Medicenna Updates Efficacy Results from Phase 2b Recurrent GBM Trial at ASCO 2020

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TORONTO and HOUSTON, May 29, 2020 /CNW/ - Medicenna Therapeutics Corp. ("Medicenna" or "the Company") (TSX: MDNA, OTCQB: MDNAF), a clinical stage immuno-oncology company, today announced virtual presentations of data from its completed Phase 2b trial of MDNA55, an IL4-guided toxin, in patients with recurrent Glioblastoma (rGBM), at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting.

The oral poster discussion led by Dr. Ian F. Parney, MD, PhD (Mayo Clinic) and a presentation by Dr. John Sampson, MD, PhD (Robert H. and Gloria Wilkins Distinguished Professor of Surgery, Duke University School of Medicine), focused on additional data demonstrating clinical superiority of MDNA55 in patients with rGBM. The study enrolled rGBM patients that had aggressive tumors (*de novo* GBM, IDH wild-type, not-resectable at recurrence) with limited treatment options and poor survival outcomes [median overall survival ("mOS") of 6-9 months, median progression free survival ("mPFS") of < 2months and progression free survival ("PFS") at twelve months ("PFS-12") of 0%].

"Currently there are no approved therapies for rGBM that can extend survival by 50%, let alone by 70 - 100% as seen with MDNA55 after just one treatment," said Dr. John Sampson. "The data presented here reinforces our conviction that MDNA55 is an important player in glioblastoma and is a promising treatment option for this devastating disease."

"We've long believed that MDNA55 has the potential to present as a superior treatment option for improved survival and tumor control in patients with recurrent glioblastoma," says Dr. Fahar Merchant, President and Chief Executive Officer, Medicenna Therapeutics. "Further refinement of new and previously reported data using a rigorous propensity-matching methodology to remove any potential selection bias further bolsters this belief. For a treatment area that has seen limited innovation for more than 20 years, the MDNA55 phase 2 clinical trial data demonstrates strong evidence that MDNA55 could change the treatment paradigm for rGBM." The Company plans to submit an end of Phase 2 meeting package for MDNA55 to the FDA in Q2 2020.

Highlights from the ASCO presentation included:

- Comparison of MDNA55 with an eligibility-matched Synthetic Control Arm ("SCA") demonstrated an improvement in mOS of 61%. When stratified by IL4R status, IL4R High subjects in the MDNA55 arm demonstrated improved mOS by 155% (**Table 1)**.

Table 1.

Eligibility-Matched Groups	**N**	**mOS**	**Improvement in mOS**	**Hazard Ratio (HR)**	**OS-12**
MDNA55 All-comers	44	12.4	61%	0.58	53%
SCA All-comers	81	7.7			25%
MDNA55 IL4R High	21	15.8	155%	0.54	62%
SCA IL4R High	17	6.2			24%

- Further refinement of the SCA using propensity-score weighting (Li *et al*), an unbiased approach to select patients that match the baseline characteristics of MDNA55 treated patients based on 11 key baseline prognostic factors, confirms these results (**Table 2**).

Table 2.

Propensity-Weighted Groups	**N**	**mOS**	**Improvement in mOS**	**HR**
MDNA55 All-comers	43	12.4	72%	0.63
SCA All-comers	40.8	7.2		

MDNA55 IL4R High	17	13.2	116%	0.52
SCA IL4R High	16.8	6.1		

- Irrespective of IL4R expression, subjects showed tumor control rate ("TCR") (tumor shrinkage or stabilization) of 76% based on modified RANO criteria; these subjects demonstrated mPFS of 4.6 months, PFS at six months ("PFS-6") of 40%, PFS-12 of 33%, mOS of 15.0 months and overall survival at twelve months ("OS-12") of 57%.

Additional updated results (not presented at ASCO) include the following:

- Patients with Low IL4R expression (H-Score ≤ 60) had a similar TCR as patients with High IL4R expression (H-Score > 60); TCR of 75% vs. 76%, respectively. However, the majority of the IL4R Low patients (11 of 16) received high doses of MDNA55 (180 - 240 mg; median 180 mg) whereas only 8 of 21 IL4R High patients received the high dose of MDNA55.

- The IL4R Low group receiving high dose also showed improved survival (mOS Not Reached, OS-12 of 53%) when compared to the low dose group (mOS = 8 months, OS-12 = 13%).

- The Proposed Population (n=32), comprised of all IL4R High (irrespective of dose) as well as IL4R Low patients receiving the high dose, were shown to benefit the most from a single treatment of MDNA55. Median survival and OS-12 in this population was 15.8 months and 62% vs 7.0 months and 18%, respectively, when compared to the eligibility matched SCA. (**Table 3**).

Table 3.

Eligibility-Matched	**N**	**mOS**	**Improvement in mOS**	**HR**	**OS-12**
Proposed Population	32	15.8	126%	0.45	62%
SCA	40	7.0			18%
Propensity-Weighted					
Proposed Population	32	15.7	118%	0.52	NA
SCA	33.9	7.2			NA

- TCR in the Proposed Population was 81% based on radiologic assessment by mRANO criteria.

- These data indicate that MDNA55 has the potential to benefit all rGBM patients treated at the high dose (180 mg) irrespective of IL4R expression. The high dose has already shown an acceptable safety profile in this and earlier clinical trials (MTD = 240 mg).

The presentation and poster is available for on-demand viewing online at:
https://meetinglibrary.asco.org/record/185973/abstract

Reference:

Li F, Zaslavsky AM, Landrum MB. Propensity score weighting with multilevel data. Stat Med. 2013 Aug 30;32(19):3373-87.

About Medicenna Therapeutics Corp.

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 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 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. Medicenna's long-acting IL2 Superkine assets, MDNA19 and MDNA11, are best-in-class next-generation IL-2's in development 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 MDNA19 or MDNA11 will be ready for the clinic in 2021. 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", "believes" and similar expressions. All statements other than statements of historical fact, included in this release, including, without limitation, statements related to our conviction that MDNA55 is an important player in glioblastoma and is a promising treatment option for this devastating disease, that MDNA55 has the potential to present as a superior treatment option for improved survival and tumor control in patients with recurrent glioblastoma, the MDNA55 phase 2 clinical trial data demonstrates strong evidence that MDNA55 could change the treatment paradigm for rGBM, that the Company plans to submit an end of Phase 2 meeting package for MDNA55 to the FDA in Q2 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 May 14, 2020 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 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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