Rain Therapeutics Announces Completion of Enrollment in Phase 3 MANTRA Trial for Milademetan in Liposarcoma

– Phase 3 MANTRA trial completed enrollment five months ahead of previous guidance –

– MANTRA topline data anticipated in 1H 2023 –

– Management to host 2Q 2022 Earnings Call today at 5:00 PM Eastern Time –

NEWARK, Calif., August 4, 2022 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a late-stage biotechnology company developing precision oncology therapeutics, today announced completion of enrollment in its Phase 3 MANTRA randomized, global, registrational trial of its lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53. The trial targeted an enrollment of 160 patients and completed enrollment five months ahead of schedule with 175 patients.

The MANTRA trial is evaluating milademetan compared to an approved standard of care in patients with well-differentiated / dedifferentiated (WD/DD) liposarcoma (LPS) that have progressed on at least one prior systemic therapy including an anthracycline. MANTRA is an event-driven trial with progression-free survival (PFS) as the primary endpoint, which will be analyzed upon reaching 105 events. The MANTRA trial is powered to show a doubling of PFS versus the standard of care.

"We are excited to have achieved a milestone in our milademetan clinical program. We believe the rapid enrollment in MANTRA reflects a patient population in LPS that may be larger than expected, and that exhibits a significant unmet medical need," said Avanish Vellanki, co-founder and chief executive officer of Rain.

Richard Bryce, MBChB, Rain's chief medical officer continued, "The rapid enrollment five months ahead of schedule, across 70 international sites, also reflects the ability of the Rain team to expedite milademetan development for patients in significant need. Rain is grateful for the patients and clinicians who made the completion of enrollment in MANTRA possible, and we remain committed to the continued development of milademetan as a targeted therapy to reactivate p53 across a variety of MDM2-dependent cancers."

About MANTRA Trial

The MANTRA trial, a randomized, multicenter, open-label, Phase 3 registrational study, is designed to evaluate the safety and efficacy of milademetan compared to trabectedin, a current standard of care, in patients with unresectable or metastatic DD LPS with or without a WD LPS component that has progressed on one or more prior systemic therapies, including at least one anthracycline-based therapy. 175 patients were enrolled and randomized in a 1:1 ratio to receive milademetan or trabectedin. The primary objective of the trial is to compare progression-free survival (PFS) by blinded independent review between the milademetan treatment arm and the trabectedin control arm. Secondary endpoints include overall survival, PFS by investigator assessment, objective response rate, duration of response, disease control rate, safety and patient reported outcomes.

About Milademetan

Milademetan (also known as RAIN-32) is an oral small molecule, inhibitor of the MDM2-p53 complex that reactivates p53. Milademetan has already demonstrated antitumor activity in an MDM2-amplified subtype of LPS and other solid tumors in a Phase 1 clinical trial, supported by a rationally-designed dosing schedule to mitigate safety concerns and widen the therapeutic window of MDM2 inhibition. Milademetan 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 anticipates commencing a Phase 2 clinical trial of milademetan (MANTRA-3), for the treatment of patients with wildtype p53 Merkel cell carcinoma who are also refractory to immune checkpoint inhibition (ICI), in the fourth quarter of 2022, as well as a Phase 1/2 clinical trial to evaluate the safety, tolerability and efficacy of milademetan in combination with Roche's atezolizumab in patients with loss of cyclin-dependent kinase inhibitor 2A (CDKN2A) and wildtype p53 advanced solid tumors (MANTRA-4), also in the fourth quarter of 2022. Milademetan has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) for patients with LPS.

About Well-Differentiated/Dedifferentiated Liposarcoma (WD/DD LPS)

Liposarcoma is a rare cancer originating from fat cells located in the soft tissues of the body. It is a malignant cancer that can spread to other parts of the body. WD LPS is less aggressive and tends to be a large painless mass found in deeper tissues. DD LPS is more aggressive, arising from WD LPS, and is usually found in tissue behind the abdominal area or the extremities. WD/DD LPS are the most frequent subtypes of LPS and share common genomic abnormalities, predominantly MDM2 gene amplification. The incidence of LPS is estimated at approximately 3,500 patients annually in the U.S. for which there are few effective treatment options.

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, milademetan, is a small molecule, oral inhibitor of MDM2-p53 complex that reactivates p53. In addition to milademetan, 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 trials for milademetan, including timing for top-line data, anticipated statistical powering, and expectations regarding the sufficiency of capital resources. 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, Rain's reliance on third parties to conduct and support its preclinical studies and clinical trials, and the other risks described in Rain's Annual Report on Form 10-K for the year ended December 31, 2021 and subsequent 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.

Investor Contact

Bob Yedid
LifeSci Advisors
646-597-6989
bob@lifesciadvisors.com

Media Contact
Jordyn Temperato
LifeSci Communications
jtemperato@lifescicomms.com