Rain Therapeutics and Roche to Collaborate on Clinical Trial of Milademetan Combination with Anti-PD-L1 Immunotherapy for Various Solid Tumor Indications

Combination Strategy of Milademetan and Atezolizumab Will Evaluate the Opportunity for MDM2-Checkpoint Inhibition in Genetically Selected Patient Populations

NEWARK, Calif., January 5, 2022 (GLOBE NEWSWIRE) -- Rain Therapeutics Inc. (NasdaqGS: RAIN), ("Rain"), a late-stage company developing precision oncology therapeutics, today announced a clinical supply agreement with Roche (SIX: RO, ROG; OTCQX: RHHBY) for the supply of the anti-Programmed Death Ligand-1 (PD-L1) monoclonal antibody, atezolizumab.

Clinical trials are planned to evaluate milademetan, an oral mouse double minute 2 (MDM2) inhibitor, in combination with atezolizumab for the treatment of patients in genetically selected populations. Under this agreement, Rain is the sponsor of the anticipated clinical trials, and Roche will supply atezolizumab.

An initial Phase 1 clinical trial is planned to evaluate the safety, tolerability and efficacy of milademetan in combination with atezolizumab in patients with loss of cyclin-dependent kinase inhibitor 2A (CDKN2A) and wildtype p53 advanced solid tumors. CDKN2A encodes for the tumor suppressor p14ARF, an inhibitor of MDM2, and the loss of CDKN2A may lead to MDM2-dependent cancers. Rain anticipates the start of the Phase 1 clinical trial in the second half of 2022. Subsequent Phase 2 clinical trials evaluating the combination of milademetan and atezolizumab may span various additional tumor types.

"We are excited to evaluate the combination of MDM2 inhibition and cancer immunotherapy with milademetan and atezolizumab, and believe it presents a strong mechanistic rationale," said Avanish Vellanki, co-founder and chief executive officer of Rain. "We believe the therapeutic index afforded by milademetan will enable synergistic combination with PD-L1 checkpoint inhibition and are excited about the potential for favorable results from the Phase 1 study to support moving into subsequent studies across various MDM2-dependent cancers."

About Milademetan

Milademetan is a small molecule, oral inhibitor of MDM2, which is oncogenic in numerous cancers. Milademetan 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. 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 also anticipates commencing a Phase 2 clinical trial of milademetan (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. Milademetan has received Orphan Drug Designation from the U.S. Food and Drug Administration (FDA) 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 planned Phase 1 clinical trial and potential Phase 2 clinical trials for milademetan in combination with atezolizumab, the timing of the planned Phase 1 clinical trial and the potential results of the planned Phase 1 clinical trial. 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 LPS patient population, 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 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.

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