Monte Rosa Therapeutics Announces First Quarter 2023 Financial Results and Provides Corporate Update

May 11, 2023

- On track to present initial data from Phase 1/2 clinical trial of MRT-2359 in MYC-driven solid tumors in the second half of 2023
- Cash runway into 2025 supports operations and advancement of pipeline of novel molecular glue degraders to key inflection points

BOSTON, May 11, 2023 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today reported business highlights and financial results for the quarter ended March 31, 2023.

“During the first quarter, we made significant progress with our Phase 1/2 clinical trial of MRT-2359 in MYC-driven solid tumors. This trial continues to attract top oncologists and academic centers, and patient enrollment is on track for us to have initial data to share in the second half of the year. We remain excited about the prospect of bringing a potential therapeutic option to a range of indications driven by MYC, one of the most frequently altered families of oncogenes,” said Markus Warmuth, M.D., CEO of Monte Rosa. “Furthermore, we expect to declare a development candidate in our VAV1 program in the second quarter. This milestone will mark a significant advancement in our pipeline of MGD-based medicines in the field of immunology and inflammation. We believe the underlying biology and our preclinical data support the potential of our VAV1-directed MGD to provide clinical benefit in multiple autoimmune diseases. Our continued progress with our pipeline speaks to the power of our QuEEN discovery engine and our position as a leading molecular glue degrader company. Backed by a strong balance sheet and a sharp focus on developing impactful medicines, we look forward to continuing to further the development of our molecular glue therapeutics.”

FIRST QUARTER 2023 AND RECENT HIGHLIGHTS

- Presented preclinical data highlighting the preferential activity of MRT-2359, an orally bioavailable GSPT1-directed MGD, in MYC-driven tumor cells at the American Association for Cancer Research (AACR) Annual Meeting 2023 in Orlando, FL
- Appointed Jan Skvarka, Ph.D., MBA, an accomplished biopharmaceutical executive with extensive operational, strategic, and financial expertise to the Company’s Board of Directors

UPCOMING MILESTONES

- On track to announce initial clinical data, including pharmacokinetic (PK), pharmacodynamic (PD), safety, and available initial efficacy data from the Phase 1 part of the ongoing Phase 1/2 clinical trial evaluating MRT-2359 in MYC-driven tumors, including non-small cell lung cancer, small cell lung cancer, and other MYC-driven tumors, in the second half of 2023
- On track to advance multiple preclinical programs to development candidates in immunology, inflammation, and oncology, including declaring a VAV1 development candidate in the second quarter of 2023

FIRST QUARTER 2023 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2023 were $26.8 million, compared to $17.9 million for the first quarter of 2022. These increases were driven by the successful achievement of key milestones in our R&D organization, including the advancement of MRT-2359 in the clinic, the progression of our preclinical pipeline in lead optimization, and the continued development of the Company’s QuEEN platform for discovery efforts. The increase in R&D expenses was driven by increased headcount and laboratory-related expenses to achieve these milestones. Non-cash stock-based compensation constituted $2.1 million of R&D expenses for Q1 2023, compared to $1.2 million in the same period in 2022.

General and Administrative (G&A) Expenses: G&A expenses for the first quarter of 2023 were $7.5 million compared to $6.4 million for the first quarter of 2022. The increase in G&A expenses was 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 $1.8 million for the first quarter of 2023, compared to $1.1 million for the same period in 2022.

Net Loss: Net loss for the first quarter of 2023 was $32 million, compared to $23.9 million for the first quarter of 2022.

Cash Position and Financial Guidance: Cash, cash equivalents, restricted cash, and marketable securities as of March 31, 2023, were $237 million, compared to cash, cash equivalents, and restricted cash of $268.1 million as of December 31, 2022. The decrease of $31.1 million was primarily related to cash used to fund operations in the first quarter, including a seasonal reduction in accrued expenses. The company expects that its cash and cash equivalents will be sufficient to fund currently planned operations and capital expenditures into 2025.

