Mersana Therapeutics Announces FDA Grant of Orphan Drug Designation to XMT-2056 for the Treatment of Gastric Cancer

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CAMBRIDGE, Mass., May 19, 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 orphan drug designation to XMT-2056, the company's lead Immunosynthen STING-agonist ADC, for the treatment of gastric cancer.

According to the American Cancer Society, gastric cancer (also referred to as stomach cancer) accounts for approximately 1.5 percent of all new cancers diagnosed in the United States each year, with an estimated 26,560 new cases reported in 2021. The FDA grants orphan drug designation to a drug or biologic intended to treat a rare disease or condition impacting fewer than 200,000 individuals in the United States. This designation qualifies Mersana for potential incentives, including tax credits for certain trials, exemption from user fees and the potential for seven years of market exclusivity following approval (if granted).

"The FDA's decision to grant orphan drug designation to XMT-2056 for the treatment of gastric cancer is an important recognition of its potential in this area of high unmet medical need," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "We are eager to bring XMT-2056 and its unique mechanism of action into the clinic mid-year to investigate its safety, tolerability and anti-tumor activity in gastric and other cancers."

XMT-2056 is designed to offer a differentiated and complementary therapeutic approach to existing and emerging solid tumor treatments. The company developed XMT-2056 leveraging a differentiated antibody that binds to a novel HER2 epitope, providing the opportunity, as demonstrated in preclinical studies, for treatment both as monotherapy and in combination with a variety of agents, including other anti-HER2 therapies. Mersana plans to initiate a Phase 1 trial of XMT-2056 in a range of HER2 expressing tumors, such as breast, gastric and non-small-cell lung cancers, in mid-2022.

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, as well as in UPGRADE, a Phase 1/2 umbrella trial evaluating UpRi in combination with other ovarian cancer therapies. Mersana's early-stage programs include XMT-1660, a Dolasynthen ADC targeting B7-H4, and XMT-2056, a STING-agonist ADC developed using the company's Immunosynthen platform and targeting a novel epitope of human epidermal growth factor receptor 2 (HER2). In addition, multiple partners are using Mersana's platforms to advance their ADC pipelines. Mersana Therapeutics was recently 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, statements concerning the therapeutic potential of Mersana's product candidates, including XMT-2056 as potential monotherapy or in combination with other agents; the potential incentives that may be available to Mersana as a result of the FDA's grant of orphan drug designation to XMT-2056 for the treatment of gastric cancer; and the design, initiation, timing and objectives of Mersana's anticipated clinical trial of XMT-2056. 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, in the initiation of clinical trials and in the clinical development of Mersana's product candidates; the risk that Mersana's anticipated clinical trials may not be initiated on schedule, if at all; the risk that Mersana may not realize the intended benefits of its platforms, technology and collaborations; whether the outcomes of preclinical studies will be predictive of clinical trial results; 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 May 9, 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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