Mersana Therapeutics Announces Corporate and Pipeline Updates and 2021 Goals and Anticipated Milestones

January 5, 2021

- *Following successful FDA meeting, the Company plans to initiate UPLIFT, a single-arm registrational strategy to evaluate XMT-1536 in platinum-resistant ovarian cancer, in Q1 2021*

- *Data from the ovarian cancer expansion cohort of the XMT-1536 Phase 1 study continued to show consistent activity and tolerability in a heavily-pretreated population*

- *XMT-1660, a first-in-class ADC targeting B7-H4, expected to complete IND-enabling studies in Q4 2021*

- *Ended Q4 2020 with approximately $255 million in cash, funding the Company's anticipated operating plan commitments for at least the next two years*

CAMBRIDGE, Mass., Jan. 05, 2021 (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 provided corporate and pipeline updates and announced its goals and anticipated milestones for 2021.

The Company will host a virtual Analyst and Investor event today at 10:00 a.m. ET, during which members of the Mersana executive team will provide an update on the XMT-1536 registration pathway informed by FDA feedback and further studies planned to evaluate XMT-1536 in earlier lines of ovarian cancer. The Company will also present preclinical data for XMT-1660, a first-in-class ADC targeting B7-H4, and outline the Company's goals and anticipated milestones for 2021. The Company will be joined by investigator Debra L. Richardson, MD, Associate Professor and Section Chief, Division of Gynecologic Oncology at the OU Health Stephenson Cancer Center and the Sarah Cannon Research Institute, who will review the updated data from the ovarian cancer expansion cohort of the XMT-1536 Phase 1 expansion study.

"2021 promises to be another transformative year for Mersana's pipeline. Our focus will be to initiate the UPLIFT single-arm registration strategy for XMT-1536 in platinum-resistant ovarian cancer and to initiate the UPGRADE combination umbrella study with the goal of informing the path into earlier lines of ovarian cancer therapy. The updated data being presented today show encouraging response rates in late-stage ovarian cancer patients and tolerability further supporting the potential of this therapy to be foundational for the treatment of ovarian cancer," said Anna Protopapas, President and CEO of Mersana Therapeutics. "Additionally, both the non-small cell lung cancer cohort of the Phase I expansion study of XMT-1536 and the XMT-1592 Phase 1 dose escalation study continue to actively enroll patients with interim data for both studies expected in the second half of this year. We will also work to advance XMT-1660, our first-in-class ADC targeting B7-H4, and XMT-2056, our first Immunosynthen STING-agonist ADC development candidate, through IND-enabling studies."

"We are very pleased with the continued activity and tolerability of XMT-1536 in heavily-pretreated patients with ovarian cancer without the severe neutropenia, peripheral neuropathy and ocular toxicity seen in other ADCs," said Arvin Yang, M.D., Ph.D., Senior Vice President and Chief Medical Officer of Mersana Therapeutics. "Based on these data and feedback from the FDA we plan to initiate a single-arm registrational strategy this quarter through an amendment to the ongoing Phase I study protocol. We believe this study design will allow for significant operational efficiencies and leverages continued momentum in patient enrollment."

UPLIFT Single-Arm Registration Strategy Studying XMT-1536 in Platinum-Resistant Ovarian Cancer

Informed by feedback from a meeting with the FDA, the Company plans to initiate UPLIFT, a single-arm registration strategy, to evaluate the safety and efficacy of XMT-1536 in platinum-resistant ovarian cancer patients who have received up to four lines of therapy. Platinum-resistant ovarian cancer patients previously treated with three or four lines of therapy may enroll without regard to prior bevacizumab treatment. Platinum-resistant ovarian cancer patients who received one or two lines of therapy will be required to have had prior bevacizumab treatment. Patients may enroll without regard to NaPi2b expression; however, the role of the biomarker will be evaluated. The primary endpoint will be the objective response rate (ORR) in the higher NaPi2b patient population and the secondary endpoints will be the ORR regardless of NaPi2b expression, as well as duration of response and safety. The single-arm registration strategy will be initiated as an amendment to the ongoing multinational, multi-center, open label study protocol and the Company expects to enroll approximately 180 patients.

