Monte Rosa Therapeutics Outlines Progress Across Portfolio of Molecular Glue Degraders and Key Anticipated Milestones for 2023

January 9, 2023

- MRT-2359 received Fast Track designation from the FDA for the treatment of patients with previously treated, metastatic non-small cell lung cancer (NSCLC) with L-MYC or N-MYC expression
- Disclosure of initial data from Phase 1 arm of ongoing Phase 1/2 clinical trial evaluating MRT-2359 expected in second half of 2023
- Nomination of multiple additional development candidates anticipated in 2023
- Company to present pipeline and corporate updates at 41st Annual J.P. Morgan Healthcare Conference on Wednesday, Jan. 11, 2023, at 11:15 a.m. PT

BOSTON, Jan. 09, 2023 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (NASDAQ: GLUE), a biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today outlined anticipated 2023 milestones ahead of its participation at the 41st Annual J.P. Morgan Healthcare Conference. The company's presentation will focus on strategic priorities for 2023, including its plans to report initial data from the Phase 1 arm of its ongoing Phase 1/2 clinical trial for MRT-2359, a highly selective and orally available GSPT1-directed MGD. Further, the company will present its development plan for its additional MGD candidates for patients with high unmet medical needs in oncology, autoimmune and inflammatory indications.

"In 2022, we made significant progress across our portfolio of highly selective molecular glue degraders, culminating in the initiation of our Phase 1/2 trial of MRT-2359 in MYC-driven tumors," said Markus Warmuth, M.D., CEO of Monte Rosa. "As we look ahead to 2023, with our lead program in the clinic, a rich pipeline of wholly owned preclinical programs, and backed by a strong cash position, we believe we are well positioned for success. We expect our programs to achieve important catalysts in 2023 that will bring us closer to fulfilling our vision of developing a new generation of MGD-based precision medicines for patients living with serious diseases."

2023 Key Milestones and Catalysts

- The U.S. Food and Drug Administration (FDA) has granted Fast Track designation to MRT-2359 for the treatment of patients with previously treated, metastatic NSCLC with L-MYC or N-MYC expression
- The company anticipates disclosing initial data from the Phase 1 arm of the ongoing Phase 1/2 clinical trial evaluating MRT-2359 in the second half of 2023
- The company anticipates the nomination of multiple development candidates in 2023 for its programs oncology, autoimmune and inflammatory diseases

J.P. Morgan Healthcare Conference

Dr. Warmuth will present Monte Rosa's pipeline and business updates during a presentation at the 41 st Annual J.P. Morgan Healthcare Conference on Wednesday, January 11, 2023, at 11:15 a.m. PT. An archived webcast of the presentation will be made available via the "Events & Presentations" section of the company's investor site at https://ir.monterosatx.com/.

About MRT-2359

MRT-2359 is a potent, selective and orally bioavailable molecular glue degrader (MGD) that induces the interaction between the E3 ubiquitin ligase component cereblon and the translation termination factor GSPT1, leading to the targeted degradation of GSPT1 protein. The MYC transcription factors (c-MYC, L-MYC and N-MYC) are well-established drivers of human cancers that maintain high levels of protein translation, which is critical for uncontrolled cell proliferation and tumor growth. Our preclinical studies have shown that this addiction to MYC-induced protein translation creates a dependency on GSPT1. By inducing degradation of GSPT1, MRT-2359 exploits this vulnerability, disrupting the protein synthesis machinery and leading to anti-tumor activity in MYC-driven tumors.

About the MRT-2359 Phase 1/2 study

Our ongoing Phase 1/2, open-label, multicenter study (Identifier: NCT05546268) will primarily assess the safety, tolerability, pharmacokinetic (PK), pharmacodynamic (PD), and preliminary clinical activity of MRT-2359 in patients with previously treated selected solid tumors, including non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), high-grade neuroendocrine cancer of any primary site, diffuse large B-cell lymphoma (DLBCL) and solid tumors with L-MYC or N-MYC amplification. In the Phase 1 portion of the study, patients will receive escalating doses of MRT-2359 to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D). Once the MTD and/or RP2D are determined, the anti-tumor activity of MRT-2359 will be assessed as part of the Phase 2 portion of the study, which includes L-MYC or N-MYC expression for stratification and selection.

About Monte Rosa

Monte Rosa Therapeutics is a biotechnology company developing novel molecular glue degrader (MGD) medicines for patients living with serious diseases such as oncology, autoimmune and inflammatory diseases. MGDs are small molecule protein degraders designed to employ the body's natural mechanisms to selectively eliminate therapeutically relevant proteins. The company's QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) platform enables it to rapidly identify protein targets and design highly selective degraders by combining diverse libraries of proprietary

MGDs with in-house proteomics, structural biology, AI/machine learning, and computational chemistry capabilities. For more information, visit www.monterosatx.com.

Forward-Looking Statements

This communication includes express and implied "forward-looking statements," including forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward looking statements include all statements that are not historical facts, and in some cases, can be identified by terms such as "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue," "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. Forward-looking statements contained in herein include, but are not limited to, statements about our product development activities, including our expectations around MRT-2359 and the potential significance of obtaining Fast Track Designation from the FDA, the ongoing development of our QuEEN™ platform and the advancement of our pipeline and the various products therein, our expectations regarding and the timing of our clinical trial for MRT-2359, our ability to initiate and the timing of initiation of additional lead optimization programs, and our expectations regarding our ability to nominate and the timing of our nominations of additional development candidates, as well as our expectations of success for our programs and the strength of our financial position, among others. By their nature, these statements are subject to numerous risks and uncertainties, including the impact that the ongoing COVID-19 pandemic will have on our development activities and operations, as well as those risks and uncertainties set forth in our most recent Quarterly Report on Form 10-Q and Annual Report on Form 10-K for the year ended December 31, 2021 filed with the US Securities and Exchange Commission, and any subsequent filings, that could cause actual results, performance or achievement to differ materially and adversely from those anticipated or implied in the statements. You should not rely upon forward looking statements as predictions of future events. Although our management believes that the expectations reflected in our statements are reasonable, we cannot guarantee that the future results, performance or events and circumstances described in the forward-looking statements will be achieved or occur. Recipients are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date such statements are made and should not be construed as statements of fact. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, any future presentations or otherwise, except as required by applicable law. Certain information contained in these materials and any statements made orally during any presentation of these materials that relate to the materials or are based on studies, publications, surveys and other data obtained from third-party sources and our own internal estimates and research. While we believe these third-party studies, publications, surveys and other data to be reliable as of the date of these materials, we have not independently verified, and make no representations as to the adequacy, fairness, accuracy or completeness of, any information obtained from third-party sources. In addition, no independent source has evaluated the reasonableness or accuracy of our internal estimates or research and no reliance should be made on any information or statements made in these materials relating to or based on such internal estimates and research.

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