



Rain Therapeutics Plans Phase 2 Merkel Cell Carcinoma Clinical Trial (MANTRA-3) of Milademetan

November 9, 2021

The Merkel cell trial will be prioritized over the previously planned Phase 2 trial in patients with intimal sarcoma, and will evaluate milademetan in patients with IO-refractory disease

Rain to host first annual research and development (R&D) day at 11am EST today

NEWARK, Calif., Nov. 09, 2021 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), (Rain), a late-stage company developing precision oncology therapeutics, today announced its plan to commence a Phase 2 clinical trial, named MANTRA-3, evaluating the efficacy of milademetan, an oral mouse double minute 2 (MDM2) inhibitor, as a monotherapy for the treatment of patients with Merkel cell carcinoma (MCC) refractory to immune checkpoint inhibition (ICI) in mid-2022.

"We are very excited about the recent preclinical data generated for milademetan in Merkel cell carcinoma, and believe the data warrant moving the program into a clinical study," said Avanish Vellanki, co-founder and chief executive officer of Rain. "We hope to address the immense unmet medical need for patients after relapsing on first-line checkpoint inhibitors."

Recent data presentations at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics demonstrated potent in vitro and in vivo activity of milademetan in several MCC models.

Rain will prioritize its financial resources towards a Phase 2 clinical trial of milademetan in MCC and replace the previously planned Phase 2 clinical trial of milademetan in intimal sarcoma.

The MANTRA-3 trial is designed to evaluate the efficacy of milademetan as a monotherapy in patients with MCC that have progressed on immune checkpoint inhibitors. Approximately 30 patients are expected to be enrolled to receive milademetan. The primary endpoint of the trial is objective response rate (ORR) as measured by RECIST criteria. Secondary endpoints include duration of response, disease control rate, progression free survival by investigator assessment, growth modulation index, overall survival and safety.

R&D Day Webinar

Rain will host its first annual R&D Day at 11am EST today, November 9, 2021 which will feature presentations from prominent key opinion leaders (KOLs) in oncology to discuss cancer populations where tumors may rely on MDM2-mediated p53 loss. Interested parties can access and register for the webinar [here](#). A replay of the event will also be archived on the Company's corporate website [here](#).

About Merkel Cell Carcinoma

Merkel cell carcinoma is a rare, aggressive type of skin cancer that frequently travels to other parts of the body. An aging population is driving increases in the number of new MCC cases and the incidence of MCC is predicted to reach >3,000 cases in 2025 in the United States alone. Immune checkpoint inhibitors are the approved first line strategy for patients with relapsed or metastatic MCC, but many patients do not respond or stop responding to these therapies.

About Milademetan

Milademetan is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. Milademetan has already demonstrated meaningful antitumor activity in an MDM2-amplified subtype of liposarcoma (LPS) and other solid tumors in a Phase 1 clinical trial, validating 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) with a planned Phase 2 tumor-agnostic basket trial in certain solid tumors (MANTRA-2) anticipated to start in the fourth quarter of 2021. Rain Therapeutics also anticipates commencing a Phase 2 clinical trial of milademetan (MANTRA-3), for the treatment of patients with Merkel cell carcinoma refractory to immune checkpoint inhibition (ICI), in mid-2022. Milademetan 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, milademetan, is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. 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 studies for milademetan, including the trial design for MANTRA-3, and the potential for milademetan. 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 given the relatively small patient populations, Rain's reliance on third parties to conduct and support its preclinical studies and clinical trials, and the other risks described in Rain's Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 and 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.

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