Aprea Therapeutics Announces Submission of IND Application for APR-1051, a Next Generation WEE1 Kinase Inhibitor

February 6, 2024

DOYLESTOWN, Pa., Feb. 06, 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 it has submitted an Investigational New Drug (IND) application to the U.S. Food & Drug Administration (FDA) to initiate clinical trials of APR-1051. APR-1051 is an oral inhibitor of WEE1 kinase, which plays important role in cell cycle regulation and DNA damage repair.

Based on preclinical studies, we believe APR-1051 is potentially differentiated from other WEE1 inhibitors in its: 1) molecular structure; 2) selectivity for WEE1 versus off-target inhibition of the polo-like kinase, or PLK, family of kinases; and 3) potentially superior pharmacokinetic properties.* Aprea has conducted extensive pre-clinical studies with APR-1051, which have demonstrated that the molecule may have highly potent anti-tumor activity, with a potentially favorable pharmacokinetic (PK) profile.

"Submission of an IND represents an important milestone for our APR-1051 development program," said Dr. Oren Gilad, President and CEO of Aprea. "APR-1051 is a next generation inhibitor of WEE1 kinase and, based on its unique characteristics, we believe it will be best in class. Pending clearance of the IND by FDA, we plan to commence clinical testing in the first half of 2024."

Clearance of the IND application will allow Aprea to initiate a Phase 1/2a dose escalation trial to evaluate the safety, tolerability, and preliminary efficacy of APR-1051 as a monotherapy in patients with a defined genetic and/or molecular signatures. Further details on the design of this study will be provided at a later date.

* No head-to-head studies have been conducted with APR-1051

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 is guiding towards FDA clearance of its IND during Q1 2024. 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 ability to continue as a going concern, 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 Contact:

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com

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Source: Aprea Therapeutics