



Monte Rosa Therapeutics Announces FDA Clearance of Investigational New Drug Application for MRT-2359, a GSPT1-directed Molecular Glue Degradator

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– Phase 1/2 Clinical Trial in Patients with MYC-driven Solid Tumors Expected to Dose in Q4 2022 –

BOSTON, Sept. 06, 2022 (GLOBE NEWSWIRE) -- Monte Rosa Therapeutics, Inc. (NASDAQ: GLUE), a biotechnology company developing novel molecular glue degrader (MGD)-based medicines, today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's investigational new drug application (IND) for MRT-2359, a potent and selective GSPT1-directed MGD. The company is on track with initiating a Phase 1/2 clinical trial of MRT-2359 in patients with MYC-driven solid tumors, including lung cancer, and expects to dose the first patient in the fourth quarter of 2022.

"The FDA's clearance of our first IND serves as a critical milestone for Monte Rosa and continues to validate our differentiated approach to protein degradation," said Markus Warmuth, M.D., CEO of Monte Rosa. "Molecular glue degraders hold tremendous promise in tackling the universe of previously undruggable proteins and fostering a new generation of precision medicine therapeutics. After reporting compelling preclinical data, we are excited to advance MRT-2359 into a Phase 1/2 study for patients with MYC-driven solid tumors who otherwise have limited treatment options."

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 (CRBN) 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. Our preclinical studies have shown that this addiction to MYC-induced protein translation creates a dependency on GSPT1. MRT-2359 exploits this vulnerability by inducing degradation of GSPT1, disrupting protein synthesis preferentially in MYC-driven cell lines and leading to anti-tumor activity in MYC-driven tumor models. A Phase 1/2 clinical study aims to evaluate the safety, tolerability and anti-tumor activity of MRT-2359.

About Monte Rosa

Monte Rosa Therapeutics is a biotechnology company developing a portfolio of novel molecular glue degrader (MGD) 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 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. 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, the ongoing development of our QuEEN™ platform and the advancement of our pipeline and the various products therein, our expectations of timing, including for initiation and patient dosing, 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. By their nature, these statements are subject to numerous risks and uncertainties, including the impact that the current COVID-19 pandemic will 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 U.S. 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.

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