



Aprea Therapeutics Announces FDA Clearance of IND for APR-1051, its Next Generation WEE1 Kinase Inhibitor for Cyclin E Overexpressing Cancers

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Company plans to initiate Phase 1 ACESOT-1051 (A Multi-Center Evaluation of WEE1 Inhibitor in Patients with Advanced Solid Tumors, APR-1051) clinical trial evaluating, highly selective, oral WEE1 inhibitor, for monotherapy treatment of Cyclin E overexpressing cancers including breast and ovarian cancers

Update from the ACESOT-1051 clinical trial expected in Q4 2024

DOYLESTOWN, Pa., March 11, 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 U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application (IND 169359) for APR-1051.

"APR-1051 is a next-generation inhibitor of WEE1 kinase and, based on its unique characteristics, we believe it will be best in class," said Dr. Oren Gilad, President and CEO of Aprea. "The FDA's clearance of our IND is a critical step in the APR-1051 development program. We look forward to evaluating therapeutic activity in patients, focusing on Cyclin E overexpressing cancers, including ovarian and breast cancers."

Based on preclinical studies, APR-1051 is 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;
3. Potentially superior pharmacokinetic (PK) properties;
4. Potential absence of QT prolongation at doses that significantly inhibit WEE1*

APR-1051 was discovered and preclinically evaluated by Aprea's team of chemists and scientists. Aprea has conducted extensive pre-clinical studies with APR-1051, which have demonstrated that the molecule has potent anti-tumor activity, along with a favorable pharmacokinetic (PK) profile. Additionally, pre-clinical data show that APR-1051 may demonstrate less toxicity than other WEE1 inhibitors.*

Clearance of the IND application will allow Aprea to initiate the Phase 1 ACESOT-1051 dose escalation trial to evaluate the safety, tolerability, and preliminary efficacy of APR-1051. Enrollment of the first patient in this study is expected in the first half of 2024 with an update expected in the fourth quarter of the year.

* 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 received FDA clearance on an IND to begin clinical studies of APR-1051, its oral, small molecule WEE1 inhibitor. 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.

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Source: Aprea Therapeutics