RAPT Therapeutics Presents Update from its Phase 1/2 Clinical Trial for FLX475 as Monotherapy and in Combination with Pembrolizumab in Patients with Advanced Cancer

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Data Presented at ESMO Immuno-Oncology Congress

SOUTH SAN FRANCISCO, Calif., Dec. 08, 2022 (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 reported a poster presentation at the ESMO IO Congress covering data from its ongoing Phase 1/2 clinical trial of FLX475 as monotherapy and in combination with pembrolizumab in patients with advanced cancer (NCT03674567).

The data showed a confirmed overall response rate of 31% (4/13 patients) in Stage 1 of a Phase 2 expansion cohort of patients with checkpoint-naïve NSCLC, including two responses which are ongoing for over one year. Of the 13 patients treated with 100 mg once-daily FLX475 and a standard regimen of pembrolizumab, eight patients had PD-L1 positive tumors (TPS ≥1%), including two with PD-L1 high tumors (TPS ≥50%), four patients had PD-L1 negative tumors (TPS <1%) and one patient's PD-L1 status was unknown. The confirmed response rate in the PD-L1 positive tumors was 38% (3/8 patients) and in the PD-L1 negative tumors was 25% (1/4 patients). None of the four responders were PD-L1 high. Most of the patients enrolled in this NSCLC cohort had been previously treated with 1-3 or more prior therapies for advanced disease (10/13 patients).

In a separate Phase 2 expansion cohort of six patients with EBV+ NK/T cell lymphoma treated with FLX475 monotherapy, there were four responses, with two durable complete metabolic responses (CMR), one unconfirmed CMR and one unconfirmed partial metabolic response.

The safety profile for FLX475 was favorable, consistent with that previously seen in healthy volunteers, and there was no evidence of increased severity or frequency of adverse events in combination therapy compared to either FLX475 or pembrolizumab monotherapy.

"These data further support the antitumor activity for FLX475 with clear demonstration as a monotherapy and encouraging activity in a combination regimen with checkpoint inhibition," said Brian Wong, M.D., Ph.D., President and Chief Executive Officer of RAPT Therapeutics. "These data meet our criteria for continued development and based on the promising activity of FLX475 with pembrolizumab in checkpoint-naïve NSCLC patients, we have moved this indication to Stage 2 and are enrolling additional patients into the cohort."

About FLX475

FLX475 is a small molecule CCR4 antagonist designed to block the migration of regulatory T cells (T_{reg}) specifically into tumors, but not healthy tissues. T_{reg} represent a dominant pathway for downregulating the immune response, generally correlate with poor clinical outcomes, and may limit the effectiveness of currently available therapies such as checkpoint inhibitors. RAPT is developing FLX475 in "charged" tumors, which represent cancer types the company believes are most likely to respond to FLX475, where a large quantity of T_{reg} cells are likely to be the cause of immune suppression within the tumor. FLX475 may restore naturally occurring antitumor immunity alone and may synergize with a variety of both conventional and immune-based therapies, such as radiation, chemotherapy, checkpoint inhibitors, immune stimulators, cancer vaccines, and adoptive T cell therapy.

About RAPT Therapeutics, Inc.

RAPT Therapeutics is 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. 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, RPT193 and 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "could," "expect," "look forward," "target," "will" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify 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 therapeutic potential of our product candidates, clinical development progress and results from the ongoing Phase 1/2 study of FLX475. Many factors may cause differences between current expectations and actual results, including unexpected or unfavorable safety or efficacy data observed during clinical studies, preliminary data and trends may not be predictive of future data or results, may not demonstrate safety or efficacy or lead to regulatory approval, clinical trial site activation or enrollment rates that are lower than expected, unanticipated or greater than anticipated impacts or delays due to the COVID-19 pandemic (along with the effects of the war in Ukraine,

inflation, rising interest rates and other economic uncertainty), changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process and the sufficiency of RAPT's cash resources. 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, 2022, filed with the Securities and Exchange Commission on November 10, 2022 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, except as required by law.

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