

Medicenna Updates On-Going Phase 2b Clinical Trial Protocol for Recurrent Glioblastoma

Safety Review Committee Reports Encouraging Drug Distribution and Tolerability

TORONTO, Ontario and HOUSTON, TX, Sept. 28, 2017 /CNW/ - Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA), a clinical stage immuno-oncology company, announced today that based on encouraging drug distribution and safety data observed in the on-going Phase 2b clinical trial of MDNA55 for the treatment of patients with recurrent glioblastoma (rGBM), the Company has commenced implementation of an updated protocol following its submission to the U.S. Food and Drug Administration (FDA) and approval by the respective Institutional Review Boards (IRBs). The amended protocol incorporates an enhanced drug delivery procedure which will be used for the treatment of the remaining patients. The updated protocol includes higher doses and volumes of MDNA55 as well as an increase in the total expected study size – from 43 patients under the original protocol to 52 total planned patients now expected to enroll. Patient enrolment and treatment continues at multiple sites.

“Based on data that will be presented at the 2017 CNS conference in Boston (7-11 October 2017), we are pleased with the encouraging drug distribution, safety and tolerability of MDNA55 in our ongoing Phase 2b rGBM study,” stated Dr. Fahar Merchant, Chairman, President and CEO of Medicenna. “These data indicate a wider therapeutic window than originally anticipated and we can leverage this new, preliminary safety understanding for the remainder of the study. The decision to amend the study protocol by increasing the dosage and volume of MDNA55 has the potential to address the needs of an expanded patient population, including patients with larger or multi-focal tumors.”

This protocol amendment was based on a planned safety analysis following a unanimous recommendation from MDNA55’s Safety Review Committee (SRC) after enrollment of the first six patients. Based on the exceptional safety profile, the concentration of MDNA55 will be doubled to 3.0 µg/mL and the volume administered will be maximized to a fixed volume of 60mL to ensure complete tumor coverage along with the surrounding margin of the tumor, irrespective of tumor size. The protocol amendment was discussed with all current investigators and input was received from thought leaders in the area of glioblastoma and Convection-Enhanced Delivery (CED) in order to optimize patient benefit following a single treatment with MDNA55. The maximum dose of 180µg is well within the established safety profile based on earlier studies.

"By increasing the infusion volume, we are seeking to ensure optimal coverage of the tumor and the surrounding penumbra. Early results from the interim safety analysis indicates that the current dose of MDNA55 has been well tolerated in the initial cohort of patients." Said John H. Sampson, MD, PhD, MBA, MHSc, Chair of the Department of Neurosurgery, Duke University School of Medicine.



In the amendment of the protocol, the primary endpoint of the study remains the same: To determine the objective response rate (ORR) per a modified RANO (Response Assessment in Neuro-Oncology) criteria following a single intra- and peri-tumoral infusion of MDNA55 using CED.

A single-stage binomial design test for a null ORR of 6% versus an alternative (“pursue”) ORR of 18%, at alpha = 0.1, 1-sided, will have 80% power with 36 evaluable subjects. The sample size of the study has been increased from 43 to 52 patients including 35 patients under the amended protocol. The Company expects enrollment to be completed by early 2018, with interim top-line results expected during the first half of 2018.

Details regarding the protocol amendment for MDNA55-05 will be available on ClinicalTrials.gov.

About Medicenna Therapeutics Corp.

Medicenna is a clinical stage immuno-oncology company developing novel highly selective versions of IL-2, IL-4 and IL-13 Superkines™ and first in class Empowered Cytokines™ (ECs). Its wholly owned subsidiary, Houston-based Medicenna BioPharma, is specifically targeting the Interleukin-4 Receptor (IL4R), which is over-expressed by at least 20 different types of cancer affecting more than one million new cancer patients every year. Medicenna's lead IL4-EC, MDNA55 is enrolling patients in a Phase 2b clinical trial for rGB at leading brain cancer centres in the US. MDNA55 has completed 3 clinical trials in 72 patients, including 66 adults with rGB, demonstrated compelling efficacy and obtained Fast-Track and Orphan Drug status from USFDA. Unlike most other cancer therapies, Medicenna's IL4-ECs have the potential to purge both the tumor and the immunosuppressive tumor microenvironment, offering a unique treatment paradigm for a large majority of cancer patients.

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 regarding future plans and objectives of the Company, the that optimal tumor coverage will be achieved with the protocol amendment described, the ongoing status of the Phase 2b clinical trial of MDNA55 for the treatment of recurrent glioblastoma and others 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 15, 2017 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 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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