Monte Rosa Therapeutics Announces First Development Candidate and Reports Third Quarter 2021 Financial Results and Business Updates

November 10, 2021

– Initiated Investigational New Drug (IND)-Enabling Activities for MRT-2359, a Molecular Glue Degrader Selectively Targeting GSPT1 –

– Presented Preclinical Data at AACR-NCI-EORTC Highlighting the Potential of GSPT1-directed Molecular Glue Degraders for the Treatment of Myc-driven Cancers –

BOSTON, Nov. 10, 2021 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (NASDAQ: GLUE), a biotechnology company developing novel molecular glue-based precision medicines, today reported business highlights and financial results for the third quarter, ended Sept. 30, 2021.

"This year has been marked by several exciting and significant milestones for Monte Rosa, culminating in the naming of our first development candidate, MRT-2359, selectively targeting GSPT1 for the treatment of cancers driven by one of the Myc family genes," said Markus Warmuth, M.D., CEO of Monte Rosa. "Preclinical data recently presented at AACR-NCI-EORTC underscores the potential of our molecular glue degraders to differentially induce cell death in Myc-addicted tumors. With the selection of MRT-2359 as our lead candidate, we are now positioned to rapidly advance our clinical development plan in both solid tumors and hematological malignancies. We have initiated IND-enabling studies and look forward to submitting our first IND to the FDA in mid-2022."

Owen Wallace, Ph.D., Chief Scientific Officer of Monte Rosa, added, "Advancing our first development candidate into IND-enabling activities is one of the most important milestones for our company to date. On a similar trajectory, our NEK7 degrader program has progressed into lead optimization, and we expect at least one additional program to move into lead optimization in 2021. In parallel, we continue to make important progress in the development of our unique and proprietary QuEEN™ platform and compound library, bringing us closer to our goal of tackling the previously undruggable target protein universe and fostering a new generation of precision medicine therapeutics."

THIRD QUARTER 2021 & RECENT HIGHLIGHTS

- **Selected first development candidate, MRT-2359, targeting GSPT1 and initiated IND-enabling activities.** The company's lead program targets GSPT1 for the treatment of cancers driven by one of the Myc family genes (c-Myc, N-Myc and L-Myc). The Myc transcription factors are some of the most frequently activated oncogenes in human cancers. Myc-driven cancer cells are highly addicted to protein translation. Because of the key role of GSPT1 in protein synthesis, GSPT1 degradation leads to apoptosis preferentially in these cells. MRT-2359 is a potent, selective and orally bioavailable GSPT1-directed molecular glue degrader *in vitro* and *in vivo*. MRT-2359 has been shown to induce tumor regression in multiple Myc-driven preclinical models of non-small cell lung cancer, small cell lung cancer and multiple myeloma.
- **Presented preclinical data highlighting potential of molecular glue degraders for the treatment of Myc-driven cancers.** The data, selected for a late-breaking poster presentation at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, demonstrate a novel link between GSPT1 and Myc-induced transcription and protein translation.
- **Presented at 4th Annual Targeted Protein Degradation Summit.** The presentation, titled, "Molecular Glue Degraders: From Serendipity to Rational Design," showcased the capabilities of Monte Rosa's QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates) platform and its impact on expanding target space.
- **Presented at the BioData World Congress.** The invited presentation showcased Monte Rosa's artificial intelligence platform and the company's pioneering work in AI and structural biology to identify molecular glue neosubstrates.
- **Added to the Russell 2000® and Russell 3000® Indexes** as part of second quarter initial public offering additions, effective Sept. 20, 2021.

UPCOMING MILESTONES + EVENTS

- Submit Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for MRT-2359 in mid-2022.
- Continue lead optimization for NEK7 and advance at least one additional program into lead optimization in 2021.
- Progress proprietary programs beyond GSPT1 and NEK7, including CDK2, VAV1, BCL11A and additional undisclosed targets.
- Present at upcoming investor conferences, including:
    - 33rd Annual Piper Sandler Virtual Healthcare Conference, Nov. 30-Dec. 2, 2021
    - 40th Annual J.P. Morgan Healthcare Conference, Jan. 9-13, 2022

THIRD QUARTER 2021 FINANCIAL RESULTS

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2021 were $15.1 million, compared to $5.5 million for the third quarter of 2020. The increase in R&D expense was primarily due to the expansion of research and development activities, including the advancement of development candidate MRT-2359, increased headcount and facilities in the United States and Switzerland, as well as corresponding increases in laboratory-related expenses.

General and Administrative (G&A) Expenses: G&A expenses for the third quarter of 2021 were $4.8 million, compared to $0.9 million for the third quarter of 2020. 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.

Net Loss: Net loss for the third quarter of 2021 was $19.8 million, compared to $6.6 million for the third quarter of 2020.

