Monte Rosa Therapeutics Announces Global License Agreement with Novartis to Advance T and B Cell-modulating VAV1-directed Molecular Glue Degraders

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Agreement expected to accelerate MRT-6160 clinical development and broadly explore therapeutic opportunities across multiple indications

Monte Rosa to receive up-front payment of $150 million and is eligible to receive milestone payments, U.S. profit and loss share, and tiered royalties on ex-U.S. net sales

BOSTON, Oct. 28, 2024 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (Nasdaq: GLUE), a clinical-stage biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced a global exclusive development and commercialization license agreement with Novartis to advance VAV1 MGDs, including MRT-6160. MRT-6160 is currently in an ongoing Phase 1, single ascending dose (SAD)/multiple ascending dose (MAD) healthy volunteer study for immune-mediated conditions. Under the terms of the agreement, Novartis will obtain exclusive worldwide rights to develop, manufacture and commercialize MRT-6160 and other VAV1 MGDs and will be responsible for all clinical development and commercialization, starting with Phase 2 clinical studies. Monte Rosa remains responsible for completion of the ongoing Phase 1 clinical study of MRT-6160.[i]

“We are thrilled to announce this agreement with Novartis, a key player in immune-mediated conditions, and we are excited about the transformative potential it provides for Monte Rosa and MRT-6160. We expect this will accelerate and broaden the scope of clinical development of MRT-6160 to advance this unique, orally bioavailable modality while retaining substantial value for Monte Rosa. We believe the transaction validates our unique and industry leading QuEEN™ discovery engine, and it further increases our conviction to rationally design and develop highly selective and safe MGDs for undruggable targets, including in the areas of immunology and inflammation, metabolism, and genetic diseases,” said Markus Warmuth, M.D., Chief Executive Officer of Monte Rosa Therapeutics. “The financial resources provided by this agreement are expected to extend our operational runway, enable us to advance our pipeline to potential value-creating milestones and anticipated proof-of-concept readouts, and further leverage our QuEEN™ discovery engine.”

"Novartis has had a long-standing interest in molecular glue degraders, which offer the potential to tackle challenging biological targets. We are excited about their application in immunology and the early progress we have seen by Monte Rosa in this space and with MRT-6160. We look forward to advancing MRT-6160 and learning more about its potential to provide a new therapeutic option for people living with a range of immune-mediated conditions,” said Fiona Marshall, President of Biomedical Research at Novartis. “Novartis is committed to bringing forward new therapeutic options for these patients, and we are happy to be working with Monte Rosa to harness the potential of this approach to address unmet medical needs.”

MRT-6160 is a potent, highly selective, and orally bioavailable investigational degrader of VAV1, a key signaling protein downstream of both the T- and B-cell receptors. Preclinical studies have demonstrated deep degradation of VAV1, resulting in a significant decrease in cytokines linked to immune-mediated conditions, with no detectable effects on other proteins. MRT-6160 has shown promising activity in preclinical models of multiple immune-mediated conditions.[ii,iii]

Agreement Details and Financial Terms
Under the terms of the agreement, Novartis has agreed to pay Monte Rosa $150 million up front. Monte Rosa is eligible to receive up to $2.1 billion in development, regulatory, and sales milestones, beginning upon initiation of Phase 2 studies, as well as tiered royalties on ex-U.S. net sales. Monte Rosa will co-fund any Phase 3 clinical development and will share any profits and losses associated with the manufacturing and commercialization of MRT-6160 in the U.S.

The agreement is subject to customary closing conditions including regulatory clearance.

Monte Rosa plans to provide further information regarding its updated cash position and runway in its third quarter 2024 earnings update.

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 in the areas of oncology, autoimmune and inflammatory diseases, and more. 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 identify degradable protein targets

and rationally design MGDs with unprecedented selectivity. The QuEEN discovery engine enables access to a wide-ranging and differentiated target space of well-validated biology across multiple therapeutic areas. Monte Rosa has developed the industry's leading pipeline of MGDs, which spans oncology, autoimmune and inflammatory disease and beyond, and has a strategic collaboration with Roche to discover and develop MGDs against targets in cancer and neurological diseases previously considered impossible to drug. 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 the closing of the transaction with Novartis, obligations under the Agreement, the receipt of upfront, milestone and other payments under the Agreement, the future development and commercialization of VAV1 MGDs, including MRT-6160, our VAV1-directed degrader, referred to as MRT-6160, our expectations regarding the potential clinical scope and benefit for this program, including results of preclinical studies, and our expectations of timings for the program, statements around the advancement and application of our pipeline, and the planned update related to 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 14, 2024, 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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[i] Details about the study, MRT-6160 in a First-in-human Study in Healthy Subjects, can be found at ClinicalTrials.gov under the identifier NCT06597799.

[ii] Cartwright A et al. MRT-6160, a VAV1-Directed Molecular Glue Degrader, Reduces Joint Inflammation and Autoantibody Production in a Collagen-Induced Arthritis Autoimmune Disease Model. Poster presented at: Digestive Disease Week 2024; May 21, 2024; Washington, DC.

[iii] Cartwright A et al. MRT-6160, a VAV1-Directed Molecular Glue Degrader, Inhibits Disease Progression in a T-cell Transfer Mediated Colitis Model Concomitant with Reduced Calprotectin Expression. Poster presented at: EULAR 2024 – Annual European Congress of Rheumatology; June 14, 2024; Vienna, Austria.