Monte Rosa Therapeutics Announces Fourth Quarter and Full Year 2022 Financial Results and Provides Corporate Update

March 16, 2023

- Phase 1/2 clinical trial evaluating MRT-2359 for treatment of MYC-driven solid tumors ongoing
- Disclosure of initial data from Phase 1 arm of study expected in second half of 2023
- MRT-2359 received Fast Track designation from FDA for treatment of patients with previously treated, metastatic non-small cell lung cancer (NSCLC) with L-MYC or N-MYC expression
- Nomination of multiple development candidates anticipated in 2023
- Year-end 2022 cash balance of approximately $268 million, with cash runway into 2025

BOSTON, March 16, 2023 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (NASDAQ: GLUE), a clinical stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today reported financial results for the fourth quarter and full year ended December 31, 2022, and provided corporate updates.

“Last year was transformational for Monte Rosa, as we initiated a Phase 1/2 clinical trial with MRT-2359 for the treatment of MYC-driven solid tumors, and advanced our VAV1 program into lead optimization. We have now shown repeatedly that our QuEEN platform has the ability to generate selective molecular glue degraders for therapeutically relevant protein targets, and our pipeline of unique and differentiated MGDs serves as strong validation of QuEEN,” said Markus Warmuth, M.D., CEO of Monte Rosa. “We look forward to presenting the first clinical data for MRT-2359 later this year, as well as nominating multiple development candidates from our pipeline programs. Backed by a strong cash runway, we are well positioned to continue showcasing the unique capabilities of our drug discovery engine and developing new treatment options for patients with serious diseases of high unmet medical need.”

Monte Rosa’s current programs are focused on delivering therapies to targets generally considered undruggable or inadequately drugged in well-characterized biological pathways across clinical indications in oncology, inflammation, immunology, and other diseases with high unmet needs. The Company’s lead program, MRT-2359, is in Phase 1/2 clinical trials. Additional programs focused on the degradation of CDK2 for oncology, VAV1 for autoimmunity and NEK7 for inflammation are at the lead optimization stage, with multiple development candidates expected to be announced in 2023. Further discovery programs are focused on sickle cell disease-related proteins, as well as multiple currently undisclosed targets.

Business Highlights and Recent Developments

- **Initiated patient dosing in October of its Phase 1/2 clinical trial evaluating MRT-2359 for the treatment of MYC-driven solid tumors, including lung cancer.** MRT-2359 is a potent, selective, and orally bioavailable GSPT1-directed MGD, designed to disrupt protein synthesis in MYC-driven tumors and lead to anti-tumor activity. The Phase 1/2 open-label, multicenter study 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 are receiving escalating doses of MRT-2359 to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D). Once the RP2D is determined, the anti-tumor activity of MRT-2359 will be assessed as part of the Phase 2 portion of the study, which includes molecular biomarkers for patient stratification and selection.

- **U.S. Food and Drug Administration (FDA) granted Fast Track designation to MRT-2359 in January for the treatment of patients with previously treated, metastatic NSCLC with L-MYC or N-MYC expression.** Fast Track designation is designed to facilitate the development and expedite the review of drug candidates to treat serious conditions and fulfill an unmet medical need. Clinical programs with Fast Track designation may be eligible for more frequent interactions with the FDA throughout the regulatory review process and may be eligible for Accelerated Approval and Priority Review if relevant criteria are met.

- **Advanced immunology-focused VAV1 degrader program into Lead Optimization.** VAV1 is a pivotal signal transduction protein in the adaptive immune system. When activated, VAV1 relays a signal cascade that results in immune cell activation and the secretion of several pro-inflammatory cytokines. Prior to Monte Rosa’s research, VAV1 had been considered undruggable. Through analysis and screening by QuEEN™, the Company developed highly potent and selective degraders that have been observed to induce rapid and deep VAV1 degradation, elicit expected on-target downstream functional effects and compelling *in vivo* activity. VAV1 has rapidly advanced into Lead Optimization and is one of three programs that may advance to IND-enabling studies in 2023.

- **Strengthened executive leadership team** with the promotion of Jennifer Champoux to Chief People & Operations Officer and the appointment of Magnus Walter, Ph.D., to Senior Vice President, Chemical Sciences and Process Development

- **Presented at recent scientific and medical conferences including:**
  - 5th Annual Targeted Protein Degradation Summit in Boston, October 25-28, 2022
  - 34th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Barcelona, October 26-28, 2022
  - Molecular Glue Drug Development Summit in Boston, January 25, 2023
  - 4th Swiss Industrial Chemistry Symposium in Basel, January 27, 2023

2023 Objectives and Upcoming Milestones

- Disclosure of initial clinical data including PK, PD, safety and available initial efficacy data from the Phase 1 arm of the ongoing Phase 1/2 clinical trial evaluating MRT-2359 is expected in the second half of 2023
- Nomination of multiple development candidates from Lead Optimization programs in immunology, inflammation and/or oncology and initiation of IND-enabling studies in 2023
- Disclosure of multiple new discovery programs
- Expand molecular glue degrader platform beyond CRBN

Upcoming Data Presentations

- Additional preclinical data from the MRT-2359 program will be presented at the upcoming American Association for Cancer Research (AACR) Annual Meeting, April 14-19, 2023, in Orlando, FL; presentation details, as follows:
  - **Oral Presentation**
    Title: New Drugs on the Horizon - Discovery of MRT-2359, an orally bioavailable GSPT1 molecular glue degrader, for MYC-driven cancers
    Session: New Drugs on the Horizon: Part 3
    Presenter: Owen Wallace, Ph.D., Chief Scientific Officer of Monte Rosa
    Date and Time: Monday, April 17; 10:15 - 11:45 a.m. ET

