

RAPT Therapeutics to Present Biomarker Data Corroborating Demonstrated Clinical Activity and Mechanism of Action of FLX475 in Advanced Cancers

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-FLX475-treated patients exhibited significant changes in immune pathways likely to enhance an antitumor response

-FLX475 modifies the tumor microenvironment (TME) to resemble those of responders to anti-PD(L)1 monotherapy

-Data to be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

SOUTH SAN FRANCISCO, Calif., May 25, 2023 (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 biomarker data for FLX475 from its ongoing FLX475-02 Phase 1/2 clinical trial which corroborate the clinical activity of FLX475 reported in Epstein-Barr virus-positive (EBV+) lymphoma, EBV+ gastric cancer and non-small cell lung cancer (NSCLC), as well as the mechanism of this novel CCR4 antagonist. These data will be presented in a poster at the 2023 American Society of Clinical Oncology (ASCO) annual meeting taking place next week at the McCormick Place Convention Center in Chicago, IL.

FLX475 is a potent and selective CCR4 antagonist, designed to block the recruitment of immunosuppressive regulatory T cells (T_{reg}) into tumors without affecting healthy tissues. In December 2022 at ESMO-IO, a clinical update from the Phase 1/2 trial reported evidence of monotherapy and combination activity. FLX475 monotherapy induced confirmed complete metabolic responses in two of the six evaluable patients with EBV+ NK/T cell lymphoma. In patients with checkpoint inhibitor naïve NSCLC, the overall confirmed objective response rate was 31% (4/13 patients), and the confirmed objective response rate in PD-L1+ tumors was 38% (3/8 patients) following treatment with FLX475 plus pembrolizumab.

As part of the clinical trial protocol, the company analyzed peripheral blood and tumor tissue biomarker data from patients with a broad range of tumor types treated with FLX475 monotherapy. These data substantiate the mechanism of action and support the combination of FLX475 with pembrolizumab. In peripheral blood, FLX475 monotherapy resulted in a small, but significant, increase in the proportion of circulating T_{reg}, consistent with blocking the migration of T_{reg} into the TME. In tumor tissues, changes in the TME conducive to anti-PD(L)1 response were observed. First, FLX475 monotherapy resulted in a decrease in T_{reg} cell populations and an increase in the distance between CD8+ effector T cells and T_{reg} in the TME. Second, transcriptomic profiles from tumors after FLX475 monotherapy exhibited significant changes known to be correlated with an enhanced response to checkpoint inhibitor therapy.

"These biomarker data provide further evidence that FLX475 reduces T _{reg} in the tumor and promotes a permissive environment that should enhance immune-based therapy including checkpoint inhibitors," said Dirk Brockstedt, Ph.D., chief scientific officer of RAPT. "In addition to inhibiting the recruitment of regulatory T cells, which are highly potent suppressors of an antitumor immune response, we saw a concomitant increase in cancer fighting effector T cells and additional beneficial changes in the tumor microenvironment that have been shown to correlate with a favorable response to anti-PD(L)1 therapy. These data are consistent with and support the clinical activity we've seen with FLX475 as monotherapy and in combination therapy with pembrolizumab."

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. 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 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, 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," "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 FLX475 to treat patients with lymphoma and non-small cell lung cancer RAPT's FLX475-02 Phase 1/2 clinical trial, 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 may not be predictive of future data or results, 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-Q for the quarter ended March 31, 2023 filed with the Securities and Exchange Commission on May 11, 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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