Medicenna Presents ABILITY-1 Data at SITC 2026 Showing 40% ORR in Gastrointestinal Cancer Patients with Biomarker Enriched Tumors Resistant to Approved Therapies

November 9, 2026

ABILITY-1 is evaluating MDNA11, a "not-alpha beta-enhanced" IL-2 Superkine, either alone or in combination with pembrolizumab, in advanced solid tumors resistant to approved therapies

Achieved 40% objective response rate (ORR; 8/20) and 80% disease control rate (DCR; 16/20) across efficacy-evaluable MSI-H or MSS TMB-H gastrointestinal (GI) cancers

Responses were durable, with median duration of response (mDOR) not reached, and with responses ongoing

In 4/4 patients with liver metastasis, MDNA11 monotherapy elicited robust regression of all target liver lesions (8/8)

ABILITY-1 demonstrated durable activity in heavily pretreated ICI refractory Stage IV cutaneous melanoma with 90% of the patients having progressed on dual checkpoint blockade

In pre-specified, protocol-defined expansion cohorts, ORR was 30% in secondary ICI resistance patients treated with MDNA11 monotherapy (n=10), and 38% in primary ICI resistance patients treated with MDNA11 + pembrolizumab (n=8)

Additional data from melanoma and endometrial cancer expansion cohorts will be presented during the KOL webinar on November 10, 2026 at 9:00 am EST

TORONTO and HOUSTON, Nov. 09, 2026 (GLOBE NEWSWIRE) -- Medicenna Therapeutics Corp. ("Medicenna" or the "Company") (TSX: MDNA, OTCQB: MDNAF), a clinical-stage immunotherapy company developing Superkines™ for cancer and autoimmune disease, today announced new clinical data from the Phase 1/2 ABILITY-1 study of MDNA11 presented during an oral session at the Society for Immunotherapy of Cancer (SITC) 2026 Annual Meeting.

The presentation, titled "MDNA11 Demonstrates Clinical Activity as Monotherapy and in Combination with Pembrolizumab in Biomarker-Enriched Gastrointestinal Malignancies, Including ICI-Refractory Disease," was delivered by Professor Paolo Ascierto, MD, Director of Department of Skin Cancers, Cancer Immunotherapy and Development Therapeutics, National Cancer Institute IRCCS, Fondazione G. Pascale Naples, Italy.

As previously announced on November 4, 2026, the Company will host a KOL webinar on November 10, 2026 at 9:00 a.m. ET with Dr. Tawbi and Dr. Mansinho to discuss the results and their clinical implications. In addition, the webinar will include a presentation of new data from the ICI-resistant cutaneous melanoma and MSS endometrial cancer cohorts.

The SITC presentation highlighted durable antitumor activity with MDNA11 alone and in combination with Merck's (known as MSD outside of the US and Canada) anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with MSI-H or MSS TMB-H gastrointestinal (GI) cancers, including patients whose disease had progressed following prior ICI therapy.

Among 20 efficacy-evaluable patients with protocol-defined MSI-H or MSS TMB-H GI cancers, MDNA11 ± pembrolizumab achieved a 40% ORR (8/20) and 80% DCR (16/20). Responses were observed across multiple GI tumor types, including colorectal cancer (CRC), pancreatic ductal adenocarcinoma (PDAC), cholangiocarcinoma and anal squamous cell carcinoma. The cohort was heavily pretreated, with a median of three prior systemic treatment lines, including adjuvant therapy (range 1-10); 65% had received prior ICI therapy, 45% had received at least four prior systemic treatment lines and 35% had active liver metastases at baseline.

"The 40% response rate observed in this 20-patient cohort of MSI-H or MSS/TMB-H gastrointestinal cancers is very promising, particularly because we are seeing responses in patients whose cancers have already progressed on immunotherapy and for whom effective treatment options are limited," stated Professor Paolo Ascierto, recipient of the 2026 SITC Lifetime Achievement Award. "What stands out even more is the activity of MDNA11 monotherapy in patients with active liver metastases - a population that is difficult to treat and typically responds poorly to checkpoint inhibitors."

