Aprea Therapeutics Announces Dosing of Patient with HPV+ Head and Neck Squamous Cell Carcinoma (HNSCC) in Ongoing ACESOT-1051 Trial

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ACESOT-1051 Trial Expanded to Include HPV+ Head and Neck Squamous Cell Carcinoma (HNSCC) Patients, Targeting Populations Most Likely to Benefit for WEEI Inhibition

DOYLESTOWN, Pa., March 31, 2025 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage biopharmaceutical company developing innovative treatments that exploit specific cancer cell vulnerabilities while minimizing damage to healthy cells, today announced that a patient with HPV+ head and neck squamous cell carcinoma (HNSCC) has been dosed in the ongoing ACESOT-1051 clinical trial evaluating APR-1051. This is the first patient to be dosed in Cohort 5 (70 mg once daily) of the study. Open label data from the study are expected in the second half of 2025.

WEE1 inhibition has emerged as a promising strategy for targeting tumor cells with high replication stress and DNA damage accumulation. HPV driven cancers, including HPV+ HNSCC, are characterized by defects in the DDR pathway, making them potentially susceptible to WEE1 inhibition. HPV+ cancers are those where the underlying cause is persistent infection with human papillomavirus, a group of viruses that infect the skin and mucous membranes. A high proportion of HNSCC cases are attributable to HPV. An estimated 70% of the 20,000 cases of oropharyngeal squamous cell carcinoma (HNSCC that occurs in the oropharynx) seen annually in the US are attributable to HPV.

APR-1051 is a potent and selective small molecule that has been designed to potentially solve tolerability challenges of the WEE1 class. The ongoing ACESOT-1051 (A Multi-Center Evaluation of WEE1 Inhibitor in Patients with Advanced Solid Tumors, APR-1051) clinical trial is a Phase 1 trial evaluating single-agent APR-1051 in patients with advanced solid tumors harboring cancer-associated specific gene alterations.

"Enrollment of the first patient with HPV+ head and neck cancer in the Phase 1 ACESOT-1051 trial is an important step and is in line with our goal of identifying patient populations most likely to benefit from WEE1 inhibition," said Philippe Pultar MD., Senior Medical Advisor and Lead WEE1 Clinical Development of Aprea. "We are pleased with the progress of the trial and encouraged by the safety profile of APR-1051 to date. We look forward to continuing the study as we work toward identifying the optimal dose for future studies. We continue to believe that APR-1051 has best in class potential."

The latest patient in ACESOT-1051 was enrolled at MD Anderson Cancer Center. Aprea recently entered into a Material Transfer Agreement (MTA) with MD Anderson to support preclinical research aimed at exploring the potential of APR-1051 in treating HPV+ and HPV- head and neck squamous cell carcinoma (HNSCC) expressing genomic markers of replication stress.

ACESOT-1051 Study Design

ACESOT-1051 (A Multi-Center Evaluation of WEE1 Inhibitor in Patients with Advanced Solid Tumors, APR-1051) is designed to assess the safety, pharmacokinetics, pharmacodynamics, and preliminary efficacy of single-agent APR-1051 in advanced solid tumors harboring cancer-associated gene alterations. Oral APR-1051 will be administered once daily for 28-day cycles. The study consists of two parts. Part 1 is dose escalation and is expected to enroll up to 39 patients with advanced solid tumors. The first three dose levels (10mg, 20mg and 30mg) used accelerated titration. Bayesian Optimal Interval (BOIN) design is now being employed for the remaining dose levels (50mg and above). Part 2 (up to 40 patients) is designed for dose optimization, with the goal of selecting the Recommended Phase 2 Dose (RP2D).

The primary objectives of the study are to measure safety, dose-limiting toxicities (DLTs), maximum tolerated dose or maximum administered dose (MTD/MAD), and RP2D; secondary objectives are to evaluate pharmacokinetics, preliminary efficacy according to RECIST or PCWG3 criteria; pharmacodynamics is an exploratory objective. The University of Texas MD Anderson Cancer Center is the lead site, and the study will be performed at between 3 and 10 sites in the U.S. For more information refer to clinicaltrials.gov NCT06260514.

About Aprea
Aprea is pioneering a new approach to treat cancer by exploiting vulnerabilities associated with cancer cell mutations. This approach was developed to kill tumors but to minimize the effect on normal, healthy cells, decreasing the risk of toxicity that is frequently associated with chemotherapy and other treatments. Aprea's technology has potential applications across multiple cancer types, enabling it to target a range of tumors, including ovarian, colorectal, prostate, and breast cancers. The company's lead programs are APR-1051, an oral, small-molecule inhibitor of WEE1 kinase, and ATRN-119, a small molecule ATR inhibitor, both in clinical development for solid tumor indications. 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.

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," "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 and on information currently available to management that involve risks, potential changes in circumstances, assumptions, and uncertainties. All statements contained in this press release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize, and achieve market acceptance of our current and planned products and services, our research and development efforts, including timing considerations and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations. 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, without limitation, risks related to the success, timing, and cost of our ongoing clinical trials and anticipated clinical trials for our current product candidates, including statements regarding the timing of initiation, pace of enrollment and completion of the trials (including our ability to fully fund our disclosed clinical trials, which assumes no material changes to our currently projected expenses), futility analyses, presentations at conferences and data reported in an abstract, and receipt of interim or preliminary results (including, without limitation, any preclinical results or data), which are not necessarily indicative of the final results of our ongoing clinical trials, our understanding of product candidates mechanisms of action and interpretation of preclinical and early clinical results from its clinical development programs, our ability to continue as a going concern, and the other risks, uncertainties, and other factors described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file 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 update such forward-looking statements for any reason, except as required by law.

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