Rain Therapeutics Reports Second Quarter 2022 Financial Results and Highlights Recent Progress

– Quarter-end cash position of $105.7 million provides ample cash runway into mid-2024 –

– Phase 3 MANTRA trial completed enrollment five months ahead of previous guidance; topline data anticipated in first half of 2023 –

– Phase 2 MANTRA-2 trial ongoing as planned with interim data anticipated in fourth quarter 2022 –

– Management to host conference call and webcast 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 with a lead product candidate, milademetan, an oral, small molecule inhibitor of the MDM2-p53 complex that reactivates p53, today reported financial results for the second quarter and six months ended June 30, 2022, along with an update on the Company's key developments, business operations and upcoming milestones.

"Rain's focus on clinical execution of the milademetan program was evidenced by the completion of enrollment of our Phase 3 MANTRA trial five months ahead of previous guidance. 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. "With the ongoing enrollment in the pan-tumor MANTRA-2 study, additional clinical studies anticipated to commence before year-end, and alongside a cash runway into mid-2024, we believe Rain is in a strong position to generate significant new data for the milademetan franchise."

Key Developments, Presentations, Operational Updates and Upcoming Milestones

- Key Presentations
  - Poster presented at 2022 American Association for Cancer Research (AACR) Annual Meeting titled, "Exploration of MDM2 gene amplification, co-mutation status, and prognosis in solid tumors"
  - Poster presented at 2022 American Society of Clinical Oncology (ASCO) Annual Meeting titled "Using CDKN2A loss in the context of wildtype TP53 to predict sensitivity for the MDM2 inhibitor milademetan"

- Phase 3 Dedifferentiated Liposarcoma Trial (MANTRA)
  - Enrollment now closed with 175 patients enrolled
  - Topline data anticipated in the first half of 2023

- Phase 2 Basket Trial of Milademetan for MDM2-Amplified Advanced Solid Tumors (MANTRA-2)
  - Enrollment ongoing and interim data anticipated in the fourth quarter of 2022

- Phase 2 Trial for Milademetan in Merkel Cell Carcinoma (MANTRA-3)
  - Trial commencement anticipated in the fourth quarter of 2022

- Phase 1/2 Basket Trial in Advanced Solid Tumors Exhibiting Loss of the CDKN2A Gene (MANTRA-4)
  - Commencement of combination trial of milademetan with Roche's FDA-approved IO therapy, atezolizumab, anticipated in the fourth quarter of 2022

Second Quarter Financial Results

For the three and six months ended June 30, 2022, Rain reported a net loss of $17.6 million and $35.0 million, respectively, as compared to a net loss of $8.2 million and $15.0 million for the same periods in 2021, respectively.

Research and development (R&D) expenses were $14.3 million and $27.8 million for the three and six months ended June 30, 2022, respectively, as compared to $5.5 million and $10.8 million for the same periods in 2021, respectively. The increases were primarily driven by the ongoing Phase 3 trial in dedifferentiated liposarcoma (MANTRA) and Phase 2 tumor-agnostic basket trial (MANTRA-2), as well as personnel costs. Non-cash stock-based compensation expenses included in R&D expenses were approximately $1.2 million and $2.1 million in the three and six months ended June 30, 2022, respectively, as compared to $0.6 million and $0.8 million in the same periods in 2021, respectively.

General and administrative (G&A) expenses were $3.5 million and $7.4 million for the three and six months ended June 30, 2022, respectively, as compared to $2.7 million and $4.2 million for the same periods in 2021, respectively. The increases were primarily due to higher costs associated with Rain becoming a public company, including personnel, legal, outside consulting, and accounting and audit fees. Non-cash stock-based compensation expense included in G&A expenses were approximately $0.2 million and $0.6 million for the three and six months ended June 30, 2022, as compared to $0.2 million for each of the same periods in 2021.

Total non-cash stock-based compensation expense were approximately $1.4 million and $2.7 million for the three and six months ended June 30, 2022, respectively, as compared to $0.8 million and $1.0 million for the same periods in 2021, respectively.

As of June 30, 2022, Rain had $105.7 million in cash, cash equivalents and short-term investments. Rain anticipates that its quarter-end cash position will provide runway into mid-2024 and therefore believes the milademetan program is well-funded.

As of June 30, 2022, Rain had approximately 26.5 million shares of common stock outstanding.

Second Quarter 2022 Results Conference Call and Webcast Details

The management of Rain Therapeutics will host a conference call and webcast for the investment community today, August 4, 2022 at 2:00 pm PT (5:00 pm ET). A live webcast may be accessed here: https://edge.media-server.com/mmc/p/tvv3pskx.The conference call can be accessed by dialing 1 (888) 394-8218 (U.S. Toll Free) / 1 (323) 701-0225 (International). The passcode for the conference call is 1307426.

Replay of the call will be available by visiting the “Events” section of the Rain website after the conclusion of the presentation and will be archived on the Rain website for 30 days.

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 liposarcoma (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), 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 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 patient enrollment, timing for topline and interim data, timing for the commencement of planned trials, expected trial designs, 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 ability to execute on its strategy; Rain's reliance on third parties to conduct and support its preclinical studies and clinical trials, positive results from a clinical trial may not necessarily be predictive of the results of future or ongoing clinical studies; the effect of the COVID-19 pandemic on Rain's clinical trials and business operations, the impact of general economic, health, industrial or political conditions in the United States or internationally, the sufficiency of Rain's capital resources and its ability to raise additional capital, 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.

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Rain Therapeutics Inc.
Condensed Consolidated Statements of Operations
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 14,257	$ 5,489	$ 27,812	$ 10,817
General and administrative	3,461	2,700	7,356	4,180
Total operating expenses	17,718	8,189	35,168	14,997
Loss from operations	(17,718)	(8,189)	(35,168)	(14,997)
Other income:				
Interest income	107	6	163	14
Net loss	$ (17,611)	$ (8,183)	$ (35,005)	$ (14,983)
Net loss per share, basic and diluted	$ (0.66)	$ (0.39)	$ (1.32)	$ (1.23)
Weighted-average shares used in computing net loss per share, basic and diluted	26,529,482	20,825,334	26,520,662	12,225,929

SUMMARY BALANCE SHEET DATA
(in thousands)

	June 30, 2022	December 31, 2021
	(unaudited)	(audited)
Cash, cash equivalents and short-term investments	$ 105,753	$ 140,218
Total assets	$ 110,663	$ 147,140
Stockholders' equity	$ 98,285	$ 130,504