Aprea Therapeutics Announces Twice Daily (BID) Dosing of Patients in ABOYA-119 Clinical Trial of ATRN-119 to Potentially Optimize Clinical Outcomes and Strengthen Clinical Path Forward

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Twice daily (BID) dosing regimen expected to maximize clinical benefit for patients by optimizing the activity of Aprea's experimental drug, ATRN-119, over a 24-hour daily cycle

New regimen potentially optimizes clinical outcomes and strengthens the clinical path forward

ATRN-119 is the first macrocyclic ATR inhibitor to enter clinical trials

DOYLESTOWN, Pa., Dec. 11, 2024 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage precision oncology company developing innovative therapies for cancers with specific genetic alterations to potentially minimize damage to healthy cells, announced today that the first patient has been dosed at Dose Level 7, evaluating ATRN-119 550 mg twice daily, in the ongoing ABOYA-119 Phase 1/2a clinical trial.

The ABOYA-119 trial is evaluating ATRN-119 as monotherapy in patients with advanced solid tumors having at least one mutation in a defined panel of DNA damage response (DDR)-related genes. The study was initially designed to dose patients with ATRN-119 once daily and has tested doses of 50 to 800 mg to date. A protocol amendment allows for twice daily dosing, beginning with 550 mg twice daily (for a total daily dose of 1,100 mg). This strategic dose adjustment is driven by robust scientific evidence suggesting that more frequent dosing of ATRN-119 will maintain optimal therapeutic levels and potentially enhance the drug's efficacy.

Twice daily dosing is expected to optimize ATRN-119's activity across a 24-hour cycle thereby providing better target coverage and maximal benefit. This will increase the likelihood of achieving superior clinical outcomes and may potentially accelerate the path to regulatory approval and commercialization. It could also strengthen Aprea's competitive positioning by addressing key pharmacokinetic and pharmacodynamic factors.

"The addition of twice daily dosing in the ABOYA-119 trial underscores Aprea's commitment to delivering innovative treatments while continuously refining our approach based on the latest data and insights," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "Twice daily dosing represents a proactive step to de-risk the trial, potentially increasing the probability of success. Importantly, it reflects our commitment to scientific excellence and we believe it positions the ATRN-119 program as a high-value asset that may be differentiated from other ATR inhibitors. To our knowledge, we believe ATRN-119 is the only ATR inhibitor in clinical development that is currently being tested as monotherapy on a continuous twice daily schedule. We believe this adjustment will further enhance shareholder value and support the long-term success of our mission."

Dr. Gilad added, "This approach not only enhances our development strategy but also creates new opportunities for partnership that could accelerate commercialization of ATRN-119 and expand patient access globally."

Anthony Tolcher, M.D., FRCPC, FACP, CEO of NEXT Oncology and Investigator in the ABOYA-119 trial commented, "Inhibition of ATR has emerged as a promising strategy for cancer treatment that exploits synthetic lethal interactions with proteins that are involved in DNA damage repair. This mechanism holds considerable promise for patients with difficult-to-treat cancers. We are pleased to continue to enroll our patients in this important study and recognize that a twice daily dosing regimen of ATRN-119 may allow us to maximize the therapeutic potential of the drug."

Dose escalation in the ABOYA-119 trial is expected to continue with both once-daily and the twice-daily dosing schedules, to be studied independently. The primary endpoint of the trial is the tolerability and pharmacokinetics of ATRN-119. Under the current updated protocol, Aprea anticipates the Phase 1 readout in the second half of 2025. For more information, please refer to clinicaltrials.gov NCT04905914.

About ATRN-119

ATRN-119 is a potent and highly selective first-in-class macrocyclic ATR inhibitor, designed to be used in patients with mutations in DDR-related genes. Cancers with mutations in DDR-related genes represent a high unmet medical need. Patients with DDR-related gene mutations have a poor prognosis and, currently, there are no effective therapies available for them.

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, and follow us on LinkedIn, or X.

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, 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.

Investor and Media Contact:

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com