Aprea Therapeutics Announces Dosing of First Patient in Phase 1/2a Clinical Trial of Oral ATR Inhibitor ATRN-119 for the Treatment of Advanced Solid Tumors

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DOYLESTOWN, Pa., Jan. 11, 2023 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing novel synthetic lethality-based cancer therapeutics targeting DNA damage response (DDR) pathways, today announced that the first patient was dosed in its Phase 1/2a monotherapy clinical trial of ATRN-119, the Company's lead ATR inhibitor for the treatment of cancers with DDR mutations.

The Phase 1/2a clinical trial is a multi-center, open-label, dose-escalation and expansion study designed to test ATRN-119 monotherapy in patients with advanced solid tumors harboring defined mutations in DDR pathways. The Phase 1 part of the study will assess tolerability, pharmacokinetics, recommended Phase 2 dose and analysis of patient biomarkers. The Phase 2a expansion portion of the trial is designed to further evaluate tolerability and efficacy of ATRN-119 monotherapy. ATRN-119 is structurally differentiated from other ATR inhibitors. In preclinical studies, ATRN-119 has demonstrated potent anti-proliferative activity against a variety of cancer cell lines, inhibited tumor growth in genetically defined ovarian, colon, pancreatic and prostate cancer xenograft models and has shown potential to have lower hematological toxicity than other ATR inhibitors.

"Initiating clinical evaluation of ATRN-119 marks a significant milestone in our efforts to advance the development of our growing pipeline of DDR inhibitors," said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea Therapeutics. "We are committed to developing and advancing next-generation, synthetic lethality-based therapies to address the unmet medical needs of patients with genetically defined cancers. We look forward to sharing the preliminary data from this study throughout 2023."

Principal Investigator for the trial, Dr. Fiona Simpkins, M.D. Assistant Professor of Obstetrics and Gynecology, Perelman School of Medicine at the University of Pennsylvania, added: "Mutations in DDR pathways are a hallmark of many aggressive cancers and inhibition of ATR is a promising therapeutic approach to selectively target and exploit the genetic vulnerabilities of tumors with these mutations. The initiation of this Phase 1 trial represents an important step in the clinical evaluation of ATR as a target for cancer therapy."

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc. is a biopharmaceutical company headquartered in Doylestown, Pennsylvania, focused on developing and commercializing novel synthetic lethality-based cancer therapeutics targeting a critical pathway and some of the most central targets in DDR and cancer progression. The Company's lead program is ATRN-119, a clinical-stage small molecule ATR inhibitor being developed for solid tumor indications. Our WEE1inhibitor is being advanced to IND submission. 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 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.

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