Updated Expansion Study Data for XMT-1536

Today's update focuses on the ovarian cancer expansion cohort of the XMT-1536 Phase 1 study which is enrolling heavily pre-treated patients with ovarian cancer who have received up to four prior lines of therapy. With a data cutoff of December 3, 2020, these data include 72 patients evaluable for safety and 47 patients evaluable for RECIST response.

Key findings include:

- **Adverse event profile consistent with previously reported expansion data**

- The most frequently reported treatment-related adverse events (TRAEs) were generally Grade 1-2 fatigue, nausea, transient AST elevation without associated changes in bilirubin or cases of Hy's law, and transient thrombocytopenia.
- 31% of patients experienced a dose reduction, delay, or discontinuation due to a treatment-related adverse event.
- Serious adverse events occurred in 39% of patients regardless of relatedness with the most common related SAEs occurring in more than 2 patients of pyrexia (4), vomiting (3), abdominal pain (2), pneumonitis (2).
- There were no reported cases of severe neutropenia, peripheral neuropathy or ocular toxicity.

- **Anti-tumor activity in platinum-resistant and platinum-refractory ovarian cancer previously treated with bevacizumab, PARP inhibitors, or both.**

- **Activity observed in higher NaPi2b expressing population**

  - 31 patients with higher NaPi2b expression were evaluable for response, with 2 achieving confirmed complete responses (CRs) and 8 achieving confirmed partial responses (PRs) for an ORR of 32% (10/31). Additionally, 13 patients achieved stable disease (SD) for a disease control rate (DCR) of 74% (23/31).
  - The median duration of response was estimated at 5 months in patients with higher NaPi2b expression.
  - A trend toward higher response rate as well as deeper and more durable responses in patients with higher NaPi2b expression supports the continued development of a NaPi2b diagnostic assay.

- **Activity observed in overall population, regardless of NaPi2b expression**
  - Among all 47 patients evaluable for response, 3 additional patients achieved PRs for an ORR of 28% (13/47). 6 additional patients achieved SD for a DCR of 68% (32/47).
  - 69% of responses were observed by the first scan.
  - 67% of patients showed reduction in target lesions.

Corporate

Cash and cash equivalents as of December 31, 2020, were approximately $255 million. The Company expects that its current cash and cash equivalents will enable it to fund its current anticipated operating plan commitments for at least the next two years. In addition, the Company has the option to draw additional funds through the debt financing agreement with Silicon Valley Bank.

2021 Goals and Anticipated Milestones

XMT-1536, first-in-class Dolaflexin ADC targeting NaPi2b:

- **UPLIFT single-arm registration strategy studying XMT-1536 in platinum-resistant ovarian cancer expected to initiate in first quarter of 2021:** The single-arm cohort, informed by FDA feedback, will evaluate the safety and efficacy of XMT-1536 in approximately 180 patients with platinum-resistant ovarian cancer. This study is intended to support the initial registration of XMT-1536.

- **UPGRADE umbrella combination study in ovarian cancer expected to initiate in the third quarter of 2021:** The Company plans to initiate the UPGRADE study to evaluate the combination of XMT-1536 with other agents, starting with a platinum chemotherapy combination dose escalation cohort. This study is designed to inform the lifecycle management strategy for XMT-1536 in earlier lines of ovarian cancer, including platinum-sensitive disease.

- **The Company plans to report updated interim data from the NSCLC adenocarcinoma expansion cohort of the XMT-1536 Phase 1 study in the second half of 2021:** The Company has increased enrollment in parallel with the opening of international sites that had been delayed because of COVID-19 and continues to recruit patients in the expansion phase of the study.

XMT-1592, first Dolasynthen ADC targeting NaPi2b:

- **The Company plans to report interim XMT-1592 Phase 1 dose escalation data in the second half of 2021:** XMT-1592 is the Company's first clinical candidate created using its new Dolasynthen ADC platform. In preclinical studies, XMT-1592 showed four times greater efficacy in a patient-derived lung tumor model in comparison to XMT-1536, the Company's Dolaflexin ADC that has already shown promising activity when targeted to NaPi2b in the clinic. The Company continues to dose escalate and plans to disclose interim dose escalation data in the second half of 2021 and outline the XMT-1592 development plan in the fourth quarter of 2021.

