Monte Rosa Therapeutics Announces Positive Interim Phase 1 Data of MRT-8102 Demonstrating Profound CRP Reductions in Elevated CVD-risk Subjects

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In subjects with elevated cardiovascular disease (CVD) risk, MRT-8102, a NEK7-directed molecular glue degrader in development for the treatment of NLRP3/IL-1/IL-6 driven inflammatory diseases, demonstrated rapid and durable reductions in systemic inflammation

After four weeks of MRT-8102 treatment, C-reactive protein (CRP) levels were reduced by 85%, and 94% of study participants achieved CRP values below 2 mg/L, a threshold associated with reduced cardiovascular disease (CVD) risk

Single ascending dose (SAD) and multiple ascending dose (MAD) cohorts demonstrated deep and sustained NEK7 degradation at doses from 5 mg to 400 mg

Favorable safety profile observed with mild to moderate adverse events (AEs) and no evidence of increased infection risk

Ongoing GFORCE-1 Study of MRT-8102 in subjects with elevated CVD risk expanded to multiple dose levels to accelerate development in atherosclerotic cardiovascular disease (ASCVD); anticipated readout in H2 2026

Plan to initiate Phase 2 ASCVD study in 2026; additional indications being evaluated

Conference call and webcast planned for today at 8 a.m. ET

BOSTON, Jan. 07, 2026 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced positive interim data from an ongoing Phase 1 clinical study evaluating MRT-8102, a NEK7-directed MGD being developed for the treatment of inflammatory conditions driven by the NLRP3 inflammasome, IL-1, and IL-6.

"Today we showcased the potential of MRT-8102, an orally bioavailable molecular glue degrader of NEK7, to transform the treatment of ASCVD and other cardiovascular and cardiometabolic diseases. In this interim data readout, after 4 weeks of dosing MRT-8102 decreased median high-sensitivity CRP (hsCRP) levels by 85% and resulted in suppression of hsCRP to <2 mg/L in 94% of subjects, despite a significantly higher median baseline level of 6.3 mg/L as compared to benchmark clinical trials. These remarkable interim data from our ongoing Phase 1 study of MRT-8102 demonstrate for the first time that treatment with an oral molecular glue degrader of NEK7 led to levels of CRP reduction comparable to those previously reported with biologic therapies," said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. "During both the SAD and MAD portions of the study, with doses ranging from 5 to 400 mg daily, we observed substantial and approximately equivalent degradation of NEK7 across all dose levels, as well as corresponding reductions in IL-1β and IL-6, along with a favorable safety profile. Importantly, we saw substantial decreases in CRP levels across all dose levels that were nearly equivalent to those achieved in Part 3 of the trial, suggesting maximum activity from the lowest dose level and pointing to a broad safe dosing range available for further development. We believe our data support the potential of MRT-8102 to be an oral best-in-class therapeutic among agents targeting the NLRP3/IL-1/IL-6 pathway and establish the significant potential opportunity for MRT-8102 in multiple chronic inflammatory diseases, including ASCVD."

Filip Janku, M.D., Ph.D., Chief Medical Officer of Monte Rosa Therapeutics, commented, "Based on the highly encouraging data for MRT-8102 we have observed so far, we are expanding our proof-of-concept GFORCE-1 study in subjects with elevated CVD risk, in order to accelerate the anticipated Phase 2 (GFORCE-2) study of MRT-8102 in ASCVD. We expect results from the GFORCE-1 study in H2 2026. Moreover, we are evaluating additional Phase 2 proof-of-concept studies in metabolic dysfunction-associated steatohepatitis (MASH), gout, and recurrent pericarditis, conditions strongly linked to NLRP3 pathway activation."

The MRT-8102 Phase 1 study (clinicaltrials.gov identifier NCT07119125) is a randomized, double-blind, placebo-controlled trial in healthy volunteers that includes both single ascending dose (SAD) and multiple ascending dose (MAD) cohorts. The study is designed to evaluate safety and tolerability, pharmacokinetics (PK), and pharmacodynamics (PD), including NEK7 degradation and *ex vivo* responses to inflammasome stimulation. Part 3 of the Phase 1 study is a randomized, placebo-controlled trial enrolling subjects with increased CVD risk due to obesity and elevated CRP, designed to evaluate safety and tolerability, changes in CRP levels, pharmacokinetics, and changes in other inflammatory markers.

