Rain Therapeutics Announces Patient Referral Partnership for the Planned MDM2-Amplified Phase 2 Basket Trial of RAIN-32

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Clinical trial for MDM2-amplified cancers expected to commence in second half of 2021

NEWARK, Calif., June 02, 2021 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (“Rain”), a clinical-stage company developing precision oncology therapeutics, today announced a patient referral partnership with Caris Life Sciences (“Caris”). Under the terms of the partnership, Caris will provide patient referral services using their molecular intelligence (MI) trials platform for Rain’s planned Phase 2 MDM2-amplified tumor-agnostic basket trial for RAIN-32, an oral MDM2 inhibitor in patients with certain solid tumors with pre-specified MDM2 amplification levels and wild type p53.

“We are thrilled to partner with Caris, a company that shares our precision oncology mission, to identify patients for our tumor agnostic, MDM2-amplified basket trial strategy,” said Robert Doebele, M.D., Ph.D., co-founder, president and chief scientific officer of Rain. “Caris’ whole exome and whole transcriptome tumor sequencing assays will be critical for enrollment for the Phase 2 study, which is expected to commence in the second half of 2021.”

“Caris puts the patient at the center of everything we do, and we are pleased to partner with Rain on this novel tissue-agnostic clinical study,” said Brian Lamon, Ph.D., Chief Business Officer, Head of BioPharma Business Development for Caris. “As the pioneer and industry leader in molecular profiling, this partnership builds upon our mission to save and extend patients’ lives through the most comprehensive molecular and artificial intelligence available in the industry.”

About RAIN-32
RAIN-32 (milademetan, formerly known as DS-3032), is a small molecule, oral inhibitor of mouse double minute 2 (MDM2), which is oncogenic in numerous cancers. Rain in-licensed RAIN-32 in September 2020 based on the results of a Phase 1 clinical trial, which demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors. This trial also validated a rationally-designed dosing schedule that has been shown to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition, unlocking the potential for RAIN-32 in a broad range of MDM2- dependent cancers. Based on these data, we anticipate commencing a pivotal Phase 3 trial in LPS in the second half of 2021, a Phase 2 tumor-agnostic basket trial in certain solid tumors in the second half of 2021 and a Phase 2 trial in intimal sarcoma by early 2022. RAIN-32 has received U.S. Food and Drug Administration (FDA) Orphan Drug Designation for patients with liposarcoma.

About Rain Therapeutics Inc.
Rain Therapeutics Inc. is a clinical-stage precision oncology company developing therapies that target oncogenic drivers for which it is able to genetically select patients it believes will most likely benefit. This approach includes using a tumor-agnostic strategy to select patients based on their tumors’ underlying genetics rather than histology. Rain’s lead product candidate, RAIN-32 (milademetan, formerly known as DS-3032), is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. In addition to RAIN-32, Rain is also developing a preclinical program that is focused on inducing synthetic lethality in cancer cells by inhibiting RAD52. For more information, visit www.rainthera.com.

About Caris Life Sciences
Caris Life Sciences® is a leading innovator in molecular science and artificial intelligence focused on fulfilling the promise of precision medicine through quality and innovation. The company’s suite of market-leading molecular profiling offerings assesses DNA, RNA and proteins to reveal a molecular blueprint that helps physicians and cancer patients make more precise and personalized treatment decisions. MI Exome™ whole exome sequencing with 22,000 DNA genes, and MI Transcriptome™ whole transcriptome sequencing with 22,000 RNA genes along with cancer-related pathogens, bacteria, viruses and fungi analysis run on every patient provides the most comprehensive and clinically relevant DNA and RNA profiling available on the market.

Caris is also advancing precision medicine with Caris Artificial Intelligence, combining its market leading service offering, Caris Molecular Intelligence® with its proprietary artificial intelligence analytics engine, DEAN™, to analyze the whole exome, whole transcriptome and complete cancer proteome. This information, coupled with mature clinical outcomes on thousands of patients, provides unmatched molecular solutions for patients, physicians, payers and biopharmaceutical organizations.

Caris Pharmatech™ is changing the paradigm and streamlines the clinical trial process by connecting biopharma companies with research-ready oncology sites for clinical trials. With over 420 research sites within the Caris Pharmatech Just-In-Time (JIT) Oncology Network, biopharma companies can identify and enroll more patients, faster. Caris Pharmatech Just-In-Time Clinical Trial Solutions focus on rapid site activation and patient enrollment to streamline the drug development process. By implementing Caris’ Just-In-Time Trial-Matching System, Caris will automatically match patients to clinical trials and sites can be activated and eligible to enroll patients within one week.

Headquartered in Irving, Texas, Caris Life Sciences has offices in Phoenix, Denver, New York, and Basel, Switzerland. Caris provides services throughout the U.S., Europe, Asia and other international markets. To learn more, please visit CarisLifeSciences.com or follow us on Twitter (@CarisLS).

Forward Looking Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the federal securities laws, including, but not limited to, our expectations regarding our clinical trials. Words such as “may,” “might,” “will,” “objective,” “intend,” “should,” “could,” “can,” “would,” “expect,” “believe,” “design,” “promises,” “estimate,” “predict,” “potential,” “develop,” “plan” or the negative of these terms, and similar expressions, or statements regarding intent, belief, or current expectations, are forward-looking statements. While we believe these forward-looking statements are reasonable, undue reliance should not be placed on any such forward-looking statements, which are based on information available to us on the date of this release. These forward-looking statements are based upon current estimates and assumptions and are subject to various risks and uncertainties (including, without limitation, those set forth in our filings with the U.S. Securities and Exchange Commission (the “SEC”)), many of which are beyond our control and subject to change. Actual results could be materially different. Risks and uncertainties include: expectations regarding the initiation our Phase 2 clinical trial; expectations regarding the partnership with Caris and other risks and uncertainties identified in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021, filed with the U.S. SEC. We claim the protection of the Safe Harbor contained in the Private Securities Litigation Reform Act of 1995 for forward-looking statements. We expressly disclaim any obligation to update or alter any statements whether as a result of new information, future events or otherwise, except as required by law.

Rain Media Contact:
Grace Fotiades
LifeSci Communications
+1.646.876.5026
gfotiades@lifescicomms.com

Caris Life Sciences Media Contact:
Lindsey Bailys
GCI Health
1-212-798-9884
lindsey.bailys@gcihealth.com