XMT-1660, first-in-class Dolasynthen ADC targeting B7-H4:

- **Completion of XMT-1660 IND-enabling studies expected in the fourth quarter of 2021:** Investigational New Drug **(**IND)-enabling studies are ongoing for XMT-1660, a first-in-class B7-H4 ADC candidate. B7-H4 is expressed on both tumor

cells and immunosuppressive tumor-associated macrophages (TAMs). This expression provides the potential for both a direct, cytotoxic antitumor effect as well as for additional payload delivery to the tumor microenvironment that can further contribute to immunogenic cell death, dendritic cell activation, and stimulation of an immune response consistent with the features of the Company's unique DolaLock payload. The Company plans to initiate a Phase 1 dose escalation study of XMT-1660 in 2022.

XMT-2056, first Immunosynthen STING-agonist ADC candidate:

- **Completion of XMT-2056 IND-enabling studies expected in the fourth quarter of 2021:** In November 2020, the Company introduced XMT-2056 and presented preclinical data that supported the potential differentiation of the Immunosynthen platform from other innate immune stimulatory approaches and its potential applicability across multiple targets. The Company plans to disclose the target for this program in the fourth quarter of 2021 and initiate a Phase 1 dose escalation study in 2022.

Webcast and Conference Call Details
A live webcast of the presentation will be available on the Investors & Media section of the Mersana website at https://ir.mersana.com/events-and-presentations. Analyst and Investors may ask a question during the live Q&A by dialing (855) 940-5308 (toll-free domestic) or (929) 517-9745 (international) and providing the Conference ID 6265117.

About Mersana Therapeutics
Mersana Therapeutics is a clinical-stage biopharmaceutical company using its differentiated and proprietary ADC platforms to rapidly develop novel ADCs with optimal efficacy, safety and tolerability to meaningfully improve the lives of people fighting cancer. Mersana's lead product candidate, XMT-1536, is in the expansion portion of a Phase 1 proof-of-concept clinical study in patients with ovarian cancer and NSCLC adenocarcinoma. XMT-1592, Mersana's second ADC product candidate targeting NaPi2b-expressing tumors, was created using Mersana's customizable and homogeneous Dolasynthen platform and is in the dose escalation portion of a Phase 1 proof-of-concept clinical study. The Company's early-stage programs include XMT-1660, a first-in-class B7-H4 targeting ADC, as well as XMT-2056, a STING-agonist ADC developed using the Company's Immunosynthen platform. In addition, multiple partners are using Mersana's Dolaflexin platform to advance their ADC pipelines.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of federal securities laws. These forward-looking statements are not statements of historical facts and are based on management's beliefs and assumptions and on information currently available to management. Forward-looking statements include information concerning the Company's business strategy and the design, progression and timing of its clinical trials, the ability of the single-arm UPLIFT cohort to enable registration, and expectations regarding future clinical trial results based on data achieved to date, and the sufficiency of the Company's cash on hand. Forward-looking statements generally can be identified by terms such as "aims," "anticipates," "believes," "contemplates," "continues," "could," "estimates," "expects," "goal," "intends," "may," "on track," "opportunity," "plans," "poised for," "possible," "potential," "predicts," "projects," "promises to be," "seeks," "should," "target," "will," "would" or similar expressions and the negatives of those terms. Forward-looking statements represent management's beliefs and assumptions only as of the date of this press release. The Company's operations involve risks and uncertainties, many of which are outside its control, and any one of which, or combination of which, could materially affect its results of operations and whether the forward-looking statements ultimately prove to be correct. Factors that may materially affect the Company's results of operations and whether these forward-looking statements prove to be correct include, among other things, that preclinical testing may not be predictive of the results or success of ongoing or later preclinical or clinical trials, that the development and testing of the Company's product candidates and new platforms will take longer and/or cost more than planned, and that the identification of new product candidates will take longer than planned, as well as those listed in the Company's Annual Report on Form 10-K filed on February 28, 2020, with the Securities and Exchange Commission ("SEC"), the Company's Quarterly Report on Form 10-Q filed on May 8, 2020, with the SEC and subsequent SEC filings. In addition, while we expect that the COVID-19 pandemic might adversely affect the Company's preclinical and clinical development efforts, business operations and financial results, the extent of the impact on the Company's operations and the value of and market for the Company's common stock will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, travel restrictions, quarantines, physical distancing and business closure requirements in the U.S. and in other countries, and the effectiveness of actions taken globally to contain and treat the disease. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future.

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