will further enhance potential partnership activities for bizaxofusp. We are excited for the year ahead and are increasingly confident about the significant potential of our evolutionary cytokines and delivering on our mission to bring revolutionary medicines to patients."

PROGRAM AND BUSINESS UPDATE:

Highlights for the three months ended December 31, 2023, along with recent developments include:

MDNA11

- **New additional iPR in the monotherapy dose expansion portion of the MDNA11 ABILITY-1 Study.** Today, the Company reports promising clinical data from the on-going monotherapy escalation and expansion arms of the ABILITY-1 study. In addition to previously announced tumor response data, a third patient in the study has also shown a partial response (PR). A melanoma patient with iPR (PR as per iRECIST) showed pseudo-progression (at week 8) with a PR (at week 12).
- **Response rate exceeds 20% in immune checkpoint failed patients.** Amongst 13 patients, all having previously failed or resistant to immune checkpoint inhibitors ("ICI"), receiving high doses of MDNA11 ($\geq 60 \mu\text{g/kg}$) with tumor types being evaluated in the monotherapy expansion cohort, the response rate, clinical benefit rate and tumor control rate increased to 23% (3 partial responses), 46% (3 PRs and 3 patients with SD for ≥ 24 weeks) and 69% (3 PRs and 6 SDs), respectively, with shrinkage of target lesions in all patients with SD.
- **Dosed first patient in the combination arm of the ABILITY-1 study.** On February 13, 2024, the Company announced that it had dosed the first patient in the combination arm of the ABILITY-1 clinical trial, evaluating potential synergistic effect of MDNA11 when administered with KEYTRUDA® (pembrolizumab). The study will evaluate the safety, tolerability, recommended combination dose for expansion ("cRDE") and therapeutic activity of MDNA11 when combined with KEYTRUDA® in the dose-escalation and dose-expansion arms of the clinical trial.
- **Presented positive MDNA11 monotherapy data at SITC 2023.** On November 6, 2023, Medicenna announced encouraging single-agent activity from the dose escalation and evaluation portion of the ABILITY-1 study in advanced cancer patients receiving MDNA11 at doses of $\geq 60 \mu\text{g/kg}$ (N = 15) who had previously failed ICI therapies. The results included ongoing partial responses with 100% and 70% reduction of target lesions in pancreatic and melanoma cancer

patients, respectively, in addition to durable stable disease in 3 melanoma patients (> 20 to 80 weeks). This data was presented at the 38th Annual Meeting of the Society for Immunotherapy of Cancer ("SITC") held in San Diego.

- On October 25, 2023, Medicenna announced dosing of the first patient in the Phase 2 monotherapy dose expansion portion of the ABILITY-1 Study.

Bizaxofusp (MDNA55)

- **Single treatment with bizaxofusp increased median overall survival (mOS) by 100%.** On November 17, 2023, the Company announced a poster presentation and an oral summary at the Annual Meeting of the Society of Neuro-Oncology (SNO) highlighting longer term follow up results from the Phase 2b clinical trial of bizaxofusp in patients with recurrent glioblastoma (rGBM). The data demonstrated that a single treatment with bizaxofusp increased median overall survival (mOS) by 100% (14.5 vs. 7.2 months) when compared to a propensity matched external control arm (ECA) irrespective of IL-4R (interleukin-4 receptor) expression and defined as the Phase 3 population. Overall survival (OS) for bizaxofusp-treated patients increased by 370% at Year 1 (62.5% vs 16.7%) and by more than 50% at Year 2 (25% vs 16.1%) when compared to the ECA. No systemic or clinically significant laboratory abnormalities were reported. Treatment-related adverse events were primarily neurological or aggravation of pre-existing neurological deficits due to rGBM.
- **Potential for Breakthrough Therapy Designation (BTD) for bizaxofusp.** With compelling longer term survival benefit with bizaxofusp in rGBM patients, as presented at the SNO meeting held in November 2023, Medicenna will seek to apply for BTD with the FDA.
- **Seek alignment with the European Medicines Agency ("EMA") for the Phase 3 registration trial of bizaxofusp incorporating an ECA and developed with the support of FDA.** The proposed Phase 3 trial design incorporating a hybrid external control arm has been supported by the FDA. Medicenna is currently working toward securing alignment with the EMA thereby enabling data from a single Phase 3 registrational trial being sufficient to file for approval in the EU and USA.

