RAPT Therapeutics Announces Clinical Hold on Studies Evaluating Zelnecirnon

February 20, 2024

- RAPT to host a conference call today at 8:30 am ET -

SOUTH SAN FRANCISCO, Calif., Feb. 20, 2024 (GLOBE NEWSWIRE) -- RAPT Therapeutics, Inc. (Nasdaq: RAPT), a clinical-stage, immunology-based biopharmaceutical company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology, today announced that the U.S. Food and Drug Administration (FDA) has verbally notified the company that a clinical hold has been placed on the company's Phase 2b trial of zelnecirnon (RPT193) in atopic dermatitis and its Phase 2a trial in asthma. The company expects to receive a formal clinical hold letter from the FDA. The clinical hold determination was based on a serious adverse event of liver failure in one patient in the atopic dermatitis trial, the cause of which is currently unknown but which has been characterized as potentially related to zelnecirnon. Dosing of zelnecirnon has been halted in both clinical trials, as has enrollment of new trial participants. The clinical hold does not apply to RAPT's ongoing trial of tivumecirnon (FLX475) in oncology.

A total of approximately 350 patients have been enrolled across three trials evaluating zelnecirnon - the two Phase 2 trials and an earlier Phase 1a/1b study. No evidence of liver toxicity has been observed with any other trial participant. Additionally, no evidence of liver toxicity was observed in nonclinical studies.

RAPT is undertaking a thorough investigation of this case, which involved a patient with a complex medical history, including a history of drug allergy to dupilumab, autoimmune disease resulting in thyroid hormone replacement therapy and use of an herbal supplement known to be associated with liver failure, as well as a reported COVID-19 infection during the time of the event.

"This is an unfortunate and unexpected event, and we are working diligently to get more information on this case," said Brian Wong, M.D., Ph.D., President and CEO of RAPT Therapeutics. "Patient safety is our top priority and we will work with the FDA to resolve this as quickly as possible."

Webcast Conference Call Information
RAPT will host a webcast conference call today, February 20, 2024 at 8:30 a.m. ET. To join the conference call via phone and participate in the live Q&A session, please pre-register online here to receive a telephone number and unique passcode required to enter the call. The live webcast and audio archive of the presentation may be accessed on the RAPT Therapeutics website at https://investors.rapt.com/events-and-presentations.

About RAPT Therapeutics, Inc.
RAPT Therapeutics is a clinical-stage, immunology-based therapeutics company focused on discovering, developing and commercializing oral small molecule therapies for patients with significant unmet needs in inflammatory diseases and oncology. Utilizing its proprietary discovery and development engine, the Company is developing highly selective small molecules designed to modulate the critical immune drivers underlying these diseases. RAPT has discovered and advanced two unique drug candidates, zelnecirnon (RPT193) and tivumecirnon (FLX475), each targeting C-C motif chemokine receptor 4 (CCR4), for the treatment of inflammation and cancer, respectively. The Company is also pursuing a range of targets that are in the discovery stage of development.

Forward-Looking Statements
This press release contains forward-looking statements. These statements relate to future events and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future performances or achievements expressed or implied by the forward-looking statements. Each of these statements is based only on current information, assumptions and expectations that are inherently subject to change and involve a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements about the company's expectations concerning the clinical hold, including its investigation of the incident and its ability to resolve issues to the FDA's satisfaction. Detailed information regarding risk factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in RAPT's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, and subsequent filings made by RAPT with the Securities and Exchange Commission. These forward-looking statements speak only as of the date hereof. RAPT disclaims any obligation to update these forward-looking statements.

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