Mersana Therapeutics Announces FDA Fast Track Designation Granted to XMT-1660 for the Treatment of Triple-Negative Breast Cancer

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XMT-1660 currently being studied in a Phase 1 trial enrolling patients with breast, endometrial and ovarian cancers

CAMBRIDGE, Mass., Sept. 12, 2022 (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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to XMT-1660 for the treatment of adult patients with advanced or metastatic triple-negative breast cancer (TNBC). XMT-1660 is a B7-H4-directed Dolasynthen antibody drug conjugate with a precise, target-optimized drug-to-antibody ratio (DAR 6) and Mersana's clinically validated DolaLock microtubule inhibitor payload with controlled bystander effect.

"While breast cancer remains an area of high unmet need, TNBC is associated with particularly poor outcomes and very limited treatment options," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "XMT-1660 has demonstrated promising anti-tumor effects in preclinical studies, and we are excited to have recently initiated our Phase 1 trial to investigate its safety and clinical activity. This Fast Track designation allows for a potentially accelerated regulatory review of XMT-1660 as we seek to offer a new therapy for patients living with a range of B7-H4 expressing tumors."

Mersana's ongoing multicenter Phase 1 trial is investigating the safety, tolerability and anti-tumor activity of XMT-1660 in patients with solid tumors, including in breast, endometrial and ovarian cancers. The initial dose escalation portion of this trial will evaluate the safety and tolerability of XMT-1660. The dose expansion portion of the trial will evaluate the safety, tolerability and efficacy of XMT-1660.

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 that is 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.

About Mersana Therapeutics

Mersana Therapeutics is a clinical-stage biopharmaceutical company using its differentiated and proprietary ADC platforms to rapidly develop novel ADCs with optimal efficacy, safety and tolerability to meaningfully improve the lives of people fighting cancer. Mersana's lead product candidate, upifitamab rilsodotin (UpRi), is a Dolaflexin ADC targeting NaPi2b that is being studied in UPLIFT, a single-arm registrational trial in patients with platinum-resistant ovarian cancer; UPGRADE, a Phase 1/2 umbrella trial evaluating UpRi in combination with other ovarian cancer therapies; and UP-NEXT, a Phase 3 clinical trial of UpRi as monotherapy maintenance following treatment with platinum doublets in recurrent platinum-sensitive ovarian cancer. Mersana is also advancing 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), in addition to other earlier-stage assets. In addition, multiple partners are using Mersana's platforms to advance their ADC pipelines. Mersana Therapeutics was named among the 2021 Top Places to Work in Massachusetts by The Boston Globe. Mersana routinely posts information that may be useful to investors on the "Investors and 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 the therapeutic potential of Mersana's product candidates, including XMT-1660, the design and expected progression of Mersana's Phase 1 clinical trial of XMT-1660 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; whether the outcomes of preclinical studies will be predictive of clinical trial results; the risk that the receipt of Fast Track designation for XMT-1660 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 XMT-1660 no longer meets the conditions for Fast Track designation or decide that the time period for FDA review or approval will not be shortened; risks to clinical trial site initiation, patient enrollment and follow-up, as well as to Mersana's abilities to meet other anticipated deadlines and milestones, whether presented by the ongoing COVID-19 pandemic or otherwise; 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 Annual Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on August 8, 2022, 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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