



Medicenna Announces Compelling Survival Benefit from Phase 2b Study of Bizaxofusp in Recurrent Glioblastoma at the 28th Annual Meeting of the Society for NeuroOncology

November 17, 2023

Single treatment of bizaxofusp doubled mOS (14.5 months vs. 7.2 months) irrespective of IL4R expression (high or low) compared to patients treated in the external control arm

Survival for bizaxofusp-treated patients increased 370% at Year 1 and increased more than 50% at Year 2

TORONTO and HOUSTON, Nov. 17, 2023 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA, OTC: MDNAF), a clinical-stage immunotherapy company focused on the development of Superkines, today announced that a poster presentation and an oral summary highlighting longer term follow up results from the Phase 2b clinical trial of bizaxofusp (formerly known as MDNA55), the Company's first-in-class IL-4R targeted therapy for the treatment of patients with recurrent glioblastoma (rGBM), will be presented by Dr. Steven Brem, M.D. (Medical Director, Centre for Precision Surgery, Abramson Cancer Center, Perelman School of Medicine, University of Pennsylvania) at the Society for Neuro-Oncology (SNO) 2023 Annual Meeting, taking place from November 15-19, 2023, in Vancouver, Canada.

"Bizaxofusp represents an exciting new approach by demonstrating a dose-dependent effect on the receptor of IL-4, an immuno-suppressive cytokine. Further, use of bizaxofusp as a single agent or in combination could "flip the switch" on glioblastoma to convert it from an immunologically "cold" (unresponsive) tumor to one that is responsive, using convection enhanced delivery to "take the fight to the tumor". The data offers new hope for patients with glioblastoma who have few treatment options at recurrence," said Dr. Steven Brem.

"We are very encouraged by the 100% increase in survival benefit in unresectable rGBM achieved from a single treatment with bizaxofusp, even after 22 months of additional follow-up, which reinforces the robustness of the initial primary analysis," said Fahar Merchant, Ph.D., President and Chief Executive Officer of Medicenna. "In conjunction with regulators, our pioneering efforts have secured us a precedent-setting Phase 3 trial design in rGBM using an external control arm and are actively pursuing partnerships to further advance the bizaxofusp registrational study. Following the publication of our Phase 2b results in the journal Neuro-Oncology® earlier this year, it is a great privilege to be able share these updated 4-year follow-up results with the medical and scientific communities at SNO 2023."

4 Year Follow-up Results from the Phase 2b Study

This multi-center, open-label, single-arm Phase 2b study, enrolled and treated 44 patients with rGBM following surgery or radiotherapy ± adjuvant therapy or other experimental therapies. A separate analysis collected rGBM data from 81 patients who had contemporaneously received treatment at major clinical centres using current standard of care, were used to establish a matched External Control Arm (ECA). The blinded survival data from the matched ECA (established by matching with the bizaxofusp-treated population based on 11 different prognostic factors using propensity scoring methods) were then used as a control arm versus survival data from the Phase 2b bizaxofusp trial.

The data demonstrated that a single treatment with bizaxofusp increased median overall survival (mOS) by 72% compared to the ECA (12.4 months vs. 7.2 months). Overall survival (OS) for bizaxofusp-treated patients increased 370% at Year 1 and increased more than 50% at Year 2. Importantly, bizaxofusp doubled mOS (14.5 months vs. 7.2 months) irrespective of IL4R expression (high or low) compared to ECA. No systemic or clinically significant laboratory abnormalities were reported. Treatment-related adverse events were primarily neurological or aggravation of pre-existing neurological deficits due to rGBM.

Details for the SNO 2023 Poster Presentation:

Title: Survival Outcomes in Recurrent Glioblastoma (rGBM) Patients Treated with a Single Intra-tumoral Administration of Bizaxofusp, an IL-4R-targeting Toxin, in a Phase IIb Trial

Presenter: Dr. Steven Brem, M.D., University of Pennsylvania

Abstract number: CTNI-52

Session: Clinical Trials: Non-immunologic

Presentation date and time: Friday, November 17, 2023; 7:30-9:30 p.m. PT

Oral presentation date and time: Friday, November 17, 2023; 7:30 p.m. PT

A copy of the poster and a related slide deck will be posted after the presentation to the "[Events and Presentations](#)" page of Medicenna's website.

About Bizaxofusp

Bizaxofusp (formerly known as MDNA55) is Medicenna's IL-4 Empowered Superkine that has been studied in 5 clinical trials in over 130 patients, including a Phase 2b trial in patients with recurrent glioblastoma (rGBM), the most common and uniformly fatal form of brain cancer. Results from the Phase 2b study, which were published in the journal Neuro-Oncology® (Sampson, et al. June 2023), demonstrated that bizaxofusp more than doubled the median survival in end-stage rGBM patients when compared to a well-matched external control arm. Medicenna has obtained agreement from the U.S. FDA on the study design for the registrational Phase 3 LIGHT™ (Localized Infusion for the treatment of recurrent Glioblastoma with High-dose bizaxofusp Therapy) trial and the Company is actively pursuing potential partnerships to conduct the LIGHT trial, and if approved, bizaxofusp's commercialization in key global markets. Bizaxofusp has been granted FastTrack and Orphan Drug status from the FDA and FDA/EMA, respectively.

About Glioblastoma

Glioblastoma multiforme (GBM) has an incidence of three per 100,000 adults per year in the U.S. and Europe, and accounts for 52 percent of all

primary brain [tumors](#). Glioblastoma is the most common and deadly brain tumor in adults. Despite technological advances in surgery and radio-chemotherapy, glioblastoma remains largely resistant to treatment. Given the limitation of all current therapeutics (surgery, chemotherapy and/or radiation), the development of novel approaches to treating glioblastoma remains a great unmet need.

About Medicenna

Medicenna is a clinical-stage immunotherapy company focused on developing novel, highly selective versions of IL-2, IL-4 and IL-13 Superkines and first in class class-empowered superkines. Medicenna's long-acting IL-2 Superkine, MDNA11, is a next-generation IL-2 with superior affinity toward CD122 (IL-2 receptor beta) and no CD25 (IL-2 receptor alpha) binding, thereby preferentially stimulating cancer-killing effector T cells and NK cells. Medicenna's IL-4 Empowered Superkine, bizaxofusp (formerly MDNA55), has been studied in 5 clinical trials enrolling over 130 patients, including a Phase 2b trial for recurrent GBM, the most common and uniformly fatal form of brain cancer. Bizaxofusp has obtained FastTrack and Orphan Drug status from the FDA and FDA/EMA, respectively. Medicenna's early-stage BiSKITs™ (**B**ifunctional **S**uper**K**ine **I**mmuno**T**herapies) and the T-MASK™ (**T**argeted **M**etalloprotease **A**ctivated **S**uper**K**ine) programs are designed to enhance the ability of Superkines to treat immunologically "cold" tumors.

For more information, please visit www.medicenna.com, and follow us on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of applicable securities laws that relate to the future operations of the Company, plans and projections and other statements that are not historical facts, including, without limitation, statements on the clinical development and potential of bizaxofusp and partnership efforts and opportunities in connection therewith. Forward-looking statements are often identified by terms such as "will", "may", "should", "anticipate", "expect", "believe", "seek", "potentially" and similar expressions and are subject to 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 latest Annual Report on Form 20-F of the Company 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, 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 hereof and except as required by law, we do not intend and do not assume any obligation to update or revise publicly any of the included forward-looking statements.

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Source: Medicenna Therapeutics Corp.