Medicenna Announces Initiation of Phase 2 Clinical Trial of MDNA55 for the Treatment of Recurrent Glioblastoma

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HOUSTON and VANCOUVER, Dec. 13, 2016 /CNW/ - Medicenna Biopharma Inc., a wholly owned subsidiary of Medicenna Therapeutics, Inc (the "Company" or "Medicenna"), developing targeted cancer immunotherapies based on its platform of Empowered Cytokines^{TM}, today announced the initiation of a Phase 2 clinical trial of its lead clinical candidate, MDNA55, for the treatment of recurrent glioblastoma (rGB), the most common and uniformly fatal form of brain cancer.

"Despite decades of effort, adult and pediatric glioblastoma patients still have extremely limited options to successfully treat this devastating form of brain cancer," said Dr. Fahar Merchant, Chairman and CEO of Medicenna BioPharma. "We are very pleased to have world class neuro-oncology centers participate in this clinical trial and look forward to advancing MDNA55 to meet the unmet needs of patients with this difficult to treat cancer."

MDNA55 is a targeted form of immunotherapy designed to purge tumor cells and adjacent immunosuppressive cells in the tumor microenvironment that over-express the interleukin-4 receptor (IL4R), which is common in a majority of patients with rGB. By directly eliminating tumor cells and boosting a therapeutic immune response in rGB patients, MDNA55 provides a two-pronged approach to treat brain cancer patients..

"We are excited to initiate this trial which uses both, a precise image guided drug delivery technique and a novel agent that, when combined, hold great promise for patients with this aggressive form of brain cancer," said Dr. Nicholas Butowski, MD, Professor of Neurosurgery at University of California, San Francisco. Dr. Butowski is a Co-Principal Investigator of this study with Dr. John Sampson, MD, Chairman of Neurosurgery at Duke University.

Study Design
The multi-center, single-arm, open-label, Phase 2 investigation of MDNA55 (ClinicalTrials.gov identifier: NCT02226965) will enroll approximately 43 adult patients with glioblastoma who have progressed or recurred following first line therapy. Patients will be administered MDNA55 by a single intra-tumoral infusion using convection enhanced delivery (CED), a minimally invasive technique used to by-pass the blood brain barrier. The use of precision image guided CED is anticipated to make the drug significantly available to the tumor and its microenvironment while dramatically reducing systemic side effects.

The primary endpoint is overall response rate (ORR), assessed by magnetic resonance imaging using the Revised Assessment in Neuro-Oncology (RANO) criteria. Secondary outcome measures include progression-free survival, overall survival, and exploratory predictors of outcome assessed by IL-4R expression in archived tumor biopsies.

The study will be conducted in approximately eight sites in the United States. Patient enrolment is expected to be completed before the end of 2017 with top-line results anticipated in the first half of 2018.

To learn more about the clinical trial visit https://clinicaltrials.gov/show/NCT02858895

About MDNA55
MDNA55 is a novel fusion protein designed to target the IL-4R which is upregulated in several cancers, most notably glioblastoma and other brain cancers, but not in healthy brain tissue. MDNA55 consists of an engineered IL-4 targeting domain linked to a potent cell-killing agent (a truncated version of Pseudomonas exotoxin). Akin to a "Molecular Trojan Horse", the toxin is released after internalization into IL-4R expressing tumor cells, resulting in targeted cell-killing. MDNA55 has received Fast Track Designation from the FDA and Orphan Drug Status from both the FDA and EMA. Earlier results from three Phase 1 and 2a clinical trials in 66 patients with glioblastoma showed potent anti-tumor effects without drug-related systemic toxicity in the majority of patients.

A summary of clinical data from earlier Phase 1 and 2 clinical trials can be found on Medicenna's website at http://www.medicenna.com/Our-Pipeline/Clinical-Development/default.aspx.

About Glioblastoma
Worldwide, there are an estimated 240,000 cases of brain and central nervous system cancers per year, of which glioblastoma (GB) is the most common and the most lethal. Of the approximately 18,000 patients diagnosed with GB every year in the US alone, 13,000 will die of the disease despite an aggressive treatment approach that includes surgery, radiation therapy and chemotherapy. As such, a significant unmet need exists for this form of brain cancer.

About Medicenna BioPharma
Medicenna BioPharma Inc., (a subsidiary of Medicenna Therapeutics Inc.) is a clinical-stage, immuno-oncology company developing first-in-class, targeted Interleukin-4 (IL-4) Empowered Cytokines^{TM} (IL4-ECs) for the treatment of cancers that over-express the IL-4 receptor (IL-4R). The Company is developing its lead candidate, MDNA55, initially for the treatment of recurrent glioblastoma (rGB) - the most common and aggressive form of brain cancer - and is conducting additional research to deploy its leading edge IL4-EC platform for the treatment of other solid tumors. The program is supported by a grant from the Cancer Prevention and Research Institute of Texas (CPRIT). For more information visit www.medicenna.com

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For further information: Company Contact: Fahar Merchant, President & Chief Executive Officer, Medicenna Therapeutics, Inc., 604-671-6673, fmerchant@medicenna.com; Investor Relations Contact: Michael Moore or Abby Garfunkel, Investor Relations, NATIONAL Equicom, 858-886-7813 / 403-218-2887, mmoore@national.ca / agarfunkel@national.ca