



Medicenna Reports Third Quarter Fiscal 2023 Financial Results and Operational Highlights

February 7, 2023

- *Phase 1/2 ABILITY study advancing to sixth dose escalation cohort following positive review of safety and pharmacodynamic data from fifth cohort*
- *Initial PK/PD data from ABILITY's fifth dose escalation cohort expected alongside updated anti-tumor data in calendar Q1 2023*
- *\$36.2 million in cash and cash equivalents at December 31, 2022 provides expected runway through the completion of the ABILITY study and through calendar Q2 2024*
- *Management hosting conference call and webcast today at 8:30 am ET*

TORONTO and HOUSTON, Feb. 07, 2023 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immunotherapy company, today announced its financial results and operational highlights for the quarter ended December 31, 2022, and that the Phase 1/2 ABILITY study of MDNA11 has advanced to a sixth dose escalation cohort. All dollar amounts are in Canadian currency unless otherwise noted.

"Encouraged with MDNA11's tolerability profile in end-stage cancer patients together with its enduring trend demonstrating dose-dependent expansion of lymphocytes, we are pleased to advance the ABILITY study to the sixth dose escalation cohort," said Dr. Fahar Merchant, President and CEO of Medicenna. "MDNA11 has thus far functioned as intended, by displaying durable tumor control with better tolerability upon repeat dosing, showing dose-dependent increase in exposure without immunogenicity, and boosting anti-cancer immune cell expansion without pro-tumoral immune suppression. With these attributes together with early signs of anti-tumor activity, we hope to bolster MDNA11's efficacy in a select group of less advanced cancer patients at the optimum dose in ABILITY's upcoming Phase 2 monotherapy dose expansion cohort."

Program highlights for the quarter ended December 31, 2022, along with recent developments include:

MDNA11: IL-2 Superkine Program

Enrollment is complete in the fifth dose escalation cohort of the Phase 1/2 ABILITY study of MDNA11, with no dose-limiting toxicities, dose interruptions, dose de-escalations, or treatment discontinuations due to safety issues observed to date. Preliminary pharmacodynamic (PD) data showed enhanced stimulation of lymphocyte expansion relative to baseline in the fifth cohort compared to all prior dose escalation cohorts, demonstrating MDNA11's ability to boost immune activity may be enhanced at higher doses. Based on these findings, the trial has advanced to a sixth dose escalation cohort. Participants in the sixth dose escalation cohort will receive 30, 60, and 90 µg/kg "priming" doses of MDNA11 followed by a further step-up to a fixed 120 µg/kg dose. MDNA11 is dosed intravenously every two weeks in the ABILITY study.

In November 2022, Medicenna presented safety, pharmacokinetic (PK), and PD data from the first four (low and mid) dose escalation cohorts of the ABILITY study at the Society for Immunotherapy of Cancer (SITC) 37th Annual Meeting. Safety data indicated that MDNA11 was well tolerated with no dose limiting toxicities observed. PK data showed dose-dependent increases in exposure that were sustained with repeat dosing, suggesting there is no clinically meaningful anti-drug-antibody response to MDNA11. PD data showed dose-dependent stimulation of anti-cancer immunity, with MDNA11 preferentially stimulating the proliferation and expansion of anti-cancer CD8⁺ T and NK cells but not Tregs (associated with pro-tumor immune pathways) or eosinophils (associated with vascular leak syndrome, a known side effect of the only approved IL-2 therapy).

The results presented at the SITC meeting provide mechanistic support for previously reported anti-tumor activity data demonstrating MDNA11's single-agent potential in advanced solid tumors unresponsive to established treatments. These data show that five of fourteen (36%) evaluable patients in the ABILITY study's first four dose escalation cohorts achieved tumor control (partial response or stable disease), including one fourth-line metastatic pancreatic cancer patient who achieved a confirmed partial response.

In December 2022, previously reported data from the Phase 1/2 ABILITY study of MDNA11 were featured in an oral presentation at the 2022 Immunotherapy Bridge Conference. The presentation, titled "*Early Results of an IL-2 Superkine (MDNA11) from the Phase 1/2 ABILITY Study in Advanced Solid Tumors*" was delivered by Arash Yavari, M.B.B.S., DPhil., M.R.C.P., Principal Investigator at the Radcliffe Department of Medicine, University of Oxford and Principal Clinical Advisor to Medicenna.

