Mersana Therapeutics Announces Positive Initial Clinical Data from Phase 1 Clinical Trial of Emiltatug Ledadotin (XMT-1660); Initiation of Expansion in Triple Negative Breast Cancer

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- Emiltatug ledadotin observed to be generally well tolerated with differentiated safety and tolerability profile
- Promising clinical activity observed in patients with triple-negative breast cancer (TNBC) previously treated with topoisomerase-1 inhibitor (topo-1) ADCs; confirmed responses observed across all enrolled tumor types
- First expansion cohort initiated in patients with TNBC previously treated with at least one topo-1 ADC; dose exploration efforts ongoing
- Company announces expected 2025 milestones and areas of focus
- Conference call today at 8:30 a.m. ET

CAMBRIDGE, Mass., Jan. 10, 2025 (GLOBE NEWSWIRE) -- Mersana Therapeutics, Inc. (NASDAQ: MRSN), a clinical-stage biopharmaceutical company focused on discovering and developing a pipeline of antibody-drug conjugates (ADCs) targeting cancers in areas of high unmet medical need, today announced positive initial clinical data from the Phase 1 dose escalation and backfill cohorts for emiltatug ledadotin (Emi-Le; XMT-1660), Mersana's lead Dolasynthen ADC candidate targeting B7-H4.

"We believe the initial safety, tolerability and efficacy data for Emi-Le demonstrate a profile that is exciting and differentiated within both the B7-H4 field and the broader ADC landscape," said Martin Huber, M.D., President and Chief Executive Officer of Mersana Therapeutics. "We have observed clinical activity across tumors, including in heavily pre-treated patients with TNBC. These clinical data have led us to initiate expansion in patients with TNBC who have previously been treated with at least one topo-1 ADC, a population with very high unmet need."

As of a December 13, 2024 data cutoff, the dose escalation portion of the Emi-Le Phase 1 clinical trial enrolled a total of 130 patients with advanced/metastatic TNBC; hormone-receptor-positive, human epidermal growth factor receptor 2 negative breast cancer; ovarian cancer; endometrial cancer and adenoid cystic carcinoma type 1. The enrolled patient population was heavily pretreated, with patients receiving up to 15 and a median of 4.5 prior lines of therapy, and approximately 92% of enrolled patients with TNBC had been previously treated with at least one topo-1 ADC. Among the 103 patients with known B7-H4 tumor expression, approximately 44% had a tumor proportion score of 70% or higher, which Mersana has preliminarily characterized as "B7-H4 high."

Emi-Le was observed to be generally well tolerated, with no Grade 4 or 5 treatment-related adverse events (TRAEs) reported. The most common TRAEs of any grade across the entire patient population were transient aspartate aminotransferase (AST) increase (38% of patients), generally asymptomatic and reversible proteinuria (31%), generally low-grade nausea (29%) and low-grade fatigue (28%). The only Grade 3 TRAEs in ≥5% or more of all patients were AST increase (14%) and proteinuria (9%). Across the entire enrolled patient population, TRAEs leading to discontinuation, dose reduction and dose delay were observed in 2.3%, 9.2% and 12.3% of patients, respectively. No dose-limiting treatment-related neutropenia, neuropathy, ocular toxicity, interstitial lung disease or thrombocytopenia were reported, which the company believes differentiates Emi-Le from many other approved and clinical-stage ADCs.

At intermediate doses in the trial (38.1 mg/m^2 to 67.4 mg/m^2), the confirmed objective response rate (ORR) among evaluable patients (those with measurable disease at baseline and at least one post-baseline scan) was 23% (6 of 26 patients) across all B7-H4 high tumors and 23% (3 of 13 patients) with B7-H4 high TNBC, all of whom had previously been treated with at least one topo-1 ADC.

In the ASCENT Phase 3 clinical trial of sacituzumab govitecan, a topo-1 ADC, the ORR with standard-of-care single-agent chemotherapy in relapsed/refractory TNBC was approximately 5% with progression free survival of approximately seven weeks. Based on these encouraging Emi-Le data at intermediate doses, Mersana has advanced a dose of 67.4 mg/m^2 every four weeks (Q4W) into an expansion cohort in patients with TNBC who have received one to four prior treatment lines, including at least one prior topo-1 ADC.

