News Release

miRecule Enters into Strategic Collaboration with Sanofi to Accelerate Discovery and Development of a Best-in-Class Antibody-RNA Conjugate to Treat Facioscapulohumeral Muscular Dystrophy (FSHD)

- *Partnership combines miRecule's unique RNA therapeutic discovery and conjugation platforms with Sanofi's* NANOBODY® *technology to create a groundbreaking treatment for FSHD*

- *miRecule will receive an upfront payment with potential future milestone payments of nearly $400 million, in addition to tiered royalties*

- *Collaboration marks the first licensing transaction leveraging miRecule's proprietary DREAmiR™ discovery platform, validating foundational science, and bolstering commitment to further expansion of the company's RNA therapeutic pipeline*

GAITHERSBURG, Maryland– October 4, 2022 – miRecule, Inc., an innovator of next-generation RNA therapeutics, today announced a strategic collaboration and exclusive license agreement with Sanofi to develop and commercialize a best-in-class antibody-RNA conjugate (ARC) for the treatment of facioscapulohumeral muscular dystrophy (FSHD). The collaboration marks miRecule's first licensing transaction leveraging its proprietary DREAmiR platform.

FSHD is the second most common type of muscular dystrophy – affecting more than one million individuals worldwide with no approved treatments. Patients with causative genetic mutations experience lifelong deterioration of muscle function and progressive disability. The collaboration will combine miRecule's anti-DUX4 RNA therapy (discovered through its proprietary DREAmiR platform) with Sanofi's proprietary muscle-targeted NANOBODY technology to join the two molecules into an ARC utilizing miRecule's NAVIgGator™ conjugation and formulation chemistry. The potential resulting best-in-class therapy may become a disease-modifying treatment that selectively targets and suppresses the underlying cause of FSHD in muscle tissue. This groundbreaking approach would enable FSHD patients to resume their normal course of aging free from the debilitating effects of this progressive disease.

Under the terms of the collaboration agreement, miRecule will grant Sanofi an exclusive worldwide license to intellectual property rights to the FSHD therapy. miRecule and Sanofi will collaborate on research activities through lead candidate selection. Following candidate selection, Sanofi will assume sole responsibility for IND enabling studies and subsequent development and commercialization activities globally. miRecule will receive an upfront payment and is eligible for near-term milestone payments, which combined could exceed $30 million. Additional development, regulatory, and commercial milestone payments could raise the total to nearly $400 million for advancement of the FSHD drug candidate, which will be exclusively developed and commercialized by Sanofi. miRecule is also eligible to receive tiered royalties on global net sales of the approved collaboration product.

Pablo Sardi
Global Head of Rare and Neurologic Diseases Research, Sanofi

"We look forward to working with miRecule to bring together our two groundbreaking technologies synergizing in a best-in-class therapy designed to suppress the underlying cause of FSHD. We hope that this will enable patients to live a life free from the debilitating symptoms of the disorder. We are excited to embark on this collaboration with miRecule as we work together to bring hope to the FSHD community."

Anthony Saleh
Founder and Chief Executive Officer, miRecule

"We are thrilled to enter our first major licensing transaction with a partner of Sanofi's caliber and capabilities as a global leader in the development and commercialization of rare disease therapies. Our goal since initiating this program has been to develop a treatment to allow FSHD patients to live a normal life. The philosophy driving our DREAmiR discovery platform focuses on patient centered drug development and strong scientific decision making. We believe Sanofi shares these core values on creating life changing therapies, making this is an ideal partnership to bring forward our anti-DUX4 RNA therapy."

miRecule's founder and CEO has a strong commitment to developing a therapy to treat FSHD as the disorder runs in his family. miRecule started its program in 2019 with strong support from the patient and academic community, receiving funding from the FSHD Society, the Friends of FSH Research, and National Institute of Neurological Disorders and Stroke (NINDS, Grant 5R44NS119147-02). Sanofi and miRecule look forward to continuing to work with these organizations to help bring forward a groundbreaking treatment for FSHD.

About miRecule

miRecule, Inc. is a biotechnology company focused on advancing next-generation RNA therapeutics utilizing personalized genomic patient data to create highly tailored therapeutics treating a variety of diseases, including cancer and muscular dystrophy. The company's proprietary DREAmiR™ genomics-based discovery platform identifies critical RNA targets for drug development in specific subsets of patients that would benefit from treatment. miRecule then creates proprietary RNA therapeutics with improved pharmacology and joins them with antibodies for targeted delivery to disease tissue. miRecule's lead candidate, MC-30 for head and neck cancer, replaces the potent tumor suppressor activity of microRNA-30 which is lost in half of head and neck cancer patients. miRecule's second program that is now licensed by Sanofi, MC-DX4 for the treatment of Facioscapulohumeral muscular dystrophy (FSHD), eliminates expression of the DUX4 gene, which causes the disease in 95% of FSHD patients. For more information, please visit: www.mirecule.com.

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