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. 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, leading to anti-tumor activity in MYC-driven tumors.

About VAV1

VAV1, a Rho-family guanine nucleotide exchange factor, is a key signaling protein downstream of both the T and B cell receptors, whose expression is restricted to blood and immune cells, including T and B cells. Preclinical studies have shown that targeted degradation of VAV1 protein via an MGD modulates both T- and B-cell receptor-mediated activity *in vitro* and *in vivo*, as displayed by a significant decrease in cytokine secretion, as well as activity in preclinical models of immune diseases. VAV1-directed MGDs have the potential to provide therapeutic benefits in multiple autoimmune indications, such as multiple sclerosis, rheumatoid arthritis, and dermatological disorders.

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. The Company's lead program, MRT-2359, is being developed in a Phase 1/2 study in MYC-driven tumors, including non-small cell lung cancer and small-cell lung cancer. MGDs are small molecule protein degraders designed to employ the body's natural mechanisms to eliminate therapeutically relevant proteins selectively. 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, A.I./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 herein include, but are not limited to, statements about our product development activities, our ongoing clinical development of our GSPT1 degrader referred to as MRT-2359, including our expectations for the nature, significance, and timing for our disclosure of any initial data from our Phase 1/2 clinical trial of MRT-2359 in MYC-driven solid tumors, statements about the advancement of our preclinical programs, pipeline and the various products therein, including the ongoing development of our VAV1 directed molecular glue degrader program in the second quarter, our expectations regarding the potential clinical benefit for this program and our expectations of timings for the program, statements around the advancement and application of our pipeline and platform, and statements concerning our expectations regarding our ability to nominate and the timing of our nominations of additional targets, product candidates, and 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 those risks and uncertainties set forth in our most recent Annual Report on Form 10-K for the year ended December 31, 2023, filed with the U.S. Securities and Exchange Commission on March 16, 2023, 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)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 51,847	$ 54,912
Marketable securities	179,887	207,914
Other receivables	2,170	7,656
Prepaid expenses and other current assets	5,692	4,444
Current restricted cash	960	960
Total current assets	240,556	275,886
Property and equipment, net	33,266	27,075
Operating lease right-of-use assets	30,534	34,832
Restricted cash, net of current	4,321	4,318
Other long-term assets	351	278

Total assets	$ 309,028	$ 342,389
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 7,382	$ 7,862
Accrued expenses and other current liabilities	10,243	14,580
Current portion of operating lease liability	2,890	3,127
Total current liabilities	20,515	25,569
Defined benefit plan liability	1,512	1,533
Operating lease liability	43,275	43,874
Total liabilities	65,302	70,976
Commitments and contingencies		
Stockholders' equity		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 49,450,063 shares issued and 49,360,984 shares outstanding as of March 31, 2023; and 500,000,000 shares authorized, 49,445,802 shares issued and 49,323,531 shares outstanding as of December 31, 2022	5	5
Additional paid-in capital	507,688	503,696
Accumulated other comprehensive loss	(1,393)	(1,752)
Accumulated deficit	(262,574)	(230,536)
Total stockholders' equity	243,726	271,413
Total liabilities and stockholders' equity	$ 309,028	$ 342,389

Consolidated Statement of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three months ended March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 26,755	$ 17,915
General and administrative	7,504	6,387
Total operating expenses	34,259	24,302
Loss from operations	(34,259)	(24,302)
Other income (expense):		
Interest income, net	2,437	149
Foreign currency exchange (loss) gain, net	(85)	96
Gain on disposal of fixed assets	—	125
Loss on sale of marketable securities	(131)	—
Total other income	2,221	370
Net loss	$ (32,038)	$ (23,932)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.65)	$ (0.51)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	49,347,473	46,595,782
Comprehensive loss:		
Net loss	$ (32,038)	$ (23,932)
Other comprehensive loss:		
Provision for pension benefit obligation	14	34
Unrealized gain (loss) on available-for-sale securities	345	(146)
Comprehensive loss	$ (31,679)	$ (24,044)

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