Medicenna and Fondazione Melanoma Onlus Announce First Patient Dosed in the NEO-CYT Study of MDNA11 in Neoadjuvant Melanoma

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NEO-CYT marks the first evaluation of MDNA11 in earlier-stage cancers, as a potentially curative treatment; extends development beyond the heavily pretreated metastatic setting of the ongoing Phase 1/2 ABILITY-1 study

NEO-CYT is a Phase 1b randomized, multi-centre trial sponsored by Fondazione Melanoma Onlus and led by Professor Paolo A. Ascierto of the Istituto Nazionale Tumori IRCCS "Fondazione G. Pascale," Naples, Italy, evaluating MDNA11 in combination with nivolumab, with or without ipilimumab, in high-risk Stage III cutaneous melanoma

TORONTO and HOUSTON, May 12, 2026 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. (“Medicenna” or the “Company”) (TSX: MDNA, OTCQX: MDNAF), a clinical-stage immunotherapy company developing Superkines for targeting cancer and autoimmune disease, today announced that the first patient has been dosed in the NEO-CYT study, a randomized, investigator-initiated neoadjuvant Phase 1b trial evaluating MDNA11, Medicenna’s long-acting, “beta-enhanced not-alpha” IL-2 Superkine, in combination with nivolumab, with or without ipilimumab, in patients with high-risk, surgically resectable Stage III cutaneous melanoma at up to 12 centers in Italy.

“Neoadjuvant therapy has demonstrated that the timing of immunotherapy can be critical,” said Professor Paolo A. Ascierto, Lead Principal Investigator of NEO-CYT. “Treating patients while the tumor is still present may generate deeper and more durable immune responses. NEO-CYT is designed to investigate whether MDNA11, a next-generation IL-2 Superkine, may potentiate the immune activity of nivolumab, with or without ipilimumab, leading to improved pathologic responses and potentially higher cure rates in patients with resectable, high-risk melanoma.”

The NEO-CYT study is designed to evaluate MDNA11 as neoadjuvant immunotherapy before curative-intent surgery in earlier-stage melanoma patients whose immune systems may be more amenable to immunotherapy and more likely to benefit from treatment. MDNA11 will be evaluated in combination with nivolumab, with or without ipilimumab, with major pathologic response as a primary endpoint, which is considered predictive of long-term survival outcomes.

NEO-CYT is sponsored by the non-profit Melanoma Foundation, Fondazione Melanoma Onlus and is led by Professor Paolo A. Asciert of the Istituto Nazionale Tumori IRCCS ‘Fondazione G. Pascale.’ Under the terms of the clinical trial collaboration, Fondazione Melanoma Onlus is the Sponsor and Medicenna is supplying the study medications.

“Dosing the first patient in the NEO-CYT study represents an important milestone in the continued clinical development of MDNA11 and expands our evaluation of this next-generation IL-2 Superkine into the neoadjuvant setting,” said Dr. Nageatte Ibrahim, Chief Medical Officer of Medicenna. “MDNA11 has already demonstrated encouraging anti-tumor activity and a manageable safety profile in heavily pretreated patients with advanced metastatic cancers in the ongoing ABILITY-1 study. NEO-CYT allows us to evaluate MDNA11 earlier in the treatment paradigm, where the immune system may be more intact and where pathologic response can provide an early and rigorous signal of clinical activity. We are honored to collaborate with Fondazione Melanoma Onlus and Professor Ascierto on this important study.”

MDNA11 is currently being evaluated in the Phase 1/2 ABILITY-1 study as both monotherapy and in combination with pembrolizumab in patients with advanced solid tumors. In prior clinical updates, MDNA11 has demonstrated encouraging anti-tumor activity in heavily pretreated patients, including patients whose tumors progressed following immune checkpoint inhibitor therapy, alongside robust immune effector cell expansion and a manageable safety profile. NEO-CYT is intended to build on these findings by evaluating MDNA11 in an earlier-stage, potentially curative treatment setting.

About MDNA11

MDNA11 is a 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 as both monotherapy and in combination with pembrolizumab.

About Fondazione Melanoma Onlus

Fondazione Melanoma Onlus is a non-profit organization based in Naples, Italy, that supports and promotes melanoma research, education, and clinical trials. It is known for organizing international conferences like the Melanoma Bridge, which bring together clinicians and researchers to discuss advancements in melanoma treatment and its related fields. The foundation also sponsors scientific awards for outstanding achievements in melanoma research.

About Medicenna Therapeutics

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 first-in-class targeted PD-1 x IL-2 bispecific, MDNA113, is in development for solid tumors and was designed using the Company’s proprietary BiSKITs ™ (Bifunctional SuperKine ImmunoTherapies) and T-MASK™ (Targeted Metalloprotease Activated SuperKine) platforms

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 Fast Track and Orphan Drug status from the FDA and FDA/EMA, respectively.

For more information, please visit www.medicenna.com, and follow us on X and LinkedIn.

Forward-Looking Statements

This news release may contain 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 potential for the NEO-CYT trial, the outcomes of any studies and/or evaluations of any products of the Company or their intended therapeutic effects (including any anticipated timing thereof), the therapeutic treatment potential and safety profile of MDNA11**,** cash runway, and the timing and/or release of any additional clinical updates. 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 pre-clinical or 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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