

Mersana Therapeutics Announces Topline Data from UPLIFT Clinical Trial in Patients with Platinum-Resistant Ovarian Cancer and Strategic Reprioritization

July 27, 2023

- UPLIFT clinical trial did not meet its primary endpoint
- Company realigns focus and significantly reduces expenses to extend cash runway into 2026
- Conference call today at 8:00 a.m. ET

CAMBRIDGE, Mass., July 27, 2023 (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 UPLIFT clinical trial of upifitamab rilsodotin (UpRi) did not meet its primary endpoint. UpRi is an ADC targeting the sodium-dependent phosphate transport protein NaPi2b and was developed utilizing the company's Dolaflexin platform.

UPLIFT was a single-arm clinical trial that enrolled platinum-resistant ovarian cancer patients with one to four prior treatment regimens. The primary endpoint for UPLIFT was the investigator-assessed objective response rate (ORR) in the NaPi2b-positive population. NaPi2b-positive status was defined by a tumor proportion score (TPS) of ≥75%. Secondary endpoints for the trial included the investigator-assessed ORR among all patients in the trial, duration of response (DOR), and safety and tolerability. The trial also included an assessment of ORR and DOR by independent radiology review (IRR).

UPLIFT enrolled a total of 268 patients, 141 of whom were determined to be NaPi2b positive. The median prior lines of systemic therapy among all patients was three, with 31% of the population having received four prior lines of treatment. Additionally, 84% of patients received prior bevacizumab and 69% received prior PARP inhibitor treatment.

Top-line results from UPLIFT as of the May 31, 2023 data cutoff date are as follows:

NaPi2b-Positive Population (n=141)

	Investigator Assessment	IRR Assessment
ORR, n (%) [95% confidence interval]	22 (15.6%) [10.0%, 22.7%]	23 (16.3%) [10.6%, 23.5%]
Partial Response, n (%)	20 (14.2%)	16 (11.3%)
Complete Response, n (%)	2 (1.4%)	7 (5.0%)
Median DOR, months	7.4	Not Reached

Total Population (n=268)

	Investigator Assessment	IRR Assessment
ORR, n (%)	35 (13.1%)	35 (13.1%)
Partial Response, n (%)	32 (11.9%)	24 (9.0%)
Complete Response, n (%)	3 (1.1%)	11 (4.1%)
Median DOR, months	7.4	10.7

Safety and tolerability data in UPLIFT were generally consistent with prior disclosures. Following the completion of its analyses, the company plans to share detailed efficacy and safety data with the medical and scientific community in an appropriate forum.

"We are deeply disappointed that UPLIFT's efficacy failed to replicate previous data from approximately 100 patients in the dose expansion portion of our Phase 1b clinical trial," said Dr. Arvin Yang, Senior Vice President and Chief Medical Officer of Mersana Therapeutics. "While the duration of response was longer than that from the dose expansion portion of UpRi's Phase 1b clinical trial, the lower bound of the confidence interval for the primary endpoint did not meet our goal of excluding a 12% ORR seen with standard-of-care single-agent chemotherapy. We are in the process of conducting an in-depth analysis of various factors to better understand the results as well as the characteristics of patients who responded to UpRi therapy, particularly those whose responses were deep and durable. We extend our deepest gratitude to all of the patients, family members, caregivers and investigators who contributed to UPLIFT."

Strategic Reprioritization and Financial Update

"As an organization driven by a mission to discover and develop potentially life-changing ADCs for patients fighting cancer, UPLIFT's outcome is clearly disappointing and requires us to reprioritize our areas of focus," said Anna Protopapas, President and Chief Executive Officer of Mersana Therapeutics. "In recent years, Mersana has advanced new product candidates and developed new partnerships utilizing its next-generation ADC

platforms, Dolasynthen and Immunosynthen. These will be our primary focus moving forward. We plan to complete the dose escalation portion of our Phase 1 clinical trial of XMT-1660 in 2023 and initiate the dose expansion portion of the trial in 2024. Our team continues working diligently to address the clinical hold on the Phase 1 clinical trial of XMT-2056. Additionally, we intend to strongly support Mersana's collaborators as they leverage our next-generation ADC platforms and advance their product candidates."

"We also are taking decisive action to extend our cash runway and ensure we have the resources to evaluate the clinical potential of our next-generation ADC product candidates," Ms. Protopapas continued. "Unfortunately, this necessitates reducing our workforce by approximately 50%. A very talented group of employees who helped to build Mersana will be departing as a result of this strategic reprioritization. We are grateful for their many contributions and intend to provide strong support through their transition."

Mersana's restructuring plan includes a wind-down of UpRi-related development activities, including its UP-NEXT and UPGRADE-A clinical trials and the company's regulatory and commercial readiness efforts. If analyses of data enable the identification of a path forward for UpRi, the company will consider strategic alternatives for the asset, including partnering.

Mersana estimates that its balance of cash, cash equivalents and marketable securities as of June 30, 2023 was \$286.6 million. This figure is preliminary and is subject to completion of the company's financial closing procedures. The company expects to report its cash, cash equivalents and marketable securities, as well as other information necessary for a complete understanding of its financial position, in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2023. The company expects that its available funds will be sufficient to support its current operating plan commitments into 2026.

Conference Call Notice

Mersana will host a conference call today at 8:00 a.m. ET. To access the call, please dial (877) 270-2148 (domestic) or (412) 902-6510 (international). A live webcast of the 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 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, statements concerning Mersana's further data analysis related to its clinical evaluation of UpRi and the presentation of UPLIFT trial data; its strategic priorities; its restructuring plans, including with respect to discontinuing clinical development of UpRi and related efforts and reducing its workforce; any potential path forward for UpRi and consideration of potential strategic alternatives for this asset; plans regarding the clinical development of XTM-1660; Mersana's efforts to address the clinical hold on XMT-2056; Mersana's cash runway; Mersana's financial closing procedures and its expectations to report additional financial information for the period ended June 30, 2023; and the development and potential of Mersana's product candidates, platforms, technology and pipeline of ADC candidates. 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 advancement, progression and completion of clinical trials and in the clinical development of Mersana's product candidates, including XMT-1660 and XMT-2056; the risks that Mersana may be unable to resolve the clinical hold with respect to its Phase 1 clinical trial of XMT-2056 and may not be able to resume that trial or to develop or commercialize XMT-2056; the occurrence of impediments to Mersana's ability to execute its planned restructuring and strategic reprioritization as currently contemplated; the risk that restructuring costs and charges may be greater than anticipated; the risk that Mersana's restructuring efforts may adversely affect its ability to retain skilled and motivated personnel and may be distracting to employees and management; the risk that Mersana's restructuring efforts may negatively impact its business operations and reputation; the risk that Mersana's restructuring efforts may not generate their intended benefits to the extent or as quickly as anticipated; 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 May 9, 2023, 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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