
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 17, 2018**

MERSANA THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation)

001-38129
(Commission File Number)

04-3562403
(IRS Employer
Identification No.)

840 Memorial Drive
Cambridge, MA 02139
Cambridge, MA
(Address of principal executive offices)

02139
(Zip Code)

(Registrant's telephone number, including area code): **(617) 498-0020**

Not Applicable

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On September 17, 2018, Mersana Therapeutics, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration has lifted the partial clinical hold on the Phase 1 study of XMT-1522. The Company’s press release is attached as Exhibit 99.1 to this current report and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Mersana Therapeutics, Inc., dated September 17, 2018

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MERSANA THERAPEUTICS, INC.

By: /s/ Eva Jack
Eva Jack
Chief Business Officer

Date: September 17, 2018

Mersana Announces FDA Lifts Partial Clinical Hold for XMT-1522

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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