Medicenna Provides MDNA55 rGBM Clinical Program Update Following Positive End of Phase 2 Meeting with the U.S. Food and Drug Administration (FDA)

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- After consultation with the FDA, the company can conduct a hybrid registration trial that allows for the use of matched external controls for two-thirds of control arm -

- The design sets a new precedent for GBM clinical trials, allowing robust OS analysis and significantly reduces the number of trial participants randomized to standard of care therapies -

- Reduced enrollment requirements in the control arm can substantially lower trial costs and expedite timelines for regulatory approval in rGBM -

TORONTO and HOUSTON, Oct. 15, 2020 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. (“Medicenna” or the “Company”) (NASDAQ: MDNA, TSX: MDNA), a clinical stage immuno-oncology company, today provided an update on the clinical development of MDNA55, an interleukin-4 (IL-4)-guided toxin targeting recurrent glioblastoma (rGBM), the most common and uniformly fatal form of brain cancer. Following a recent End of Phase 2 meeting with the FDA regarding the regulatory and commercial pathway for MDNA55, the Company has been advised to proceed with an innovative open-label hybrid control design for a Phase 3 registration trial of MDNA55 in rGBM patients with no mutation in 1DH1/1DH2 genes. The FDA has also expressed a willingness to possibly consider an interim analysis of the trial if certain criteria are met.

“We thank the FDA for their constructive and pioneering recommendations on our proposed trial design and are excited to proceed with this hybrid study approach,” said Dr. Fahar Merchant, President and CEO of Medicenna. “We believe that this approach may provide us with the opportunity to deliver high integrity, robust overall survival data for MDNA55 in rGBM while minimizing the number of patients randomized to standard of care in this difficult to treat population. Conventional randomized control trials have been routinely required for registrational studies for new oncology therapeutics, and to our knowledge this groundbreaking design may be the first in oncology to include a substantial external control arm in a trial designed to support regulatory approval. This is expected to reduce overall enrollment requirements, expedite the time to study completion and invigorate our efforts to execute on a partnership strategy for future development. We look forward to providing additional updates on our clinical timelines and partnership discussions as our plans progress.”

Dr. John Sampson, MD, PhD, a Robert H. and Gloria Wilkins Distinguished Professor and Chair of Neurosurgery at Duke University School of Medicine added, “Patients with rGBM suffer from one of humankind's most lethal diseases. No therapy extends survival significantly. Data from clinical trials evaluating MDNA55 in rGBM demonstrate an extraordinary advance in drug delivery and therapy and suggest that this drug may extend survival in these patients.”

Dr. David A. Reardon, MD, Clinical Director at the Center for Neuro-Oncology at Dana-Farber Cancer Institute and a Professor at Harvard Medical School who participated in the FDA meeting as part of the Medicenna team commented, “The FDA conveyed a strong level of support for Medicenna’s pivotal trial design for patients with rGBM based on the promising efficacy and safety achieved in the trials of MDNA55 to date and their appreciation of the critical need to efficiently develop effective treatments for patients with these devastating tumors. I am very grateful and encouraged by FDA's response, which is potentially groundbreaking particularly for novel therapeutics such as MDNA55 which are delivered directly into the tumor, and could set a new paradigm for drug development for this poorly served population.”

The proposed Phase 3 clinical trial design includes a concurrent 3:1 randomized cohort (3 subjects receiving MDNA55 for every 1 subject receiving standard of care (SOC)) and an additional matched external control arm. The primary endpoint of overall survival (OS) will be determined by a 1:1 analysis of the MDNA55 arm versus the pooled control arm, which will consist of external controls and subjects randomized to SOC. This hybrid trial design will reduce the overall number of subjects needed to enroll in the study to achieve the primary endpoint, and notably reduce the number of subjects that would be randomized to SOC treatment under a conventional 1:1 randomization.

About External Control Arms (Also known as Synthetic Control Arms)
Among the many issues faced by companies that conduct clinical trials, at least two of them — the large number of participants needed for trials and participants’ fears they will be end up getting a potentially inferior SOC — can be eased by using an innovative approach to collecting comparison data called external control arms (ECAs). Instead of collecting data from subjects recruited for a trial who have been assigned to the SOC arm, ECAs model those comparators using contemporary but historical clinical trial data. By reducing the need to enroll control subjects, an ECA can increase efficiency, reduce delays, lower trial costs, and speed lifesaving therapies to market. Medicenna has earlier demonstrated promising results for MDNA55 in a Phase 2b clinical trial when compared to retrospective and a well-balanced ECA.

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 Cytokines™ (ECs) for the treatment of a broad range of cancers. Medicenna's long-acting IL2 Superkine asset, MDNA11, is a next-generation IL-2 with superior CD122 binding without CD25 affinity and therefore preferentially stimulating cancer killing effector T cells and NK cells when compared to competing IL-2 programs. It is anticipated that MDNA11 will be ready for the clinic in 2021. Medicenna's lead IL4-EC, 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. For more information, please visit www.medicenna.com.

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. 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, without limitation, statements related to the willingness of the FDA to possibly consider an interim analysis of the Company's clinical trial; the impacts of the Phase 3 trial of MDNA55, including its design, reduced number of participants, costs, timeline, survival data and partnership opportunities for MDNA 55, the anticipated timing as to when MDNA11 will be ready for the clinic 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 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 and that study results could change over time as the study is continuing to follow up all subjects 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 and United States securities law.

Further Information

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