



Medicenna Presents Promising Clinical Data from Phase 2b Recurrent Glioblastoma Trial of MDNA55

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TORONTO and HOUSTON, TX, Feb. 7, 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, reported interim data from its on-going Phase 2b trial of MDNA55 for the treatment of recurrent glioblastoma ("rGBM"). MDNA55 is a fusion protein designed to target the Type II interleukin-4 receptor (consisting of the IL4R α and IL13R α 1), a biomarker that is over-expressed in a majority of GBM patients but not in healthy brain. GBM patients with a positive Type 2 IL4R profile typically have a worse prognosis than the overall glioblastoma population, including poor long term survival. Results being presented today demonstrate promising signs of clinical benefit, particularly in recurrent patients with an aggressive form of GBM.

New clinical study results will be delivered today in a podium presentation titled, "The IL4 Receptor as a Biomarker and Immunotherapeutic Target for Glioblastoma: Preliminary Evidence with MDNA55, a Locally Administered IL-4 Guided Toxin" by John H. Sampson, MD, PhD, Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University in Durham, NC, during the 5th Annual Immuno-Oncology 360 Conference being held in New York, NY.

"MDNA55 provides impressive prolonged survival, especially in IL4R positive tumors, a marker highly expressed on brain cancers and the tumor microenvironment and known to be associated with aggressive disease," states Dr. Sampson. "Seeing evidence of clinical benefit in trial participants treated thus far with low doses of MDNA55 offers promise for patients with rGBM given the overall bleak prognosis and response to current therapy for this population."

A summary of the main results from the study so far are as follows:

- Following treatment with MDNA55 at the low dose, the IL4R positive group showed a remarkable increase in median overall survival ("mOS") of 15.2 months when compared to 8.5 months in the IL4R negative group. Survival rates at 6, 9, and 12 months were 100%, 67% and 55% versus 73%, 40%, and 30%, in the IL4R positive and negative groups, respectively.
- Irrespective of IL4R expression, mOS was 11.8 months in all patients following a single treatment with MDNA55 at the low dose with an overall survival rate of 89% at 6 months, 59% at 9 months and 46% at 12 months, substantially exceeding landmark mOS and survival rates reported for approved drugs for rGBM (mOS is 8 months for Avastin and Lomustine and survival rates at 6, 9 and 12 months are 62%, 38%, 26% and 65%, 43%, 30%, respectively).¹
- In the above participants, patients with IL4R positive tumors showed a faster time to relapse (10.3 months) following initial diagnosis of GBM when compared to patients with low to no expression of IL4R (16.7 months) supporting published research showing that the Type 2 IL4R is a key biomarker for more aggressive forms of GBM.^{2,3}

"These preliminary data showing longer median survival in MDNA55-treated subjects with positive IL4R expression are highly encouraging and could help determine which subjects will receive optimal therapeutic benefit from MDNA55 treatment," states Dr. Martin Bexon, Head of Clinical Development at Medicenna. "As the second half of our trial continues to enroll at higher doses of MDNA55, we expect to see more data supporting IL4R as an important biomarker and immunotherapeutic target for rGBM and to improve the benefit-risk profile for subjects treated with MDNA55." The safety and tolerability of MDNA55 has generally remained within the profile established in previous studies.

"The interim data presented today are extremely encouraging and continue to add to an impressive and consistent data set for MDNA55 across multiple studies," said Fahar Merchant, Ph.D, President and CEO of Medicenna. "We believe these interim data are clinically important to patients with rGBM and, if the final data remain consistent, it would be practice-changing for neurosurgeons treating glioblastoma and offer new hope to patients and their families."

Enrolment in the second half of the study incorporating a higher dose of MDNA55 is expected to be completed in the next couple of months with top-line results expected in mid-2019.

About the Interleukin-4 receptor (IL4R)

The IL4R target for MDNA55 is an ideal but under-exploited drug target for central nervous system ("CNS") tumors, including glioblastoma ("GBM"). The majority of cancer biopsy samples from adult and pediatric CNS tumors, including recurrent GBM, over-express the IL4R while there is little or no IL4R expression in normal adult and pediatric brain tissue.⁴ Expression of IL4R correlates with increased tumorigenicity in mouse models and poor long term survival in clinical studies of patients with GBM^{2,3}. In addition, the IL4R is known to be expressed by Myeloid Derived Suppressor Cells and Tumor Associated Macrophages, which are known to be key components of the immunosuppressive tumor micro-environment (TME), which hides the tumor from cancer killing immune cells^{5,6}.

About the MDNA55-05 Clinical Trial

MDNA55-05 is a 52 subject open-label study of MDNA55, an IL4R directed toxin, in patients with GBM at first or second relapse. In the study, investigators administer MDNA55 only once directly into the brain tumor using a technique known as Convection Enhanced Delivery (CED). CED allows precision delivery of MDNA55 directly into the tumor tissue and the surrounding healthy brain containing infiltrative tumor cells, while avoiding exposure to the rest of the body. Retrospective analysis of GBM tissue obtained at first diagnosis is performed by immunohistochemistry for IL-4R α expression. Biopsy samples are categorized based on IL4R α expression levels and compared against survival outcomes.

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 significant non-dilutive grant from CPRIT (Cancer Prevention and Research Institute of Texas), Medicenna's lead IL4-EC, MDNA55, is 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 completed three clinical trials in 72 patients, including 66 adults with rGBM, demonstrated compelling efficacy and obtained Fast-Track and Orphan Drug status from the FDA and FDA/EMA respectively. For more information, please visit www.medicenna.com.

References

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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 ongoing Phase 2b clinical trial of MDNA55 for the treatment of rGBM (including, without limitation, patient enrolment and top line data reporting timelines, that MDNA55 could be practice changing and offer new hope to patients) 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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