

Medicenna Reports Compelling Results from Recurrent Glioblastoma Trial When Compared to an Eligibility-Matched Control Arm

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TORONTO and HOUSTON, Jan 13, 2020 /CNW/ - Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (TSX: MDNA, OTCQB: MDNAF), a clinical stage immuno-oncology company, today announced that it has completed a retrospective study on subjects with recurrent Glioblastoma (rGBM) who matched eligibility requirements of subjects enrolled in the MDNA55-05 clinical trial.

This study was conducted to compare the survival of subjects treated with MDNA55, an interleukin-4 receptor (IL4R) targeted therapy, in the Phase 2b rGBM clinical trial versus matched patients (Synthetic Control Arm or SCA) recently treated using other approved therapies. The SCA comprised of 81 rGBM patients receiving approved therapies including Avastin, Lomustine and Temozolomide with similar baseline features as patients treated in the MDNA55 trial such as age, tumor size, ineligibility for surgery, interleukin-4 receptor (IL4R) expression and other parameters known to affect survival.

"This first true apples-to-apples comparison of the data shows that a single treatment with MDNA55 has the ability to more than double the survival rates in patients with the most aggressive form of rGBM," said Dr. Fahar Merchant, President and CEO of Medicenna Therapeutics. "We hope that these results are a watershed moment in the battle against this aggressive and fatal disease, and are particularly meaningful considering that an even modest improvement in survival of 25% has not been demonstrated by any of the approved treatments of rGBM in more than two decades."

Key data from the study are summarized below and have been computed from the date of relapse rather than from the date of treatment in results previously reported by the Company:

- When comparing IL4R High groups across the two populations, a 150% survival advantage is seen in patients who
 received MDNA55.
 - IL4R High subjects treated with MDNA55 (n=21) had a median Overall Survival (mOS) of 15.8 months versus 6.2 months in the SCA (n=17), a survival advantage of an impressive 9.6 months.
 - The 12 month Overall Survival (OS-12) was 62% in the MDNA55 arm versus 24% in the SCA.
- Regardless of IL4R status, subjects treated with MDNA55 (n=44 subjects comprising the complete per protocol analysis population) demonstrated 112% increase in OS-12 than subjects in the SCA (n=81).
 - o OS-12 for the MDNA55 arm was 53% versus 25% in the SCA.
 - o mOS in the MDNA55 arm was 12.4 versus 7.7 months in the SCA.

"When compared to real-world data, our results show a considerable increase in survival benefit particularly in patients with high expression of the IL4R who are known to have very poor prognosis, " adds Dr. Merchant. "We are thrilled with the results from this new study which further solidifies our belief that MDNA55 could be breakthrough therapy for patients with rGBM and other types of brain cancer.

The results of this analysis will be included in the End of Phase 2 meeting package which will be submitted to the USFDA in the first quarter of 2020.

The purpose of the new study was to obtain more reliable survival results from a matched Synthetic Control Arm (SCA). As the patient population in the MDNA55 clinical trial consisted of rGBM tumors with the most aggressive disease and worse potential outcomes which are not generally the subject of published literature, results from the SCA more accurately reflects the patient population that would have been enrolled in a control arm setting. Furthermore, none of the published studies provide a sub-analysis based on IL4R status. The SCA study allowed Medicenna to use the same methods for IL4R analysis as was used in the MDNA55 clinical trial.

About the MDNA55 Synthetic Control Arm

Subjects in the Synthetic Control Arm (SCA) were identified from patient registries at neurosurgery tissue banks under IRB-approved protocols. Subjects were selected based on key eligibility criteria of the MDNA55 trial: male or female subjects \geq 18 years of age with *de novo* WHO grade IV GBM at 1st or 2nd relapse following standard first-line treatment(s) with surgery and radio-chemotherapy; subjects must have tumor size no smaller than 1cm x 1cm and no larger than 4cm x 4cm, Karnofsky Performance Status (KPS) of \geq 70, must not be candidates for surgery/resection at relapse, and must have no known mutation in either the isocitrate dehydrogenase 1 (IDH1) and/or the IDH2 gene.

Demographic and clinical information were extracted from clinical records. Archived GBM tumor tissue sample from initial diagnosis was collected where available and analyzed for IL4R expression using the same validated immunohistochemistry (IHC) assay that was used in the MDNA55-05 trial. Survival time was computed from date of relapse to the date of death. Median overall survival was calculated using the Kaplan-Meier method. The log-rank test was used for between-group comparisons. In order to avoid potential bias, Medicenna remained blinded to the survival data throughout the project. The blind on survival analysis was lifted only after the IL4R results were reported in order to avoid selection bias.

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, that the SCA is a true apples-to-apples comparison, that the disclosed results are a watershed moment in the battle against an aggressive and fatal disease, that the results from this new study further solidifies that MDNA55 could be breakthrough therapy for patients with rGBM and other types of brain cancer, that the End of Phase 2 meeting package will be submitted to the USFDA in the first quarter of 2020 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. 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 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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