Mersana Announces FDA Lifts Partial Clinical Hold for XMT-1522

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Phase 1 Clinical Trial to Resume Enrollment of New Patients

CAMBRIDGE, Mass., Sept. 17, 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 lifted the partial clinical hold on the Phase 1 study of XMT-1522.

Mersana and the FDA reached alignment on changes to the protocol, including increased monitoring as well as the exclusion of patients with advanced hepatic impairment. Although XMT-1536, Mersana's Dolaflexin ADC targeting NaPi2b, was not subject to a clinical hold, Mersana has decided to implement similar modifications to the XMT-1536 protocol.

In addition, alternative dosing regimens will be evaluated for both clinical trials. The XMT-1522 trial will begin with a once-every-four-week dose regimen. This dosing regimen has already been implemented in the XMT-1536 trial at previously explored dose levels in order to enable a comparison of relevant doses and their impact on the safety, efficacy and PK profile of the drug candidate. The company may evaluate additional regimens as well. Data on XMT-1536 is expected in the first half of 2019.

"We are excited to resume enrollment on the XMT-1522 trial and to work with investigators to explore the full potential of both promising drug candidates in the solid tumor setting," said Anna Protopapas, Chief Executive Officer of Mersana.

About XMT-1522

XMT-1522 is a Dolaflexin ADC targeting HER2-expressing tumors. XMT-1522 contains 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 (NSCLC). More information on the ongoing Phase 1 clinical trial can be found at clinicaltrials.gov.

About XMT-1536

XMT-1536 is a highly potent immunoconjugate targeting the sodium-dependent phosphate transport protein (NaPi2b) and is comprised of an average of 10-15 DolaLock™ payload molecules conjugated to XMT-1535, a proprietary humanized anti-NaPi2b antibody, via the Dolaflexin ADC platform. NaPi2b is an antigen highly expressed in the majority of non-squamous NSCLC and epithelial ovarian cancer. XMT-1536 is in Phase 1 clinical trials in patients with tumors expressing NaPi2b, including ovarian cancer, NSCLC and other cancers. More information on the ongoing Phase 1 clinical trial 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 the potential for increased efficacy and 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 tumors expressing HER2, including breast cancer, NSCLC and gastric cancer patients. The company's second drug 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, including the risk that our clinical trials will not be completed on schedule, if at all, and the risk that our early encouraging preclinical results for XMT-1522 and XMT-1536 are not necessarily predictive of the results of our ongoing or future discovery programs or clinical studies. These risks are discussed in the company's filings with the U.S. Securities and Exchange Commission (SEC) including, without limitation, the company's Annual Report on Form 10-K filed on March 28, 2018, the company's Quarterly Report on Form 10-Q filed on August 14, 2018, and subsequent SEC filings. 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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