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

In January 2023, the full results of a single-arm Phase 2b trial of bizaxofusp (formerly MDNA55) in patients with recurrent glioblastoma were [published](#) in the peer-reviewed journal *Neuro-Oncology*. Results showed that the trial met its primary endpoint, with median overall survival (mOS) in the primary and supportive analysis populations exceeding the trial's pre-defined success criteria. Medicenna continues to pursue potential partnership opportunities to facilitate bizaxofusp's further development and, if approved, commercialization.

Intellectual Property

In January 2023, the U.S. Patent and Trademark Office issued U.S. Patent No. 11,542,312. The patent provides intellectual property protection for methods of treating cancer with an IL-2 Superkine and PD1/PDL1 or CTLA-4 checkpoint inhibitor, administered in combination or as a single agent BiSKIT™. The patent's term extends into at least 2039 without accounting for any potential extensions.

Expected Upcoming Milestones

Initial PK/PD data from the ABILITY study's fifth dose escalation cohort and updated anti-tumor activity data from the first four dose escalation cohorts are expected in calendar Q1 2023.

Early anti-tumor activity data from the ABILITY study's sixth dose escalation cohort and single agent expansion phase (Phase 2) are expected in calendar Q3 2023.

Early anti-tumor activity data from the ABILITY study's combination arm are expected in calendar Q4 2023.

Financial Results

Medicenna had cash and cash equivalents of \$36.2 million at December 31, 2022. These funds are expected to provide the Company with sufficient capital to execute its current planned expenditures through the completion of the ABILITY study and through calendar Q2 2024 based on its current plans and projections.

Net loss for the quarter ended December 31, 2022, was \$1.1 million, or (\$0.02) per share, compared to a net loss of \$4.8 million or (\$0.09) per share for the quarter ended December 31, 2021. The decrease in net loss for the quarter ended December 31, 2022, compared with the quarter ended December 31, 2021, was primarily a result of a non-cash gain of \$3.7 million related to the change in valuation of a non-cash warrant liability associated with the August 2022 financing.

Research and development expenses of \$2.9 million were incurred during the quarter ended December 31, 2022, compared with \$2.9 million incurred in the quarter ended December 31, 2021. Research and development expenses were consistent quarter over quarter.

General and administrative expenses of \$2.0 million were incurred during the quarter ended December 31, 2022, compared with \$2.0 million during the quarter ended December 31, 2021. General and administrative expenses were consistent quarter over quarter.

Medicenna's condensed consolidated interim financial statements for the quarter ended December 31, 2022 and the related management's discussion and analysis (MD&A) will be available on SEDAR at www.sedar.com and EDGAR at www.sec.gov.

Conference Call and Webcast

Medicenna will host a conference call and webcast today at 8:30 am ET. To access the call please dial 1-877-407-9716 from the United States or 1-201-493-6779 internationally and refer to conference ID: 13735304. To access the live webcast, visit this [link to the event](#). Following the live webcast, an archived version of the call will be available on Medicenna's website.

About Medicenna

Medicenna is a clinical stage immunotherapy company focused on the development of 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 CD122 (IL-2 receptor beta) binding without CD25 (IL-2 receptor alpha) affinity thereby preferentially stimulating cancer killing effector T cells and NK cells. Medicenna's early-stage BiSKITs™ program, (Bifunctional SuperKine ImmunoTherapies) is designed to enhance the ability of Superkines to treat immunologically "cold" tumors. Medicenna's IL-4 Empowered Superkine, bizaxofusp (formerly MDNA55), has been studied in 5 clinical trials including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. Bizaxofusp has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

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, but not limited to, statements related to the clinical potential, safety and tolerability profile and development of MDNA11, the clinical potential an development of bizaxofusp (formerly MDNA55) and partnering efforts in connection therewith, intellectual property protection, expected upcoming milestones and cash runway and planned expenditures. 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 Information Form and 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 and the United States.

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.

Further Information

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