"The ABILITY-1 data presented at SITC strengthens our conviction that MDNA11 can address a meaningful unmet need after checkpoint inhibitor failure in many different cancers," said Fahar Merchant, PhD, President and Chief Executive Officer of Medicenna. "We are particularly encouraged by the single-agent activity of MDNA11 in ICI-refractory GI cancers and the durability of these responses across multiple tumor types. Results from the melanoma and endometrial cancer cohorts, all refractory to immune checkpoint inhibitors, are similarly promising, positioning MDNA11 for potential registrational studies as we strengthen evidence to confirm durability of tumor control."

Key Findings in MSI-H/TMB-H Gastrointestinal Cancers

- Combined cohort: 40% ORR (8/20) and 80% DCR (16/20); 5/8 responses were confirmed; ORR includes unconfirmed and ongoing responses.
- Median duration of response was not reached with responses ongoing
- MDNA11 monotherapy: 36% ORR (4/11) and 82% DCR (9/11).
- MDNA11 + pembrolizumab: 44% ORR (4/9) and 78% DCR (7/9).ICI-refractory subset: 31% ORR (4/13), including 33%

ORR (3/9 with MDNA11 monotherapy and 25% ORR (1/4) with MDNA11 + pembrolizumab.

- Tumor regression was observed in 55% of evaluable patients (11/20).

Published post-ICI datasets in MSI-H/dMMR GI cancers have reported limited activity with available salvage approaches, including ORRs of approximately 11% with ICI rechallenge and approximately 12-13% with chemotherapy ± targeted therapy. Emerging salvage programs have reported ORRs in the approximately 7-22% range. These cross-trial comparisons are descriptive; patient populations, prior treatment exposure and response assessment differ across studies.

Single-Agent Activity in Patients with Liver Metastases

Liver metastases are associated with lower response rates and shorter progression-free survival following checkpoint inhibition in MSI-H/dMMR GI cancers. In ABILITY-1, MDNA11 showed single-agent activity in patients with active liver metastases:

- All 4 evaluable MSI-H GI patients with measurable liver target lesions treated with MDNA11 monotherapy experienced regression of their liver lesions.
- All 8 measurable hepatic target lesions (100%) regressed in patients with PDAC, CRC and cholangiocarcinoma

“The activity observed in patients whose cancers had already progressed on checkpoint therapy is clinically important, particularly the consistent regression of active liver lesions with MDNA11 monotherapy,” said André Mansinho, MD, a principal investigator in the ABILITY-1 study and Director of Clinical Research at START Lisbon. “These patients often have limited effective treatment options, and liver metastases are associated with poorer outcomes even with checkpoint inhibition. The durability and breadth of activity suggests differential activity likely driven by the unique beta-enhanced design and albumin directed localization supporting the potential of MDNA11 to address unmet needs in cancer immunotherapy.”

Clinical Activity in ICI-Resistant Cutaneous Melanoma and MSS Endometrial Cancer

ABILITY-1 also demonstrated durable activity with MDNA11 alone and in combination with pembrolizumab in heavily pretreated, Stage IV cutaneous melanoma. In the protocol defined expansion cohorts (N=18), 100% had Stage IV disease, 90% had prior exposure to both PD-1 and CTLA-4 therapy, and 30% had liver metastases.

- In patients with secondary ICI resistance treated with MDNA11 monotherapy (n=10), ORR was 30% and DCR was 60%.
- In patients with primary ICI resistance treated with MDNA11 + pembrolizumab (n=8), ORR was 38% and DCR was 38%.

MDNA11 plus pembrolizumab also showed efficacy signals in MSS endometrial cancer

- In an expansion cohort comprising patients with secondary resistance to prior immune checkpoint inhibitor therapy (including multiple patients who had progressed following prior pembrolizumab plus lenvatinib), MDNA11 in combination with pembrolizumab achieved a confirmed objective response rate of 28.6% (2/7).

Additional data on melanoma and endometrial cancers will be shared during the KOL event.