Summary of Key Interim Study Results

- SAD cohorts enrolled 48 subjects and MAD cohorts enrolled 40 subjects. In the Part 3 cohort, 24 subjects have completed 4 weeks of dosing.
- Rapid, deep and sustained degradation of NEK7 was observed in peripheral blood T cells (~80 to 90%) in the SAD, MAD, and Part 3 cohorts across all dose levels.
- MRT-8102 led to significant reductions in serum hsCRP across all dose levels following single dose drug administration and 7-day multiple dose drug administration.
- In the MAD cohorts, MRT-8102 led to marked suppression of IL-1β secretion in patients with elevated CRP levels at baseline.
- When analyzing high CRP subjects across all dose levels, significant reductions of endogenous IL-6 were observed, with median IL-6 levels dropping by 55%, to levels below the cardiovascular risk threshold.
- In two subjects with elevated basal levels of cerebrospinal fluid (CSF) IL-6, a significant decrease of 75% in CSF IL-6 was noted; plasma IL-6 levels at baseline for these two subjects was low, potentially suggesting central nervous system /CSF-specific effects of MRT-8102.
- In Part 3 of the study in subjects with elevated CVD risk, in 24 subjects dosed for 4 weeks as of the data cutoff of December 23, 2025, MRT-8102 resulted in a decrease of hsCRP of 85% after four weeks of dosing, compared with no significant change in hsCRP for the placebo group. In addition, 94% of subjects showed suppression of hsCRP to <2mg/L after four weeks of dosing (median baseline level was 6.3 mg/L).
- The MRT-8102 safety profile observed to date was favorable. Based on blinded safety data for MRT-8102 and placebo, as of the data cutoff, AEs were limited in number, mild to moderate, and self-resolving. There was no dose-dependent relationship in frequency or severity of AEs observed and no evidence of increased infection risk.

ANTICIPATED UPCOMING CORPORATE MILESTONES AND DEVELOPMENT PRIORITIES
Immunology and Inflammation disease programs

- Share data from the GFORCE-1 study of MRT-8102 in subjects with elevated CVD risk in H2 2026.
- Initiate Phase 2 GFORCE-2 study of MRT-8102 in ASCVD in 2026.
- Monte Rosa expects its collaborator, Novartis, to initiate multiple Phase 2 studies of VAV1-directed MGD MRT-6160 in immune-mediated diseases in 2026.
- Submit an IND application for a next-generation NEK7-directed MGD in 2026.

Oncology programs

- Initiate MODeFIRe-1 Phase 2 study of MRT-2359 in combination with a second-generation androgen receptor inhibitor in castration-resistant prostate cancer (CRPC) in 2026.
- Present updated data from the ongoing Phase 1/2 study of MRT-2359 at the ASCO Genitourinary Cancers Symposium in February 2026.
- Submit an IND application for a CDK2 and/or cyclin E1-directed MGD in 2026.

Investor Conference Call
Monte Rosa will host a conference call and webcast presentation today, January 7, 2026, at 8:00 a.m. ET. A webcast of the presentation will be accessible via the “Events & Presentations” section of Monte Rosa’s website at ir.monterosatx.com. Registration for the conference call is available at the following link. An archived version of the webcast will be made available for 30 days following the presentation.