Other Pipeline Programs

- On November 3, 2023, the Company presented preclinical data on its first-in-class IL-13Ra2 targeted candidate, MDNA113, from its T-MASK™ platform, which specifically delivers a masked bispecific anti-PD1-IL2 SuperKine to IL-13Ra2 expressing tumors (affecting over 2 million cancer patients annually) where it is activated by cancer specific enzymes. This data was presented at the 38th Annual Meeting of the SITC held in San Diego.
- On October 3, 2023, new preclinical data characterizing MDNA223, an anti-PD1-IL-2 BiSKIT (Bifunctional SuperKine for ImmunoTherapy), including its synergy when combined with STING agonists were presented at the 2023 AACR Special Conference in Cancer Research: Tumor Immunology and Immunotherapy, held in Toronto, Canada.

Corporate Highlights

- **Transition of CMO to consultant role** - Dr. Humphrey Gardner has transitioned from Chief Medical Officer to a consulting role. Dr. Arash Yavari, Chair of Medicenna's Development Advisory Committee, will henceforth lead the clinical activities as Director of Clinical Strategy.
- **Appointment of new CFO** – David Hyman has been appointed as Chief Financial Officer of the Company. David Hyman, CA, CBV is an experienced financial professional with over 25 years of experience spanning public practice, capital markets, private equity and industry. For the past five years, Mr. Hyman has provided fractional and full time CFO services to multiple public and private companies, including two early-stage pharmaceutical companies.
- **Appointment of new Auditor** – On January 12, 2024, the Company announced that its Board of Directors approved the appointment of MNP LP as the auditor of the Company.
- **OTCQB Listing** - On December 19, 2023, the Company announced the commencement of trading on the OTCQB Venture Market in the United States.
- **NASDAQ delisting** - On October 27, 2023, Medicenna announced that it was delisted from the Nasdaq as the Company did not meet the listing requirements and that it was reducing its presence in the US to conserve cash. The Company's common shares continue to trade on the Toronto Stock Exchange.

Expected Upcoming Milestones

- Preliminary monotherapy and dose expansion data of MDNA11's ABILITY-1 study, to be presented at medical conferences in H1 and H2 of 2024.
- Clinical update from the combination arm of the ABILITY-1 study evaluating MDNA11 in with KEYTRUDA® expected in H1 and H2 of 2024.

Financial Results

As of December 31, 2023, cash and cash equivalents were \$21.8 million, compared to \$25.7 million on September 30, 2023.

Net loss for the quarter ended December 31, 2023, was \$5.0 million or (\$0.07) per share compared to a net loss of \$1.1 million or (\$0.02) per share for the quarter ended December 31, 2022. The increase was primarily a result of a reduction in the non-cash gain related to the change in valuation of the Company's derivative warrant liability.

Research and development expenses of \$3.0 million were incurred during the quarter ended December 31, 2023, compared with \$2.9 million incurred in the quarter ended December 31, 2022. Higher clinical costs associated with the MDNA11 ABILITY-1 study relative to the prior year quarter were mostly offset by reductions in stock-based compensation and licensing fees.

General and administrative expenses of \$1.8 million were incurred during the quarter ended December 31, 2023, compared with \$2.0 million during the quarter ended December 31, 2022. The decrease in general and administrative expenses in the current quarter is primarily related to a reduction in directors' and officers' liability insurance premiums.

Medicenna's interim consolidated financial statements for the three and nine months ended December 31, 2023, and the related management's discussion and analysis (MD&A) are available on SEDAR+ at www.sedarplus.ca and EDGAR.

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](#).

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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 Company's cash runway, clinical development activities, clinical potential, safety profiles and upcoming milestones and data reporting, including with respect to MDNA11, the ABILITY study and its expansion, bizaxofusp (MDNA55), MDNA113, MDNA223, partnership activities and opportunities and strategic outlook. 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 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. 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.

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