Manageable Safety Profile

Across the pooled monotherapy and combination cohorts of the ABILITY-1 safety population (N=69 monotherapy; N=73 combination), MDNA11 continued to demonstrate a manageable safety profile:

- No dose-limiting toxicities were observed through 120 µg/kg.
- More than 90% of treatment-related adverse events (TRAEs) were Grade 1 or Grade 2 and were predominantly transient, with a median duration of one to two days.
- Approximately 65% of ≥ Grade 3 TRAEs were laboratory abnormalities, mostly asymptomatic.
- Grade 4 TRAE were exceedingly rare, comprising 0.3% of all TRAE events in both treatment groups, and all but one were asymptomatic laboratory abnormalities.
- One transient Grade 4 cytokine release syndrome event occurred in a patient with baseline low blood pressure and resolved within four days.
- No Grade 5 treatment-related adverse events were reported.
- No new safety signals were observed with the addition of pembrolizumab.
- Treatment related dose reductions in monotherapy and combination were 2.9% and 5.5%, respectively. Treatment related permanent discontinuation were 0% and 4% in the monotherapy and combination arms, respectively.

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KOL Event

Medicenna will host a KOL event on November 10, 2026 from 9:00 to 10:00 a.m. ET featuring Hussein A. Tawbi, MD, PhD, Professor of Melanoma Medical Oncology and Director of Personalized Cancer Therapy at The University of Texas MD Anderson Cancer Center, and André Mansinho, MD, MSc, Director of Clinical Research at START Lisbon, to discuss the SITC data, the new melanoma and endometrial cohort data, and the clinical development potential for MDNA11. To register, visit https://lifescievents.com/event/mjg29kp/.

About MDNA11 and the ABILITY-1 Study

MDNA11 is an investigational, long-acting IL-2 Superkine engineered to preferentially activate and expand cancer-fighting CD8+ T cells and natural killer cells, with minimal stimulation of immunosuppressive regulatory T cells.

ABILITY-1 (NCT05086692) is an open-label, multicenter Phase 1/2 dose-escalation and expansion study evaluating the safety, tolerability, pharmacokinetics, pharmacodynamics and anti-tumor activity of MDNA11 alone and in combination with pembrolizumab in patients with advanced solid tumors. The study is being conducted in collaboration with Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

About Medicenna Therapeutics

Medicenna is a clinical-stage immunotherapy company developing engineered cytokine therapies designed to selectively engage the immune system to treat cancer and autoimmune diseases. Medicenna is advancing MDNA11, a long-acting IL-2 Superkine designed to selectively activate cancer-fighting immune cells, which is currently being evaluated in the Phase 1/2 ABILITY-1 study and the Phase 1b NEO-CYT study. The Company is also developing MDNA113, a targeted PD-1 x IL-2 bifunctional immunotherapy for solid tumors, and MDNA209, an antagonist of CD122 blocking IL-2/IL-15 signaling, using its proprietary BiSKIT and T-MASK platforms. The Company's most advanced program, bizaxofusp (formerly MDNA55), is a targeted IL-4 Empowered Superkine that has been evaluated in more than 130 patients across five clinical trials, including a Phase 2b study in recurrent glioblastoma. Bizaxofusp has received Fast Track designation from the FDA, and Orphan Drug designation from the FDA and orphan designation in the EU.

For more information, 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 statements regarding the continued clinical development and potential therapeutic benefits of MDNA11; plans to advance MDNA11 toward a Phase 2 registrational trial in ICI-resistant MSI-H/TMB-H GI cancers and further development in ICI-resistant melanoma; potential future regulatory interactions and trial designs involving the Company or any of its products; potential patient-selection strategies of the Company; projected market opportunities for the Company; and the Company's future operations, plans, objectives and expectations. Forward-looking statements are subject to risks and uncertainties, and actual results and future events could differ materially from those anticipated. Important factors that could cause actual results to differ materially from the Company's expectations include the risks detailed in the Company's latest annual information form and other filings with applicable securities regulators.

The reader is cautioned that assumptions used in the preparation of forward-looking information may prove to be incorrect. Actual results may differ materially from those predicted as a result of known and unknown risks, uncertainties and other factors. Readers should not place undue reliance on forward-looking information. Forward-looking statements are made as of the date hereof and, except as required by law, the Company does not intend and does not assume any obligation to update or revise them.

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

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