European Commission Designates UpRi as an Orphan Medicinal Product for the Treatment of Ovarian Cancer

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CAMBRIDGE, Mass., Dec. 14, 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 European Commission (EC) has designated upifitamab rilsodotin (UpRi) as an orphan medicinal product for the treatment of ovarian cancer. UpRi is Mersana's first-in-class NaPi2b-targeting ADC with a novel scaffold-linker-payload that is designed to enable a high drug-to-antibody ratio and controlled bystander effect.

"Receiving this orphan designation in the European Union is an important regulatory milestone for Mersana as we seek to expedite UpRi's global development," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "This designation reinforces the unmet needs that patients with ovarian cancer continue to face today. We look forward to advancing our ongoing clinical trials, which aim to establish UpRi as a foundational medicine in ovarian cancer."

The European Commission designates drugs as orphan medicinal products based on positive opinions adopted by the European Medicines Agency (EMA) Committee for Orphan Medicinal Products (COMP). Orphan designations are granted for potential treatments for rare diseases that are life-threatening or chronically debilitating that affect fewer than five in 10,000 people across the European Union. Medicines designated as orphan medicinal products by the EMA may qualify for financial and regulatory incentives, including protocol assistance at reduced fees during product development, access to centralized marketing authorization and 10 years of marketing exclusivity in the European Union after product approval.

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, a Phase 1/2 clinical trial evaluating UpRi in combination with carboplatin; 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 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 the therapeutic potential of Mersana's product candidates, including UpRi; Mersana's efforts to expedite the global development of UpRi; Mersana's advancement of the clinical development of UpRi; and the potential advantages of designation as an orphan medicinal product. 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 the clinical development of Mersana's product candidates; whether the outcomes of preclinical studies will be predictive of clinical trial results; whether initial or interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; the risk that UpRi's designation as an orphan medicinal product may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional EMA procedures; the risk that the EMA may later decide that UpRi no longer meets the conditions for designation as an orphan medicinal product or decide that the time period for EMA review or approval will not be shortened; risks to clinical trial site initiation, patient enrollment and follow-up, as well as to Mersana's and its collaborators' 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 Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on November 7, 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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