Mersana Therapeutics Announces Clinical Hold on XMT-2056 Phase 1 Clinical Trial

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CAMBRIDGE, Mass., March 13, 2023 (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 Phase 1 trial of XMT-2056 has been placed on clinical hold by the U.S. Food and Drug Administration (FDA). This action follows the company's communication to FDA that Mersana was voluntarily suspending the trial due to a recent Grade 5 (fatal) serious adverse event (SAE) that was deemed to be related to XMT-2056. The SAE and its cause remain under investigation.

XMT-2056 is Mersana's first Immunosynthen STING-agonist ADC product candidate to enter the clinic, and the SAE occurred in the second patient who had been enrolled at the initial dose level in the dose escalation portion of the Phase 1 trial in previously treated patients with HER2+ recurrent or metastatic solid tumors. During the clinical hold, no patients will be enrolled or dosed in the trial.

"In line with our steadfast commitment to patient safety, we have been proactive in our response to this event. With the clinical hold in place, our efforts for XMT-2056 are now focused on undertaking the work required to fully analyze this SAE and consider potential next steps for development," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "At the same time, we continue to make progress with our UpRi and XMT-1660 clinical trials, which remain unaffected."

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, upifitamab rilsodotin (UpRi), is a Dolaflexin ADC targeting NaPi2b that is being studied in UPLIFT, a single-arm registrational trial in patients with platinum-resistant ovarian cancer; UPGRADE-A, a Phase 1 clinical trial evaluating UpRi in combination with carboplatin; and UP-NEXT, a Phase 3 clinical trial of UpRi as monotherapy maintenance following treatment with platinum doublets in recurrent platinum-sensitive ovarian cancer. Mersana's pipeline also includes XMT-1660, a Dolasynthen ADC targeting B7-H4 in a Phase 1 clinical trial, and XMT-2056, an Immunosynthen ADC targeting a novel epitope of human epidermal growth factor receptor 2 (HER2), in addition to other earlier-stage assets. In addition, multiple partners are using Mersana's platforms to advance their ADC pipelines. 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 future plans and activities, including those related to XMT-2056 and the Phase 1 clinical trial of XMT-2056, Mersana's investigation of the SAE and its cause, and the progress of Mersana's clinical trials investigating UpRi and XMT-1660. 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 initiation and advancement of clinical trials and in the clinical development of Mersana's product candidates; the risk that Mersana may not realize the intended benefits of its platforms, technology and collaborations; whether the outcomes of preclinical studies will be predictive of clinical trial results; uncertainty regarding whether Mersana will elect to or be able to resume enrollment in the clinical trial following its review of the available data surrounding the SAE and its cause; risks related to regulatory interactions; 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") on February 28, 2023, 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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