Rain Therapeutics Doses First Patient in Phase 2 Basket Trial of Miladametan for MDM2-Amplified Advanced Solid Tumors (MANTRA-2)

November 19, 2021

The interventional, multicenter, open-label Phase 2 basket trial will evaluate the safety and efficacy of miladametan in patients with MDM2-amplified advanced solid tumors

NEWARK, Calif., Nov. 19, 2021 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), ("Rain"), a late-stage company developing precision oncology therapeutics, today announced that the first patient has been dosed in the multicenter, single arm, open-label, Phase 2 basket trial evaluating miladametan, an oral mouse double minute 2 (MDM2) inhibitor, for the treatment of MDM2-amplified advanced solid tumors.

"The Rain team has worked extraordinarily hard to now commence our second clinical trial for miladametan," said Avanish Vellanki, chief executive officer of Rain Therapeutics. "The MANTRA-2 study reflects our precision oncology focus to base our development strategy on the underlying biological drivers in cancer, now across a tumor-agnostic clinical trial. We have also identified a level of gene amplification of MDM2 that we believe will select for patients most likely to benefit."

Richard Bryce, MBChB, chief medical officer of Rain Therapeutics continued, "the opening of our Phase 2 basket trial is a significant step forward in leveraging the safety profile of miladametan for patients with advanced tumors that exhibit wild-type p53 and amplified MDM2 who do not respond, or stop responding, to standard-of-care therapy."

The MANTRA-2 trial is designed to evaluate the safety and efficacy of miladametan in patients with advanced or metastatic solid tumors refractory or intolerant to standard-of-care therapy and that exhibit wild-type p53 and a prespecified minimum MDM2 gene copy number. Approximately 65 patients are anticipated to be enrolled to receive miladametan. The primary endpoint of the trial is objective response rate as measured by RECIST criteria. Secondary endpoints include duration of response, disease control rate progression-free survival by investigator assessment, overall survival and, and growth modulation index. An interim analysis from MANTRA-2 is anticipated in the second half of 2022.

About Miladametan
Miladametan is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. Miladametan has already demonstrated antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors in a Phase 1 clinical trial, supporting a rationally-designed dosing schedule to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition. Miladametan is being evaluated in an ongoing Phase 3 clinical trial in patients with LPS (MANTRA), as well as a Phase 2 tumor-agnostic basket trial in certain solid tumors (MANTRA-2). Rain Therapeutics also anticipates commencing a Phase 2 clinical trial of miladametan (MANTRA-3), for the treatment of patients with Merkel cell carcinoma who are polyoma virus-positive and refractory to immune checkpoint inhibition (ICI), in mid-2022. Miladametan has received U.S. Food and Drug Administration Orphan Drug Designation for patients with LPS.

About Rain Therapeutics Inc.
Rain Therapeutics Inc. is a late-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, miladametan, is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. In addition to miladametan, Rain is also developing a preclinical program that is focused on inducing synthetic lethality in cancer cells by inhibiting RAD52.

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. Such forward-looking statements include statements regarding, among other things, Rain's ongoing and planned studies for miladametan. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans," "will," "anticipates," "goal," "potential," "expects" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Rain's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with Rain's business in general and limited operating history, difficulty enrolling patients in our clinical trials, Rain's reliance on third parties to conduct and support its preclinical studies and clinical trials, the results of Rain's clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities, and the other risks described in Rain's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Rain undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

Media Contact
Jordyn Temperato
LifeSci Communications
+1.646.876.5196

jtemperato@lifescicomms.com

Investor Contact:
Bob Yedid
LifeSci Advisors
+1.646.597.6989
bob@lifesciadvisors.com