About MRT-8102
MRT-8102 is a potent, highly selective, and orally bioavailable investigational molecular glue degrader (MGD) that targets NEK7 for the treatment of inflammatory diseases linked to NLRP3, IL-1, and IL-6 dysregulation. NEK7 has been shown to be required for NLRP3 inflammasome assembly, activation and IL-1β release both *in vitro* and *in vivo*. Aberrant NLRP3 inflammasome activation and the subsequent release of active IL-1β and interleukin-18 (IL-18) has been implicated in multiple inflammatory disorders, including cardiovascular disease, gout, osteoarthritis, asthma, neurodegenerative diseases, and metabolic disorders. In a non-human primate model, MRT-8102 was shown to potently, selectively, and durably degrade NEK7, and resulted in near-complete reductions of IL-1β and caspase-1 following *ex vivo* stimulation of whole blood. MRT-8102 has demonstrated a considerable safety margin (>200-fold exposure margin over projected human efficacious dose) in GLP toxicology studies. MRT-8102 is currently being investigated in a Phase 1 study (clinicaltrials.gov identifier NCT07119125) in healthy participants and participants at elevated cardiovascular disease risk. In an interim analysis from the Phase 1 study, in subjects with elevated cardiovascular disease (CVD) risk, MRT-8102 demonstrated rapid and durable reductions in systemic inflammation, including reduction of CRP levels by 85% after four weeks of treatment.

About Monte Rosa
Monte Rosa Therapeutics is a clinical-stage biotechnology company developing highly selective molecular glue degrader (MGD) medicines for patients living with serious diseases. MGDs are small molecule protein degraders that have the potential to treat many diseases that other modalities, including other degraders, cannot. Monte Rosa’s QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) discovery engine combines AI-guided chemistry, diverse chemical libraries, structural biology, and proteomics to rationally design MGDs with unprecedented selectivity. Monte Rosa has developed the industry’s leading pipeline of first-in-class and only-in-class MGDs, spanning autoimmune and inflammatory diseases, oncology, and beyond, with three programs in the clinic. Monte Rosa has ongoing collaborations with leading pharmaceutical companies in the areas of immunology, oncology and neurology. 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 herein include, but are not limited to, statements about our ability to grow our product pipeline, our ability to successfully complete research and further development and commercialization of our drug candidates in current or future indications, including the timing and results of our clinical trials and our ability to conduct and complete clinical trials, statements regarding the positive interim Phase 1 data and potential benefits of MRT-8102, our expectations regarding the potential of MRT-8102 to transform the treatment of ASCVD and other cardiovascular and cardiometabolic diseases, our belief that our data supports the potential of MRT-8102 to be an oral best-in-class therapeutic among agents targeting the NLRP3/ IL-1/IL-6 pathway and establish the significant potential of MRT-8102 in multiple chronic inflammatory diseases, including ASCVD, our statements regarding the expansion of our proof-of-concept GFORCE-1 study in subjects with elevated CVD risk and acceleration of the anticipated Phase 2 (GFORCE-2) study of MRT-8102 in ASCVD patients, our expectations regarding the timing for sharing data from the GFORCE-1 study of MRT-8102 and timing of initiation of a Phase 2 GFORCE-2 study of MRT-8102 in ASCVD, our statements and expectations regarding our evaluation of additional Phase 2 proof of concept studies in MASH, gout, and recurrent pericarditis, conditions strongly linked to NLRP3 pathway activation, statements regarding our expectations that our collaborator, Novartis, will initiate multiple Phase 2 studies of VAV1-directed MGD MRT-6160 in immune-mediated diseases in 2026, our expectations regarding the submission of an IND application for a next-generation NEK7-directed MGD and timing thereof, our expectations to initiate a MODeFIRe-1 Phase 2 study of MRT-2359 in combination with a second-generation androgen receptor inhibitor in CRPC in 2026, as well as to present updated data from the ongoing Phase 1/2 study of MRT-2359 at the ASCO Genitourinary Cancers Symposium in February 2026, our expectations regarding the submission of an IND application for a CDK2 and/or cyclin E1-directed MGD and timing thereof, statements regarding the clinical significance of the clinical data read-out at upcoming scientific meetings and timing thereof, statements around our ability to capitalize on and potential benefits resulting from our research and translational insights, among others. By their nature, these statements are subject to numerous risks and uncertainties, including those risks and uncertainties set forth in our most recent Annual Report on Form 10-K for the year ended December 31, 2024, filed with the U.S. Securities and Exchange Commission on March 20, 2025, most recent Quarterly Reports on Form 10-Q 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, as well as the risk that outcomes of preclinical studies may not be predictive of clinical trial results and the risk that initial or interim results from a clinical trial may not be predictive of the final results of the trial or the results of future trials. 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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