Aprea Therapeutics Announces that Safety Review Committee (SRC) Endorses Dosing of Patients with ATRN-119 at 800 mg Once Daily in Ongoing ABOYA-119 Clinical Trial

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ATRN-119 is the first and only macrocyclic ATR inhibitor in the clinic, with best in class potential

On track to complete dose escalation in ABOYA-119 clinical trial and potentially generate initial human efficacy data in 2H 2024

Through the first 5 cohorts, ATRN-119 has been found to be safe and well tolerated with no dose limiting toxicities (DLTs) observed

DOYLESTOWN, Pa., May 28, 2024 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage biopharmaceutical company focused on precision oncology through synthetic lethality, today announced that the Safety Review Committee (SRC) overseeing the ongoing ABOYA-119 clinical trial has determined that dosing of patients with ATRN-119 at 800 mg once daily (Cohort 6) can commence and that Cohort 6 is open for enrollment. This decision follows review of the safety and pharmacokinetic data from patients treated at 550 mg once daily (Cohort 5).

"We are very pleased with the progress in the ABOYA-119 clinical trial and with the SRC's recent endorsement to commence dosing of patients with ATRN-119 at 800 mg once daily representing progress in ATRN-119 development," said Nadeem Q. Mirza, M.D., M.P.H., Chief Medical Officer of Aprea. "Pharmacokinetic data show that the duration of systemic exposure substantially increases with each dose level of ATRN-119. New data reported at the recent AACR annual meeting show that plasma concentrations of the drug are entering the expected therapeutic range at dose levels of 550 mg and above[1]. We anticipate to announce additional safety and initial efficacy data from this study in the second half of 2024 and to complete dose escalation by the fourth quarter. Overall, we are very excited by ATRN-119, which we believe is differentiated from other ATR inhibitors in selectivity and toxicity profile."

ABOYA-119 is a Phase 1/2a multi-center, open-label, dose-escalation and expansion clinical trial designed to test ATRN-119 monotherapy in patients with advanced solid tumors harboring defined mutations in DDR pathways. Part 1 (Phase 1) of the study is assessing tolerability, pharmacokinetics, recommended Phase 2 dose (RP2D) and analysis of patient biomarkers. At completion of Part 1, the company anticipates identification of a recommended Phase 2 dose that will be used in a Phase 2a cohort expansion (Part 2) to test the tolerability and potential efficacy of ATRN-119 monotherapy For more information, refer to please refer to clinicaltrials.gov NCT04905914.

A total of 17 patients have been enrolled in the first five cohorts of the dose escalation stage (50 mg once daily, 100 mg once daily, 200 mg once daily, 350 mg once daily, and 550 mg once daily). Based on the safety profile, in March 2024 Aprea submitted an amendment to the FDA for the additional cohorts of 1100 mg and 1300 mg, with the goal of dosing patients in up to eight cohorts in total.

Preliminary signs of clinical benefit have been observed with two patients (data cutoff of March 12, 2024) achieving stable disease (SD) – one in the 50 mg once daily cohort and a second patient who showed longer duration when treated at 200 mg once daily. The latter patient at 200 mg once daily had SD at Days 55, 112, and 168. An update on the trial was featured in a poster at the AACR Annual Meeting this past April. For further details, including the status of all patients who were enrolled at that time, refer to the AACR poster on the Aprea corporate website here.

Initial efficacy data from Part 1 of the study may potentially be announced in 2H 2024. The Phase 1 dose escalation is expected to be completed in 4Q 2024, and RP2D is expected to be determined in 1Q 2025. Enrollment in the Phase 2a cohort is expected to begin in 1Q 2025 with additional safety and efficacy data expected in 3Q 2025.

ATRN-119 is a differentiated, potent and highly selective first-in-class macrocyclic inhibitor of ATR, a clinically validated target. It designed to be given to patients with mutations in DDR-related genes. Cancers with mutation in DDR-related genes represent a high unmet medical need and these patients have poor prognosis and, currently, have no approved effective therapies.

[1] A copy of the poster that features the pharmacokinetic data on ATRN-119 presented at the AACR Annual Meeting can be found on the Aprea corporate website here. The data demonstrate near dose proportional exposure following oral administration of ATRN-119 doses between 50 mg once daily to 550 mg once daily.

About Aprea

Aprea Therapeutics, Inc. is a clinical-stage biopharmaceutical company headquartered in Doylestown, Pennsylvania, focused on

precision oncology through synthetic lethality. The Company's lead program is ATRN-119, a clinical-stage small molecule ATR inhibitor in development for solid tumor indications. Aprea has completed all IND enabling studies for its oral, small molecule WEE1 inhibitor, APR-1051, and recently received FDA clearance of its IND. 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, 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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