Based on Recent FDA Feedback RAPT Therapeutics Stops Zelnecirnon Program Following Clinical Hold Due to Single SAE of Severe Liver Injury

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Continues to advance preclinical pipeline, including next generation CCR4 compounds, and pursue licensing opportunities

SOUTH SAN FRANCISCO, Calif., Nov. 11, 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 it is terminating its zelnecirnon (RPT193) program. Zelnecirnon was being evaluated in two randomized, placebo-controlled Phase 2 clinical trials in asthma and atopic dermatitis (AD), and both trials were placed on clinical hold by the U.S. Food and Drug Administration (FDA) in February 2024 due to a serious adverse event (SAE) of liver injury requiring transplant in one patient in the AD trial. No liver toxicity nor other treatment-related SAEs were reported in any other trial participant. The company subsequently closed both studies before completing the planned enrollment. Following feedback recently received from the FDA, the company has stopped its zelnecirnon program.

“In light of the agency’s feedback, we do not see a viable path forward for zelnecirnon, although we continue to believe that CCR4 remains an exciting target with the potential to provide a safe, oral therapeutic option across a number of inflammatory diseases,” commented Brian Wong, M.D., Ph.D., President and CEO of RAPT. “We plan to continue advancing our next generation CCR4 compounds with improved safety margins for inflammatory disease and expect to identify a new candidate in the first half of 2025. Additionally, we continue to actively pursue in-licensing opportunities for clinical-stage assets.”

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.

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 termination of the zelnecirnon program; the company’s business and clinical development plans, including future CCR4 molecules and pursuit of licensing opportunities for clinical-stage assets; and other statements that are not historical fact. Factors that may cause actual results to differ materially from the plans, intentions and expectations disclosed in these forward-looking statements include uncertainties inherent in the initiation, progress and completion of clinical trials and clinical development of RAPT’s product candidates; the risk that clinical trials may have unsatisfactory outcomes; risks associated with preclinical development of product candidates; risks that efforts to secure licensing and other business development opportunities may not be successful; and other important factors, detailed in RAPT’s Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, 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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