"In terms of both tolerability and clinical activity, these Emi-Le data are encouraging," Erika Hamilton, M.D., Director Breast Cancer Research, Sarah Cannon Research Institute in Nashville, Tennessee, said. "It is notable that all the TNBC patients who responded to Emi-Le had previously been treated with at least one topo-1 ADC. The results indicate that Emi-Le may help address an already substantial and growing need among topo-1 experienced breast cancer patients for new treatments."

At high doses above 76 mg/m^2, the confirmed ORR among evaluable patients was 22% (2 of 9 patients) across all B7-H4 high tumors. Additionally, 78% (7 of 9 patients) had ≥30% tumor reduction in target lesions. At these high dose levels, objective responses in multiple evaluable patients with B7-H4 high tumors were not confirmed after protocol-mandated dose delays for proteinuria. Mersana is implementing proteinuria mitigation efforts and continues to explore higher doses in dose escalation and backfill cohorts to identify a second dose for the expansion portion of the trial.

Mersana's Expected 2025 Milestones and Areas of Focus

Emi-Le

- 1H2025: Continue enrollment in expansion at a dose of 67.4 mg/m^2 Q4W in patients with TNBC who have previously received at least one prior topo-1 ADC
- 2025: Initiate enrollment in expansion at a second dose in patients with TNBC who have previously received at least one

prior topo-1 ADC
- 2025: Present additional Phase 1 clinical data from dose escalation and backfill cohorts

XMT-2056, Mersana's lead Immunosynthen ADC targeting a novel HER2 epitope

- 2025: Present initial clinical pharmacodynamic STING activation data

Pipeline

- Continue to support internal pipeline and existing collaborations with Johnson & Johnson and Merck KGaA, Darmstadt, Germany

Conference Call Information

Mersana will host a conference call today at 8:30 a.m. ET to discuss the initial clinical data from its Phase 1 clinical trial of Emi-Le. To access the call, please dial 833-255-2826 (domestic) or 412-317-0689 (international). A live webcast that includes the data presentation will be available on the Investors & Media section of the Mersana website at www.mersana.com, and a replay of the webcast will be available in the same location following the conference call for approximately 90 days.

About Mersana Therapeutics

Mersana Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel antibody-drug conjugates (ADCs) and driven by the knowledge that patients are waiting for new treatment options. The company has developed proprietary cytotoxic (Dolasynthen) and immunostimulatory (Immunosynthen) ADC platforms that are generating a pipeline of wholly-owned and partnered product candidates with the potential to treat a range of cancers. Its pipeline includes Emi-Le (emiltatug ledadotin; XMT-1660), a Dolasynthen ADC targeting B7-H4, and XMT-2056, an Immunosynthen ADC targeting a novel epitope of human epidermal growth factor receptor 2 (HER2). Mersana routinely posts information that may be useful to investors on the "Investors & Media" section of its website at www.mersana.com.

Forward-Looking Statements

This press release contains "forward-looking" statements and information within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will" and variations of these words or similar expressions, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, but are not limited to, statements concerning Mersana's plans regarding the clinical development of Emi-Le and XMT-2056, including with respect to the progress and design of the clinical trials of these product candidates; the potential clinical benefits of Emi-Le; Mersana's efforts to identify an additional dose for investigation in the expansion portion of its Phase 1 clinical trial of Emi-Le; Mersana's planned data presentations, including with respect to its Phase 1 clinical trial of Emi-Le and to clinical pharmacodynamic STING activation data related to XMT-2056; Mersana's collaborations with third parties; and the development and potential of Mersana's product candidates, platforms, technology and pipeline of ADC candidates. Mersana may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various factors, including, among other things, uncertainties inherent in research and development, in the advancement, progression and completion of clinical trials and in the clinical development of Mersana's product candidates, including Emi-Le and XMT-2056; the risk that Mersana may face delays in patient enrollment in its Phase 1 clinical trials of Emi-Le and XMT-2056; the risk that outcomes of preclinical studies may not be predictive of clinical trial results; the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials; the risk that clinical trial data may not support regulatory applications or approvals; the risk that Mersana may not realize the intended benefits of its platforms, technology and collaborations; and other important factors, any of which could cause Mersana's actual results to differ from those contained in the forward-looking statements, that are described in greater detail in the section entitled "Risk Factors" in Mersana's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on November 13, 2024, as well as in other filings Mersana may make with the SEC in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and Mersana expressly disclaims any obligation to update any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise, except as otherwise required by law.

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