RAPT Therapeutics Announces Promising Results from Phase 2 Trial of Tivumecirnon in Combination with Anti-PD-1 Immunotherapy in CPI-Experienced Head and Neck Cancer Patients

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- Confirmed objective response rate (ORR) of 15.6% in all patients regardless of PD-L1 or HPV status

- Confirmed ORR of 17.4% in subset of patients with PD-L1+ disease

- Confirmed ORR of 22.2% in subset of patients with HPV+ disease

- Median duration of treatment in responders was 19.6 months at the time of data cutoff

SOUTH SAN FRANCISCO, Calif., April 09, 2024 (GLOBE NEWSWIRE) -- RAPT Therapeutics, Inc. (Nasdaq: RAPT), 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, today announced safety and efficacy data from its ongoing Phase 2 trial of tivumecirnon in combination with the anti-PD-1 checkpoint inhibitor (CPI) pembrolizumab in the cohort of patients with advanced head and neck squamous cell carcinoma (HNSCC) whose disease progressed despite previous treatment with CPI therapy (CPI-experienced). The results were presented at the American Association for Cancer Research (AACR) Annual Meeting in San Diego, CA.

The AACR poster highlighted data from the 32-patient CPI-experienced HNSCC cohort in the trial evaluating tivumecirnon, an oral small molecule CCR4 antagonist designed to block the migration of regulatory T cells, in combination with pembrolizumab. Patients in this cohort had heavily pretreated disease, with 69% of patients having received three or more (up to six) prior lines of treatment. In the entire cohort, confirmed responses were observed in 5/32 patients (15.6%) regardless of PD-L1 or HPV status. In the 23 patients known to have PD-L1+ disease (CPS ≥1), an ORR of 17.4% (4/23) was observed, and in the 18 patients known to have HPV+ disease, an ORR of 22.2% (4/18) was observed. These findings compare favorably to the expected ORR of anti-PD-1 monotherapy in patients with recurrent or metastatic HNSCC who have progressed on, or relapsed after, previous anti-PD-1 therapy, which is believed to be <5-10%.

Phase 2 Data Summary in HPV+ CPI-experienced HNSCC Patients (n=13)

PD-L1+ Status	**(n)**	**Confirmed ORR**
All (regardless of PD-L1 or HPV status)	5/32	15.6% (95% CI 6-32%)
PD-L1+ (CPS ≥1)	4/23	17.4% (5-39%)
HPV+	4/18	22.2% (9-46%)

These data complement previously reported clinical data for tivumecirnon, which has now been dosed in more than 350 patients with various advanced cancers either as monotherapy or in combination with pembrolizumab. Findings to date have shown the combination treatment to be well tolerated with no signal of increased immune-related toxicity over that expected with pembrolizumab alone.

“As the trial progresses and cohorts mature, we continue to be impressed by the promise and expanded clinical activity of tivumecirnon,” said Brian Wong, M.D., Ph.D., President and Chief Executive Officer of RAPT. “These results add to the growing data supporting the efficacy of tivumecirnon across a number of oncology indications, including non-small cell lung cancer, head and neck cancer, gastric cancer and non-Hodgkin lymphoma, and we are evaluating the next steps to advance its development.”

Phase 1/2 Clinical Trial Design
The ongoing open-label Phase 1/2 study enrolled patients with multiple types of cancer at leading cancer centers across the United States, Australia and Asia. The Phase 2 portion is designed to evaluate the degree of antitumor activity of tivumecirnon as monotherapy and in combination with pembrolizumab specifically in patients with several types of T_{reg} and CCR4 pathway-enriched tumors. Changes in the tumor microenvironment and other biomarkers are being evaluated in both phases of the study. For more information please visit clinicaltrials.gov identifier NCT03674567.

About Tivumecirnon (FLX475)
Tivumecirnon is a small molecule CCR4 antagonist designed to block the migration of regulatory T cells (Treg) specifically into tumors, but not healthy tissues. Treg 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. Tivumecirnon 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 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 within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipate," "could," "expect," "look forward," "plan," "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 tivumecirnon to treat patients with lymphoma, non-small cell lung cancer, head and neck cancer and gastric cancer; RAPT's FLX475-02 Phase 1/2 clinical trial; plans for potential future development of tivumecirnon and other statements that are not historical fact. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during clinical studies, preliminary data and trends that may not be predictive of future data or results, clinical trial results that may not demonstrate safety or efficacy or lead to regulatory approval by the FDA or other regulatory agencies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, the uncertainties and timing of the regulatory approval process, the timing and results of unexpected litigation or other disputes 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 Form 10-K for the year ended December 31, 2023 filed with the Securities and Exchange Commission on March 10, 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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