



Medicenna Presents Preliminary Top-Line Clinical Results from their Phase 2b Trial of MDNA55 in Recurrent Glioblastoma

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TORONTO and HOUSTON, June 18, 2019 /CNW/ - Medicenna Therapeutics Corp. ("**Medicenna**" or "**the Company**") (TSX: MDNA, OTCQB: MDNAF), a clinical stage immunotherapy company developing first-in-class Superkines and Empowered Cytokines, will present today preliminary top-line clinical results from their Phase 2b trial of MDNA55, an IL4-guided toxin, in patients with recurrent Glioblastoma (rGBM), the most common and uniformly fatal form of brain cancer, at the Inaugural Immuno-Oncology Pharma Congress held from June 18-20, 2019 during World Pharma Week in Boston, MA.

The presentation by Dr. Fahar Merchant, Chairman, President & CEO of Medicenna, will focus on safety and preliminary efficacy results from the Phase 2b clinical trial MDNA55-05, which recently completed its enrollment (N=46).

"The preliminary top-line clinical results of the Phase 2b trial of MDNA55 are very promising when compared to approved therapies for rGBM especially in patients exhibiting high levels of IL4R expression, a biomarker for more aggressive forms of brain cancer," said Dr. Fahar Merchant. "While treatment options for patients with rGBM are very limited, MDNA55 has shown early evidence of substantial clinical benefit as well as improved survival for patients. We believe these results are evidence of the opportunity for MDNA55 to become a leading treatment option for a sizeable patient population with this devastating disease."

Highlights from the presentation included:

Disease control rate of up to 83% overall achieved

To account for initial local inflammation (called pseudo-progression) that can occur up to six months after treatment with MDNA55 in some subjects (and which can mask underlying tumor response), assessment of response from the nadir (largest tumor size) was also conducted.

This demonstrated 35 of 42 subjects with tumor shrinkage or stabilization following MDNA55 treatment (disease control rate of 83%). Use of advanced imaging techniques (such as perfusion and diffusion MRI) was able to show underlying tissue response amidst inflammation and edema in some subjects.

Strong safety and promising survival results

Safety data from the Phase 2b clinical trial show a similar safety profile to previous MDNA55 trials, with no systemic toxicities, no clinically significant laboratory abnormalities and no drug-related deaths.

Current median Overall Survival (mOS) in subjects treated with low doses of MDNA55 (median 63µg; n=21) is 11.8 months. When stratified by IL4 receptor (IL4R) expression status, a biomarker for more aggressive GBM, IL4R+ve subjects (mOS 15.2 months; n=8) showed a survival advantage of seven months compared to IL4R-ve subjects (mOS 8.1 months; n=10).

The clinical trial also showed that there may be an association between pseudo-progression and longer survival. Subjects showing disease stabilization or better from nadir (indicating possible pseudo-progression) were seen to live longer than those with progressive disease (mOS of 13.7 months versus 8.5 months, respectively). These results are consistent with earlier reports suggesting that occurrence of initial pseudoprogression and immunogenic cell death following treatment with MDNA55 is associated with improved clinical prognosis and survival (*Leshem and Pastan, 2019: Toxins, 11, p20*).

"Glioblastoma is a uniformly fatal disease where virtually all tumors will recur, and where the Blood Brain Barrier (BBB) blocks transport of therapies to the tumor," says Dr. John H. Sampson, MD, PhD, Chair of Neurosurgery at Duke University. "New drug delivery methods, like those undertaken with MDNA55, are needed to change the treatment paradigm and potentially improve patient outcomes."

"This trial is advancing neurosurgical methods in a number of very important ways, including more precise drug delivery to the brain, potential use of IL4R expression as a biomarker, and optimal use of advanced imaging techniques to support clinical decision making," states Dr. Martin Bexon, Head of Clinical Development at Medicenna. "These findings should be of great benefit both to those impacted by rGBM, but to the broader neurosurgical community as a whole."

Key Opinion Leader Call

Medicenna will host a Key Opinion Leader call and webcast for the investment community today at 1 PM EDT

To access the conference audio:

Local dial in: 416-764-8609

North American Toll Free: 1-888-390-0605

Conference ID No.: 65571448

To access the webcast and slide presentation: <https://event.on24.com/wcc/r/2026770/60D3AF6E95425955DD3DC147B6FC70BB>

Following the event, the archived webcast and Medicenna presentation will be available on the Company's website at www.medicenna.com. The webcast will be archived for 30 days after the event.

About the MDNA55-05 Clinical Trial

MDNA55-05 is a Phase 2b study of the safety and efficacy of MDNA55, an IL4R-directed toxin, in patients with *de novo* GBM at first or second relapse

where the tumor is not amenable to surgical resection. In the study, investigators administer MDNA55 once directly into the brain tumor using a technique known as Convection Enhanced Delivery (CED). CED allows precision delivery of MDNA55 into the tumor and the surrounding healthy brain containing infiltrative tumor cells, while avoiding systemic exposure.

The primary endpoint of the study is median Overall Survival (mOS) comparing a null survival rate of 8.0 months (based on historical control) with an alternative pursue rate of 11.5 months (1-sided alpha = 0.10 and 80% power for 46 ITT subjects). The secondary endpoint is objective response rate (ORR) assessed by the modified Response Assessment in Neuro-Oncology (mRANO)-based criteria incorporating advanced imaging modalities according to a null response rate of 6% with alternative pursue rate of 18% (1-sided alpha = 0.10 and 80% power for at least 35 subjects evaluable for response).

About Medicenna Therapeutics Corp.

Medicenna is a clinical stage immunotherapy company focused on oncology and the development and commercialization of novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first in class Empowered Cytokines™ (ECs) for the treatment of a broad range of cancers. Supported by a US\$14.1M non-dilutive grant from CPRIT (Cancer Prevention and Research Institute of Texas), Medicenna's lead IL4-EC, MDNA55, has completed enrolling patients in a Phase 2b clinical trial for rGBM, the most common and uniformly fatal form of brain cancer, at top-ranked brain cancer centres in the US. MDNA55 has been studied in five clinical trials involving 132 patients, including 112 adults with rGBM. MDNA55 has demonstrated compelling efficacy and has obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA respectively. For more information, please visit www.medicenna.com.

This news release contains forward-looking statements relating to the future operations of the Company and other statements that are not historical facts. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expects" and similar expressions. All statements other than statements of historical fact, included in this release, including, without limitation, statements related to the recently completed Phase 2b clinical trial of MDNA55 for the treatment of rGBM including, without limitation, the use of the IL4R as a biomarker to treat rGBM, use of novel imaging modalities for measuring tumor response, the acceptance of primary and secondary endpoints by regulatory agencies, the opportunity for MDNA55 to become a leading treatment option in a sizeable market and that MDNA55 offers promise for patients with aggressive forms of GBM and 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 June 26, 2018 and in other filings made by the Company with the applicable securities regulators from time to time.

The reader is cautioned that assumptions used in the preparation of any forward-looking information (including, without limitation, the ability of the Company to fully replicate these interim data results) 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 securities law.

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For further information: Fahar Merchant, President and Chief Executive Officer, 604-671-6673, fmerchant@medicenna.com; Elizabeth Williams, Chief Financial Officer, 416-648-5555, ewilliams@medicenna.com