Medicenna Presents Promising Update from its MDNA55 Clinical Trial in Recurrent Glioblastoma at the Targeting Innate Immunity Congress

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TORONTO and HOUSTON, Sept 25, 2019 /CNW/ - Medicenna Therapeutics Corp. ("**Medicenna**" or "the **Company**") (TSX: MDNA, OTCQB: MDNAF), a clinical stage immuno-oncology company developing first-in-class Superkines and Empowered Cytokines, today presented updated clinical results from its Phase 2b clinical 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 Targeting Innate Immunity Congress held from September 23-25, 2019 in Cambridge, MA.

The presentation by Dr. Fahar Merchant, President & CEO of Medicenna, focused on updated efficacy results from the Phase 2b clinical trial MDNA55-05 in rGBM patients using the interleukin 4 receptor (IL4R) as an immunotherapy target, as it is overexpressed in glioblastoma as well as in cells that make up the brain tumor microenvironment (TME).

"The data continues to show very promising results for MDNA55 when compared to approved therapies for rGBM. These new findings are consistent with previous results showing that patients suffering from rGBM, particularly those with the IL4R biomarker an indicator of a more aggressive form of rGBM, are surviving substantially longer with just one treatment," states Dr. Fahar Merchant. "This is very exciting for both Medicenna and the broader health community, as this not only offers considerable benefit to patients with this devastating disease, but also offers hope for patients with at least 20 other cancer indications where the tumor and associated tumor microenvironment over-expresses the IL4R."

These data imply that targeting the TME, particularly in GBM, is critical where almost half of the tumor mass consists of non-cancerous cells that make up the TME - a cancer swamp that hides the tumor from the immune system. The TME is emerging as one of the key reasons why glioblastoma is extremely aggressive, and continues to be one of the most difficult cancers to treat. Since MDNA55 can simultaneously purge both the tumor and the TME by targeting the IL4R, the results to date continue to show that MDNA55 is likely to emerge as a new treatment modality for this deadly disease.

"We're beginning to truly understand and appreciate the TME and the many layers of immunosuppression that evolve to protect and prevent an immune attack on the tumor," adds Dr. Merchant. "This means it is necessary to find a sustained way to break down the tumor's protective walls, as well as attack the tumor itself. The multi-pronged approach utilized by MDNA55 allows us to do just that."

Highlights from the presentation are summarized below:

- Irrespective of IL4R status, median overall survival (mOS) in subjects treated at low doses of MDNA55 (n=21) is 11.8 months; this is sustained when high dose subjects with mature survival data are added (n=33 total; mOS 11.9 months). However in the first 12 of 25 patients receiving the high dose, mOS is 16.7 months. This substantially exceeds landmark mOS reported for approved drugs for rGBM (mOS is 8-9 months for Avastin and Lomustine).[1-3]

- Following treatment with MDNA55 at low doses (median 63µg; n=21), mOS of subjects with high IL4 receptor expression ($IL4R^{High}$; n=12), a biomarker for aggressive disease, is 13.7 months compared to 8.1 months in subjects expressing no/low IL4R ($IL4R^{Low}$; n=8).

- When updated to include survival data from subjects treated at higher doses (median 180µg; n=12), MDNA55 continues to show promising survival outcomes in subjects with high IL4R expression: mOS in the $IL4R^{High}$ group (n=19) is 15.2 months as compared to 8.5 months in the $IL4R^{Low}$ group (n=11).

- In the 33 subjects, irrespective of IL4R expression, subjects showing tumor shrinkage or stabilization from nadir (tumor control rate of 81%; 25 of 31 evaluable subjects) were seen to live longer than those with progressive disease (mOS of 16.1 months versus 8.3 months, respectively). These results are consistent with earlier reports suggesting that occurrence of immunogenic cell death following treatment with MDNA55 is associated with improved clinical prognosis and survival.[4]

- Furthermore, safety data in the 12 additional subjects treated at higher doses of MDNA55 (median total dose 180µg) show a similar safety profile to previous MDNA55 trials with no systemic toxicities or drug related deaths.

Results for the majority of remaining patients participating in the Phase 2b clinical trial MDNA55-05 will be released before the end of 2019 followed by an End of Phase 2 meeting with the US FDA in Q1 2020.

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 enrolled Phase 2b clinical trial of MDNA55 for the treatment of rGBM including that the new data is very exciting for the broader health community, that MDNA55 offers considerable benefit to patients with rGBM but also offers hope for patients with at least 20 other cancer indications where the tumor and associated tumor microenvironment over-expresses the IL4R, that MDNA55 can simultaneously purge both the tumor and the TME by targeting the IL4R, that MDNA55 is likely to emerge as a new treatment modality for rGBM 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 24, 2019 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 and that study results could change over time as the study is continuing to follow up all patients and new data are continually being received which could materially change study results. 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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