



Medicenna Announces the Peer-Reviewed Publication of Clinical Data from Phase 2b Trial Evaluating MDNA55 in Recurrent Glioblastoma

May 7, 2021

-- Data published in *Clinical Cancer Research* indicate that early determination of PFS with modified RANO criteria may be a strong surrogate for overall survival in recurrent glioblastoma

-- Medicenna's proposed patient population shows a tumor control rate of 81% (26/32) based on modified RANO criteria

TORONTO and HOUSTON, May 07, 2021 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (NASDAQ: MDNA TSX: MDNA), a clinical stage immuno-oncology company, today announced the peer-reviewed publication of clinical data from the Company's Phase 2b recurrent glioblastoma (rGBM) trial in *Clinical Cancer Research*. The [paper](#), entitled "Modified RANO, Immunotherapy RANO, and Standard RANO Response to Convection-enhanced Delivery of IL4R-targeted Immunotoxin MDNA55 in Recurrent Glioblastoma," was published in collaboration with researchers at several prestigious institutions including University of California Los Angeles and Duke University.

Fahar Merchant, PhD, President and Chief Executive Officer of Medicenna, commented, "This Phase 2b trial has generated compelling data, and we are very pleased to have them published in such a prestigious peer-reviewed journal. In particular, we are highly encouraged by results showing that early determination of progression free survival (PFS) using modified RANO (mRANO) may be a strong surrogate for overall survival in rGBM. We believe this finding and the positive mRANO PFS and overall survival (OS) data from our proposed patient population bode well for the outcome of the planned Phase 3 trial, which utilizes an innovative open label hybrid design with OS as the primary endpoint. Medicenna is pursuing a partnership strategy to continue the Phase 3 development."

The Phase 2b trial evaluated MDNA55, an interleukin-4 (IL-4)-guided toxin, as a treatment for rGBM, the most common and uniformly fatal form of brain cancer. Results presented in the peer-reviewed paper show that the median OS of radiographically evaluable patients in the trial irrespective of dose or IL4R expression was 11.8 months, which is longer than what would be expected from the approved drugs carmustine (OS of 5.1 – 7.5 months)^{1,2}, lomustine (OS of 7.1 – 9.8 months)³⁻⁵, or temozolomide (OS of 5.4 – 9.9 months)^{3,6,7}. Notably, the data also show a potential link between patients experiencing radiographic progression and those exhibiting insufficient MDNA55 penetration into the tumor, suggesting that at least a portion of patients who did not respond well to MDNA55 may have benefited from higher drug concentrations.

Additional analyses from the publication show that both locally and centrally determined PFS using mRANO criteria strongly correlated with OS, suggesting that the mRANO criteria may be superior to the standard RANO and iRANO at predicting OS, particularly for immunotherapies. These analyses supplement previously presented findings observed in Medicenna's proposed patient population showing an 81% tumor control rate (26/32) based on mRANO and a median OS of 15.7 months, which represents a >100% improvement compared to an external control arm (median OS of 7.2 months). The proposed patient population included all MDNA55-treated trial participants with high IL4R expression and participants with low IL4R expression that received a high dose of MDNA55 treatment.

Medicenna is currently pursuing a partnership strategy to facilitate MDNA55's further development through the planned Phase 3 clinical trial. Following an End of Phase 2 meeting with the United States Food and Drug Administration (FDA), the agency agreed that Medicenna could conduct an open label hybrid Phase 3 trial that allows use of a substantial number of subjects (two-thirds) from a matched external control arm to support regulatory approval of MDNA55 for rGBM. The FDA also expressed their willingness to consider an interim analysis of the trial if certain criteria are met. Unlike conventional randomized control trials, the hybrid trial design will reduce the overall number of subjects needed in the study to achieve the primary endpoint as well as reduce the cost and timelines associated with completing the trial.

References

1. Brandes AA et al. *Neurology* 2004; 63: 1281–4.
2. Reithmeier T et al. *BMC Cancer* 2010; 10: 30.
3. Weller M et al. *Neuro Oncol* 2013; 15: 4–27.
4. Wick W et al. *J Clin Oncol* 2010;28: 1168–74.
5. Batchelor TT et al. *J Clin Oncol* 2013; 31: 3212–8.
6. Balmaceda C et al. *Cancer* 2008;112: 1139–46.
7. Wick A et al. *J Clin Oncol* 2007;25:3357–61.

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 for the treatment of a broad range of cancers. Medicenna's long-acting IL-2 Superkine asset, MDNA11, is a next-generation IL-2 with superior CD122 binding without CD25 affinity and therefore preferentially stimulates cancer killing effector T cells and NK cells when compared to competing IL-2 programs. Medicenna's early-stage program on **Bifunctional SuperKine ImmunoTherapies** (BiSKITs™) is designed to further enhance the ability of Superkines to treat immunologically "cold" tumors. Medicenna's lead IL4 Empowered Superkine, MDNA55, has completed a Phase 2b clinical trial for rGBM, the most common and uniformly fatal form of brain cancer. MDNA55 has been studied in five clinical trials involving 132 subjects, including 112 adults with rGBM. MDNA55 has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

Forward-Looking Statement

This news release contains forward-looking statements under applicable securities laws and relate to the future operations of the Company and other statements that are not historical facts including statements related to a potential partnership for MDNA55. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects", "believes" and similar expressions. All statements other than statements of historical fact, included in this release, including the future plans and objectives of the Company, are forward-looking statements that involve 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 annual information form of the Company dated May 14, 2020 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 at the time of preparation, 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 of this news release and the Company will update or revise publicly any of the included forward-looking statements only as expressly required by Canadian and United States securities law.

Further Information

For further information about the Company please contact:

Elizabeth Williams, Chief Financial Officer, 416-648-5555, ewilliams@medicenna.com

Investor Contact

For more investor information, please contact:

Dan Ferry, Managing Director, LifeSci Advisors, 617-430-7576, daniel@lifesciadvisors.com



Source: Medicenna Therapeutics Corp.