Aprea Therapeutics Presents Data From Phase 1/2 Trial of Eprenetapopt (APR-246) in Advanced Solid Tumors at ESMO Congress 2021

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BOSTON, Sept. 20, 2021 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing and commercializing novel cancer therapeutics that reactivate the mutant tumor suppressor protein, p53, today presented data at the European Society of Medical Oncology (ESMO) Congress 2021 from its Phase I/II clinical trial in advanced solid tumors. The trial is evaluating the safety and efficacy of eprenetapopt in combination with pembrolizumab.

As of the July 31, 2021 data cutoff, 33 patients were enrolled on study and 31 had initiated treatment. The Phase I safety lead-in part was a dose de-escalation design and no dose-limiting toxicities were reported in the 6 enrolled patients. A Phase II expansion part was initiated and, as of the data cutoff, has enrolled 3 patients in the gastric/GEJ cancer, 3 in the bladder/urothelial cancer and 19 in the non-small cell lung cancer (NSCLC) cohorts. Patients in the NSCLC Phase II cohort were required to have prior exposure to a PD-1 or PD-L1 inhibitor. Across all patients, 25 (76%) had a mutation in the *TP53* gene. The trial continues to enroll and treat patients and exploratory studies involving analyses of patient-derived immune cell populations are ongoing.

In the bladder/urothelial cohort, 1 patient with locally advanced *TP53* mutant high-grade transitional cell bladder cancer had achieved complete remission (CR) by RECIST criteria at the first response assessment at 9 weeks. In the NSCLC cohort, 2 patients with *TP53* mutant squamous NSCLC had reductions in target lesions of 26.7% and 8.2%, respectively, from baseline by RECIST criteria at the first response assessment at 9 weeks. Adverse events, regardless of causality, were mostly grade 1/2. Grade ≥3 events occurring in more than 1 patient included anemia (3), dyspnea (3), dizziness (2), pain (2) and malnutrition (2). Dizziness (2 patients) was the only grade ≥3 adverse event assessed by an investigator as eprenetapopt-related and occurring in more than 1 patient. One patient experienced a fatal adverse event of disease progression which was assessed by an investigator as not related to study treatment, and one patient experienced adverse events of fatigue, dyspnea and maculo-papular rash leading to discontinuation of eprenetapopt.

“The emerging data for the combination of eprenetapopt and pembrolizumab in these difficult-to-treat patients is very encouraging,” said Dr. Haeseong Park of Washington University in St. Louis. “Particularly promising are tumor reductions in lung cancer patients who previously received I/O therapy, and the complete remission in a bladder cancer patient with prior chemotherapy exposure, which is rare. In addition, the clinical experience to-date suggests the combination is well-tolerated with adverse events readily managed with standard of care measures. The other investigators and I look forward to maturation of the data from this clinical trial as we seek to enroll and treat additional patients with this novel combination.”

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc. is a biopharmaceutical company headquartered in Boston, Massachusetts with research facilities in Stockholm, Sweden, focused on developing and commercializing novel cancer therapeutics that reactivate mutant tumor suppressor protein, p53. The Company’s lead product candidate is eprenetapopt (APR-246), a small molecule in clinical development for hematologic malignancies and solid tumors. A pivotal Phase 3 clinical trial of eprenetapopt and azacitidine for frontline treatment of *TP53* mutant MDS has been completed and failed to meet the primary statistical endpoint of complete remission. Eprenetapopt is currently on clinical hold in myeloid and lymphoid malignancies. Eprenetapopt has received Orphan Drug and Fast Track designations from the FDA for myelodysplastic syndromes (MDS), Orphan Drug and Fast Track designations from the FDA for acute myeloid leukemia (AML), and Orphan Drug designation from the European Commission for MDS and AML. APR-548, a next generation small molecule reactivator of mutant p53, is being developed for oral administration. For more information, please visit the company website at www.aprea.com.

The Company may use, and intends to use, its investor relations website at https://ir.aprea.com/ as a means of disclosing material nonpublic information and for complying with its disclosure obligations under Regulation FD.

About p53, eprenetapopt and APR-548

The p53 tumor suppressor gene is the most frequently mutated gene in human cancer, occurring in approximately 50% of all human tumors. These mutations are often associated with resistance to anti-cancer drugs and poor overall survival, representing a major unmet medical need in the treatment of cancer.

Eprenetapopt (APR-246) is a small molecule that has demonstrated reactivation of mutant and inactivated p53 protein – by restoring wild-type p53 conformation and function – thereby inducing programmed cell death in human cancer cells. Pre-clinical anti-tumor activity has been observed with eprenetapopt in a wide variety of solid and hematological cancers, including MDS, AML, and ovarian cancer, among others. Additionally, strong synergy has been seen with both traditional anti-cancer agents, such as chemotherapy, as well as newer mechanism-based anti-cancer drugs and immuno-oncology checkpoint inhibitors.

APR-548 is a next-generation small molecule p53 reactivator. APR-548 has demonstrated high oral bioavailability, enhanced potency relative to eprenetapopt in TP53 mutant cancer cell lines and has demonstrated in vivo tumor growth inhibition following oral dosing of tumor-bearing mice.

Forward-Looking Statement

Certain information contained in this press release includes “forward-looking statements”, within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, related to our study analyses, clinical trials, regulatory submissions, and projected cash position. We may, in some cases use terms such as “future,” “predicts,” “believes,” “potential,” “continue,” “seeks,” “anticipates,” “estimates,” “expects,” “plans,” “intends,” “targeting,” “confidence,” “may,” “could,” “might,” “likely,” “will,” “should” or other words that convey uncertainty of the future events or outcomes to identify these forward-looking statements. Our forward-looking statements are based on current beliefs and expectations of our management team that involve risks, potential changes in circumstances, assumptions, and uncertainties. Any or all of the forward-looking statements may turn out to be wrong or be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. These forward-looking statements are subject to risks and uncertainties including risks related to the success and timing of our clinical trials or other studies, risks associated with the coronavirus pandemic and the other risks set forth in our filings with the U.S. Securities and Exchange Commission. For all these reasons, actual results and developments could be materially different from those expressed in or implied by our forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which are made only as of the date of this press release. We undertake no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

Source: Aprea Therapeutics, Inc.

Corporate Contacts:

Scott M. Coiante
Sr. Vice President and Chief Financial Officer
617-463-9385

Gregory A. Korbel
Sr. Vice President and Chief Business Officer
617-463-9385

Source: Aprea Therapeutics