  - **Oral Presentation**
    Title: Development of MRT-2359, an orally bioavailable GSPT1 molecular glue degrader, for the treatment of lung cancers with MYC-induced translational addiction
    Session: Mini Symposium
    Abstract: 3449
    Presenter: Gerald Gavory, Ph.D., Senior Director of Drug Discovery and Translational Research at Monte Rosa
    Date and Time: Monday, April 17; 2:30 - 4:30 p.m. ET

FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2022 were $24.9 million compared to $18.1 million for the fourth quarter of 2021, and $85.1 million for the year ended December 31, 2022, compared to $57.2 million for the year ended December 31, 2021. The increase in R&D expense was primarily due to the expansion of research and development activities, including the advancement of MRT-2359 into the clinic, pipeline advancement of the VAV1, NEK7 and CDK2 programs, increased headcount and facilities in the United States and Switzerland, and corresponding increases in laboratory-related expenses. R&D expense included non-cash lease expense and non-cash stock compensation expense of $1.6 million and $1.8 million, respectively, for the quarter ended December 31, 2022, and $4.8 million and $6.1 million for the year ended December 31, 2022, respectively. Non-cash stock compensation expense was $1.0 million and $2.6 million for the same periods in 2021.

General and Administrative (G&A) Expenses: G&A expenses for the fourth quarter of 2022 were $7.6 million compared to $5.3 million for the fourth quarter of 2021, and $27.3 million for the year ended December 31, 2022, compared to $15.7 million for the year ended December 31, 2021. The increase in G&A expenses were a result of increased headcount and expenses in support of the company's growth and operations as a public company. G&A expenses included non-cash stock-based compensation of $1.6 million for the fourth quarter of 2022 and $5.6 million for the year ended December 31, 2022, compared to $1.0 million and $2.6 million, respectively, for the same periods in 2021.

Net Loss: Net loss for the fourth quarter of 2022 was $30.8 million compared to $23.4 million for the fourth quarter of 2021, and $108.5 million for the year ended December 31, 2022, compared to $74.0 million for the year ended December 31, 2021.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of December 31, 2022, were $268.1 million, compared to $351.4 million as of December 31, 2021. The company expects its cash, cash equivalents, restricted cash and marketable securities will be sufficient to fund planned operations and capital expenditures into 2025.

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, including the timing for initiation of IND-enabling studies for VAV1 and other programs, 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 COVID-19 pandemic may 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.

Consolidated Balance Sheets

(in thousands, except share amounts)

	December 31,	
	2022	**2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 54,912	$ 346,071
Marketable securities	207,914	—
Other receivables	7,656	—
Prepaid expenses and other current assets	4,444	2,595
Current restricted cash	960	—
Total current assets	275,886	348,666
Property and equipment, net	27,075	12,325
Operating lease right-of-use assets	34,832	—
Restricted cash, net of current	4,318	5,338
Other long-term assets	278	—
Total assets	$ 342,389	$ 366,329
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,862	$ 6,558
Accrued expenses and other current liabilities	14,580	10,080
Current portion of operating lease liability	3,127	—
Total current liabilities	25,569	16,638
Defined benefit plan liability	1,533	2,176
Operating lease liability	43,874	—
Total liabilities	70,976	18,814
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 49,445,802 shares issued and 49,323,531 shares outstanding as of December 31, 2022; and 500,000,000 shares authorized, 46,794,295 shares issued and 46,535,966 shares outstanding as of December 31, 2021	5	5
Additional paid-in capital	503,696	471,566
Accumulated other comprehensive loss	(1,752)	(2,021)
Accumulated deficit	(230,536)	(122,035)
Total stockholders' equity	271,413	347,515

Total liabilities and stockholders' equity	$ 342,389	$ 366,329

Consolidated Statements of Operations and Comprehensive Income (Loss)
(In thousands, except share and per share amounts)

	Three months ended December 31,		Year ended December 31,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 24,868	$ 18,130	$ 85,061	$ 57,155
General and administrative	7,621	5,257	27,323	15,727
Total operating expenses	32,489	23,387	112,384	72,882
Loss from operations	(32,489)	(23,387)	(112,384)	(72,882)
Other income (expense):				
Interest income, net	1,990	13	3,764	46
Foreign currency exchange gain (loss), net	(283)	(66)	10	(162)
Gain on disposal of fixed assets	—	—	109	—
Changes in fair value of preferred stock tranche obligations, net	—	—	—	(960)
Total other income (expense)	1,707	(53)	3,883	(1,076)
Net loss	$ (30,782)	$ (23,440)	$ (108,501)	$ (73,958)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.63)	$ (0.50)	$ (2.30)	$ (2.96)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	48,893,160	46,509,897	47,227,370	25,000,124
Net loss	$ (30,782)	$ (23,440)	$ (108,501)	$ (73,958)
Other comprehensive income (loss):				
Provision for pension benefit obligation	619	(71)	718	(965)
Unrealized gain (loss) on available-for-sale securities	231	—	(449)	—
Comprehensive loss	$ (29,932)	$ (23,511)	$ (108,232)	$ (74,923)

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