



Mersana Therapeutics Announces Partial Clinical Hold for XMT-1522 Clinical Trial

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CAMBRIDGE, Mass., July 19, 2018 (GLOBE NEWSWIRE) -- Mersana Therapeutics, Inc. (NASDAQ:MRSN), a clinical-stage biopharmaceutical company focused on discovering and developing a pipeline of antibody drug conjugates (ADCs) based on its Dolaflexin[®] and other proprietary platforms, today announced that the U.S. Food and Drug Administration (FDA) has placed the Phase 1 study of XMT-1522 on partial clinical hold. While the partial clinical hold remains in effect, no new patients will be enrolled in the study, though current study participants in its ongoing dose levels will continue to receive drug and otherwise participate in the trial consistent with its protocol.

The partial clinical hold was initiated following Mersana's recent report to the FDA of a Grade 5 Serious Adverse Event (patient death) in dose level 7 of the XMT-1522 Phase I trial, which was classified by the investigator as possibly drug-related. Mersana will be working closely with the FDA and the site investigators to review this event and to seek to resolve this clinical hold.

"Patient safety is our utmost concern," said Anna Protopapas, CEO of Mersana. "Based on the totality of the data we have for XMT-1522, we believe that it continues to be a promising drug candidate in the solid tumor setting and we will be initiating the proper steps with the objective of resuming enrollment."

The partial clinical hold does not affect the ongoing clinical development of Mersana's product candidate XMT-1536, currently in Phase 1 clinical trials for NaPi2b-expressing cancers.

About XMT-1522

XMT-1522 is a Dolaflexin ADC targeting HER2-expressing tumors. XMT-1522 comprises a proprietary HER2 antibody which is conjugated with Mersana's Dolaflexin platform – a Fleximer polymer linked with a proprietary auristatin payload. XMT-1522 provides a drug load of approximately 12 molecules per antibody, specifically designed to improve potency while simultaneously increasing tolerability. XMT-1522 has the potential to extend HER2-targeted therapy beyond the current "HER2-positive" populations into patients with lower levels of HER2 expression. The Phase 1 protocol will evaluate XMT-1522 in patients with advanced HER2-positive breast and gastric cancer, as well as advanced breast cancer with low HER2 expression and non-small cell lung cancer. More information on the ongoing Phase 1 clinical study can be found at clinicaltrials.gov.

About Mersana Therapeutics

Mersana Therapeutics is a clinical-stage biopharmaceutical company using its differentiated and proprietary ADC platforms to develop highly targeted drugs with increased tolerability and expanded opportunities to deliver meaningful clinical benefit to patients. Mersana's product candidate XMT-1522 is in Phase 1 clinical trials in patients with advanced tumors expressing HER2, including breast cancer, non-small-cell-lung-cancer (NSCLC) and gastric cancer patients. The Company's second product candidate, XMT-1536, is in Phase 1 clinical trials in patients with tumors expressing NaPi2b, including ovarian cancer, NSCLC and other cancers. In addition, multiple partners are using Mersana's platform to advance their ADC pipelines.

Forward-Looking Statements

This press release contains "forward-looking" statements within the meaning of federal securities laws. These are not statements of historical facts and are based on management's beliefs and assumptions and on information currently available. They are subject to risks and uncertainties that could cause the actual results and the implementation of the Company's plans to vary materially. These risks include the risk of delays or failure in reaching agreement with the FDA regarding the release of a clinical hold and other risks that are discussed in the Company's SEC filings including, without limitation, the Company's Annual Report on Form 10-K filed on March 28, 2018. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, even if new information becomes available in the future.

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