Mersana Therapeutics Announces Additional FDA Fast Track Designation Granted to Emiltatug Ledadotin (XMT-1660)

January 10, 2025

Conference call to discuss positive initial Phase 1 clinical data today at 8:30 a.m. ET

CAMBRIDGE, Mass., Jan. 10, 2025 (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 the U.S. Food and Drug Administration (FDA) recently granted an additional Fast Track designation to XMT-1660. The company also announced that the World Health Organization has approved emiltatug ledadotin (abbreviated as Emi-Le) as XMT-1660's international nonproprietary name (INN).

The new Fast Track designation is for the treatment of advanced or metastatic breast cancer in patients with human epidermal growth factor receptor 2 (HER2) low (IHC 1+ or IHC 2+/ISH–) or HER2-negative (IHC 0) disease, including triple-negative breast cancer (TNBC), who have received a prior topoisomerase-1 inhibitor ADC. Additionally, hormone-receptor positive patients should also have received or be ineligible for endocrine therapy. The FDA previously granted Fast Track designation to Emi-Le for the treatment of adult patients with advanced or metastatic recurrent TNBC.

"Topoisomerase-1 inhibitor ADCs are rapidly becoming the standard of care for metastatic TNBC and hormone-receptor positive breast cancer, and an increasing amount of research shows that these patients are exceedingly difficult to treat thereafter," said Martin Huber, M.D., President and Chief Executive Officer of Mersana Therapeutics. "This growing population is a primary focus for us as we advance the development of Emi-Le. We are excited to announce this additional Fast Track designation and the initial clinical data from our ongoing Phase 1 clinical trial that were press released separately this morning."

The FDA's Fast Track program is designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fill an unmet medical need. A product candidate granted Fast Track designation may be eligible for several benefits, including more frequent meetings and communications with the FDA and, if certain criteria are met, the potential for Accelerated Approval, Priority Review or Rolling Review of a Biologics License Application (BLA) by the FDA.

Conference Call Information

Mersana will host a conference call today at 8:30 a.m. ET to discuss the initial clinical data from its Phase 1 clinical trial of Emi-Le. To access the call, please dial 833-255-2826 (domestic) or 412-317-0689 (international). A live webcast that includes the data presentation will be available on the Investors & Media section of the Mersana website at www.mersana.com, and a replay of the webcast will be available in the same location following the conference call for approximately 90 days.

About Mersana Therapeutics

Mersana Therapeutics is a clinical-stage biopharmaceutical company focused on the development of novel antibody-drug conjugates (ADCs) and driven by the knowledge that patients are waiting for new treatment options. The company has developed proprietary cytotoxic (Dolasynthen) and immunostimulatory (Immunosynthen) ADC platforms that are generating a pipeline of wholly-owned and partnered product candidates with the potential to treat a range of cancers. Its pipeline includes Emi-Le (emiltatug ledadotin; XMT-1660), a Dolasynthen ADC targeting B7-H4, and XMT-2056, an Immunosynthen ADC targeting a novel epitope of human epidermal growth factor receptor 2 (HER2). 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, those concerning Mersana's areas of focus; the continued development and therapeutic potential of Mersana's product candidates, including Emi-Le (XMT-1660); Mersana's anticipated disclosure of initial clinical trial data from its Phase 1 clinical trial of Emi-Le; and the potential advantages of Fast Track Designation. 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 and clinical development of Mersana's product candidates, including Emi-Le; whether the outcomes of preclinical studies will be predictive of clinical trial results; the risk that the receipt of Fast Track designation for Emi-Le may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures the risk that the FDA may later decide that Emi-Le no longer meets the conditions for Fast Track designation or decide that the time period for FDA review or approval will not be shortened; the risk that Mersana may not realize the intended benefits of its platforms, technology and collaborations; 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on November 13, 2024, 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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