Medicenna Presents Preclinical Data on MDNA11 and Bizaxofusp at the 2024 Annual Meeting of the Society for Neuro-Oncology (SNO)

November 25, 2024

MDNA11 shows significant survival benefits in preclinical glioblastoma models, expanding $CD8^+$ T and NK cells

Bizaxofusp selectively targets human tumor cells and immune-suppressive cells, enhancing anti-tumor immunity

Combination therapy with MDNA11 and Bizaxofusp demonstrates synergistic tumor-killing in human GBM tumoroids

TORONTO and HOUSTON, Nov. 25, 2024 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. (“Medicenna” or the “Company”) (TSX: MDNA, OTCQX: MDNAF), a clinical-stage immunotherapy company focused on the development of Superkines, today announced the presentation of preclinical data on MDNA11, a long-acting “β-enhanced Not-α” IL-2 Superkine, and bizaxofusp (MDNA55), an IL-4 Empowered Superkine, at the 2024 Annual Meeting of the Society for Neuro-Oncology (SNO) held in Houston, Texas from November 21 – 24, 2024. These data provide compelling evidence of their combined potential to simultaneously enhance immune activation with MDNA11 and weaken the tumor microenvironment (TME) with bizaxofusp, for the treatment of “cold tumors” such as glioblastoma (GBM).

Clinical results reported earlier this month have shown that MDNA11 can effectively attack aggressive cancers such as pancreatic and colon cancers, by boosting the quality and quantity of cancer fighting immune cells, such as $CD8^+$ T cells and NK cells, in patients that have failed or do not benefit from blockbuster immunotherapies.

Bizaxofusp acts by targeted delivery of a potent toxin to several types of aggressive cancers that express the interleukin-4 receptor (IL-4R), such as GBM, without harming healthy cells. In addition, we have now shown that bizaxofusp weakens the TME, by selectively killing immunosuppressive cells, such as regulatory T cells (Tregs), which promote cancer cells to grow, metastasize, evade the immune system, and resist treatment.

“The data presented at SNO 2024 this weekend and at SITC earlier this month, highlight the transformative potential of our pipeline to address the challenges associated with some of the most aggressive and recalcitrant tumors such as pancreatic, colon and brain cancer,” said Fahar Merchant, PhD, President and CEO of Medicenna. “These results are particularly exciting because they demonstrate, for the first time, the synergistic potential of combining MDNA11’s ability to reinvigorate the cancer fighting immune system with bizaxofusp’s capacity to dismantle the protective tumor microenvironment associated with the most formidable and devastating cancers such as GBM. Our findings point to a potential breakthrough in addressing this significant unmet medical need for 70% of cancers that do not benefit from the current class of immunotherapies. At Medicenna, we remain committed and look forward to pushing the boundaries of our superkine platforms to deliver bold and synergistic approaches to significantly improve patient outcomes.”

The presentation, titled "*Invigorating Effector Immune Cells With Highly Selective IL-2R Agonists and Potential Synergy With Tumor Targeting Therapeutics for Treatment of Glioblastomas*", showcased the ability of MDNA11 and bizaxofusp to target GBM’s immunosuppressive environment and synergize to elicit robust anti-tumor responses.

MDNA11 is a next-generation IL-2 superkine designed to selectively stimulate effector immune cells ($CD8^+$ T cells and NK cells) by enhancing affinity for IL-2Rβ (CD122) while avoiding IL-2Rα (CD25), which reduces Treg activation and associated toxicities. Bizaxofusp is designed to target both the tumor and the TME, by selectively killing IL4R-expressing cancer cells, immune suppressive myeloid-derived suppressor cells (MDSCs) and Tregs.

Key findings presented at the conference include:

MDNA11: A Long-Acting IL-2 Superkine

- Demonstrated significant survival benefit ($p = 0.031$) in an aggressive orthotopic GBM model, with preferential expansion of $CD8^+$ T cells and NK cells.

Bizaxofusp: An IL-4 Empowered Superkine Designed to Deliver a Toxin Payload

- Selectively kills IL4R-expressing tumor cells and immunosuppressive MDSCs, while invigorating anti-tumor immune responses.
- Potently ($IC_{50} = 0.011$ nM) and selectively eliminated Tregs without impacting $CD8^+$ T cells and NK cells

Combination Therapy

- MDNA11 and bizaxofusp synergistically enhanced tumor cell killing in patient-derived GBM tumoroids, offering a novel combination approach for treating immunologically "cold" tumors.
- Findings suggest the combination strategy could redefine treatment paradigms for GBM and other challenging cancers.

A copy of the presentation will be available on the “Scientific Presentations” page of Medicenna’s website.

About MDNA11

MDNA11 is an intravenously administered, long-acting 'beta-enhanced not-alpha' IL-2 Superkine specifically engineered to overcome the shortcomings of aldesleukin and other next generation IL-2 variants by preferentially activating immune effector cells ($CD8^+$ T and NK cells) responsible for killing cancer cells, with minimal or no stimulation of immunosuppressive Tregs. These unique proprietary features of the IL-2 Superkine have been achieved by incorporating seven specific mutations and genetically fusing it to a recombinant human albumin scaffold to improve the pharmacokinetic (PK) profile and pharmacological activity of MDNA11 due to albumin's natural propensity to accumulate in highly vascularized sites, in particular tumor and tumor draining lymph nodes. MDNA11 is currently being evaluated in the Phase 1/2 ABILITY-1 study (NCT05086692) as both monotherapy and in combination with pembrolizumab.

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™ (**L**ocalized **I**nfusion for the treatment of recurrent **G**lioblastoma with **H**igh-dose bizaxofusp **T**herapy) 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 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 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 ™ (**Bi**functional **S**uper**K**ine **I**mmuno**T**herapies) and the T-MASK™ (**T**argeted Metallo/Protease **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 X and LinkedIn.

Forward-Looking Statements

This news release contains forward-looking statements within the meaning of applicable securities laws. Forward-looking statements include, but are not limited to, express or implied statements regarding the future operations of the Company, estimates, plans, strategic ambitions, partnership activities and opportunities, objectives, expectations, opinions, forecasts, projections, guidance, outlook or other statements that are not historical facts, such as statements on the Company's cash runway and planned expenditures, the clinical performance and potential, safety profile of MDNA11 and bizaxofusp, as well as MDNA11's and bizaxofusp's treatment potential, the reporting of additional results, and anticipated corporate milestones. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. You should not place undue reliance on these statements or the scientific data presented. 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. Forward-looking statements are based on a number of assumptions believed by the Company to be reasonable at the date of this news release. Although the Company believes that the expectations reflected in such forward-looking statements are reasonable, there can be no assurance that such statements will prove to be accurate. These statements are subject to certain risks and uncertainties and may be based on assumptions that could cause actual results and future events to differ materially from those anticipated or implied 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 information form of the Company and in other filings made by the Company with the applicable securities regulators from time to time in Canada.

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 or implied in forward-looking statements. 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.

This news release contains hyperlinks to information that is not deemed to be incorporated by reference in this news release.

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