Cash Position and Financial Guidance: Cash and cash equivalents as of Sept. 30, 2021, were $367.0 million, compared to $41.7 million as of December 31, 2020. The company expects its cash and cash equivalents, including the aggregate net proceeds from the initial public offering, will be sufficient to fund planned operations and capital expenditures into late 2024.

About Monte Rosa

Monte Rosa Therapeutics is a biotechnology company developing a portfolio of novel molecular glue degrader precision medicines. These medicines are designed to employ the body's natural mechanisms to selectively eliminate therapeutically relevant proteins. The company has developed a proprietary protein degradation platform, called QuEEN™ (Quantitative and Engineered Elimination of Neosubstrates), that enables it to rapidly identify protein targets and molecular glue degrader, or MGD, product candidates that are designed to eliminate therapeutically relevant proteins in a highly selective manner. The company's drug discovery platform combines diverse and proprietary chemical libraries of small molecule protein degraders with in-house proteomics, structural biology, AI/machine learning-based target selection and computational chemistry capabilities to predict and obtain protein degradation profiles. Monte Rosa was launched from founding investor Versant Ventures' Ridgeline Discovery Engine and is headquartered in Boston, Mass., with research operations in both Boston and Basel, Switzerland.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding MRT-2359 including the timing for filing of an IND with the U.S. FDA, the development of the NEK7 and other programs, including timing for lead optimization and development candidate selection in each program, and the Company's expected cash runway. Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of the Company's program development activities and IND-enabling studies, the Company's ability to execute on its strategy, regulatory developments in the United States, the Company's ability to fund operations, and the impact that the current COVID-19 pandemic will have on the Company's clinical trials and pre-clinical studies, supply chain, and operations, as well as those risks and uncertainties set forth in its registration statement on form S-1 filed, the quarterly report on Form 10-Q to be filed for the quarter ended September 30, 2021, and its other filings with the United States Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. The Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

(in thousands, except share and per share amounts)	**September 30,**	**December 31,**
(unaudited)	**2021**	**2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 367,034	$ 41,699
Prepaid expenses and other current assets	3,485	1,892
Total current assets	370,519	43,591
Property and equipment, net	11,801	4,623
Restricted cash	1,729	1,164
Total assets	$ 384,049	$ 49,378
Liabilities, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 3,530	$ 7,066
Accrued expenses and other current liabilities	9,213	2,529
Preferred stock tranche obligations	—	19,680
Total current liabilities	12,743	29,275
Defined benefit plan liability	2,001	1,067
Total liabilities	14,744	30,342
Commitments and contingencies		
Convertible preferred stock, $0.0001 par value; 10,000,000 shares authorized, an no shares issued and outstanding as of September 30, 2021; and 77,631,514 shares authorized and 53,631,514 shares issued and outstanding as of December 31, 2020	—	67,764

Stockholders' equity (deficit)		
Common stock, $0.0001 par value; 500,000,000 shares authorized, 46,780,847 shares issued and 46,483,918 shares outstanding as of September 30, 2021; and 97,500,000 shares authorized, 2,180,803 shares issued and 1,685,534 shares outstanding as of December 31, 2020	5	1
Additional paid-in capital	469,845	404
Accumulated other comprehensive loss	(1,950)	(1,056)
Accumulated deficit	(98,595)	(48,077)
Total stockholders' equity (deficit)	369,305	(48,728)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 384,049	$ 49,378

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

(in thousands, except share and per share amounts)	**Three months ended September 30,**		**Nine months ended September 30,**	
(unaudited)	**2021**	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 15,115	$ 5,472	$ 39,025	$ 14,142
General and administrative	4,753	914	10,470	1,932
Total operating expenses	19,868	6,386	49,495	16,074
Loss from operations	(19,868)	(6,386)	(49,495)	(16,074)
Other income (expense):				
Interest income, net	13	2	33	—
Foreign currency exchange gain (loss), net	18	(174)	(96)	(149)
Changes in fair value of preferred stock tranche obligations, net	—	—	(960)	—
Total other (expense) income	31	(172)	(1,023)	(149)
Net loss	$ (19,837)	$ (6,558)	$ (50,518)	$ (16,223)
Provision for pension benefit obligation	(535)	—	(894)	—
Comprehensive loss	$ (20,372)	$ (6,558)	$ (51,412)	$ (16,223)
Reconciliation of net loss to net loss attributable to common stockholders				
Net loss	$ (19,837)	$ (6,558)	$ (50,518)	$ (16,223)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.43)	$ (4.29)	$ (2.85)	$ (11.01)
Weighted-average number of shares outstanding used in computing net loss per common share—basic and diluted	45,987,866	1,529,881	17,751,410	1,474,045

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