Mersana Therapeutics Receives FDA Fast Track Designation for XMT-1536 for the Treatment of Patients with Platinum-resistant Ovarian Cancer

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CAMBRIDGE, Mass., Aug. 11, 2020 (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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for XMT-1536, for the treatment of patients with platinum-resistant high-grade serous ovarian cancer who have received up to three prior lines of systemic therapy or patients who have received four prior lines of systemic therapy regardless of platinum status.

"We are very encouraged by the FDA's decision to grant us Fast Track Designation for our lead program XMT-1536, which has shown very encouraging activity and tolerability in our Phase 1 study in ovarian cancer to date. We believe this recognition underscores the high unmet medical need for a treatment for patients with platinum-resistant ovarian cancer," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "With this designation in hand, we plan to be able to quickly advance through the administrative steps of XMT-1536's development and bring forth a therapy for these patients as soon as possible."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill unmet medical needs. A drug granted Fast Track Designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if certain criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a Biologics License Application (BLA).

About XMT-1536
XMT-1536, a first-in-class ADC targeting the sodium-dependent phosphate transport protein NaPi2b, utilizes the Dolaflexin platform to deliver an average of 10-12 DolaLock payload molecules per antibody. The NaPi2b antigen is broadly expressed in ovarian cancer and non-small cell lung cancer (NSCLC) adenocarcinoma. XMT-1536 is in an ongoing Phase 1 proof-of-concept clinical trial in patients with tumors expressing NaPi2b, including ovarian cancer and NSCLC adenocarcinoma. More information on the ongoing Phase 1 clinical trial can be found at clinicaltrials.gov (NCT03319628).

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 a B7-H4 targeting ADC, as well as 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. Forward-looking statements generally can be identified by terms such as "aims," "anticipates," "believes," "contemplates," "continues," "could," "estimates," "expects," "goal," "intends," "may," "on track," "plans," "possible," "potential," "predicts," "projects," "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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