Mersana Therapeutics Announces Strategic Priorities and Goals for 2019 and Beyond

January 4, 2019

Company to Focus its Resources on Advancing XMT-1536, its First-in-Class ADC Candidate Targeting NaPi2b, Showing Encouraging Early Signs of Efficacy

Dose Selection and Initiation of XMT-1536 Expansion Cohorts on Track for First Half 2019

XMT-1522 Development Discontinued Following Strategic Evaluation

CAMBRIDGE, Mass., Jan. 04, 2019 (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 need, today announced that after a strategic evaluation the Company will prioritize its resources to focus on the advancement of XMT-1536, a first-in-class ADC candidate targeting NaPi2b. As a result, Mersana and its partner, Takeda, plan to terminate the co-development collaboration for XMT-1522. Mersana will work with investigators to ensure that patients benefitting from XMT-1522 will continue to have access to the therapy as needed.

“While still in early clinical development, we are encouraged with the safety, tolerability, and activity of XMT-1536 as well as the pace at which the current study is advancing. For this reason, we have decided to focus our resources on advancing XMT-1536, our first-in-class ADC candidate targeting NaPi2b, a clinically validated ADC target broadly expressed in ovarian and non-small cell lung cancer (NSCLC) adenocarcinoma, for which there remains a significant unmet medical need,” said Anna Protopapas, President and CEO, Mersana Therapeutics. “We have made the difficult decision to terminate the further development of XMT-1522 despite a favorable emerging profile of efficacy and tolerability due to the competitive environment for HER2-targeted therapies.”

“Looking forward, we’re very enthusiastic about our clinical progress with XMT-1536 and the expansion of our clinical pipeline,” said Dirk Huebner, M.D., Chief Medical Officer, Mersana Therapeutics. “On behalf of the Company and our partner Takeda we want to thank the patients and their families for their participation in the study, as well as the investigators and our team for their diligent work on the clinical development of XMT-1522. We are committed to leveraging our proprietary ADC platforms to generate a differentiated pipeline of ADCs.”

Update on XMT-1536

- XMT-1536 is a first-in-class ADC against a clinically validated target. Ovarian and non-small cell lung cancer (NSCLC) adenocarcinoma express NaPi2b and remain areas of significant unmet need. XMT-1536 has the potential to play a significant role in the treatment of these diseases.
- The data to date from the ongoing XMT-1536 dose escalation study indicate that the trial has reached clinically relevant dose levels but has not yet reached a maximum tolerated dose. The once-every-three-week regimen has been fully explored. The once-every-four-week schedule is currently being evaluated. The 20 mg/m2 dose cohort has been shown to be well tolerated and the 30 mg/m2 is currently being evaluated.
- As of December 31, 2018, the dose escalation study of XMT-1536, in multiple tumor types, includes eight heavily pretreated and evaluable ovarian cancer patients treated at clinically relevant doses. These patients are unselected for NaPi2b expression and had 3 to 11 (median 6) prior regimens in the platinum resistant or refractory setting. Of these eight patients, two achieved a partial response and the remaining six achieved stable disease. The higher dose levels currently being evaluated, as well as additional patient enrollment, provide the opportunity to further define and optimize the profile of XMT-1536.

Mersana Therapeutics 2019 Corporate Goals

XMT-1536

- The Company expects to select a dose for use in its Phase 1 expansion studies and to initiate enrollment of patients in the expansion cohorts in the first half of 2019. The expansion cohorts will focus on platinum-resistant ovarian cancer and NSCLC adenocarcinoma. The Company also plans to utilize its proprietary and validated immunohistochemistry assay to retrospectively determine NaPi2b expression to determine whether a companion diagnostic would facilitate the clinical development of XMT-1536.
- The Company plans to report Phase 1 dose escalation data in the first half of 2019.

Pipeline Expansion

- The Company expects to disclose its next clinical candidate in the second half of 2019 and is targeting the filing of an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in the first half of 2020.

Research and Discovery

- Mersana continues to build a pipeline of promising ADCs across a variety of tumor types with significant unmet need, leveraging its three proprietary ADC platforms (Dolaflexin, Dolasynthen, and Alkymer).
- The Company is applying its expertise in ADCs to optimize and validate Immunosynthen, a new platform designed to allow systemic delivery of a potent immunostimulatory molecule to provide optimal efficacy and tolerability.
- Mersana plans to disclose the progress of these research and discovery efforts at scientific meetings throughout the year.

Corporate Developments

- The Company is proactively evaluating the potential for strategic collaborations that maximize the value of each of its pipeline candidates and platforms.
- Mersana is focused on the continued recruitment and retention of top talent, while maintaining a culture of scientific excellence, focused execution, and patient needs.

Upcoming Events

- The Company will provide further details during its presentation at the 37th Annual J.P. Morgan Healthcare Conference in San Francisco, CA on Wednesday, January 9, 2019 at 3:00 pm PT.

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 lead product candidate, XMT-1536, is in a Phase 1 clinical trial 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 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 "anticipates," "believes," "could," "seeks," "estimates," "intends," "may," "plans," "potential," "predicts," "projects," "should," "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 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 March 28, 2018, with the Securities and Exchange Commission ("SEC"), the Company's Quarterly Report on Form 10-Q filed with the SEC on November 13, 2018, and subsequent SEC filings. 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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