Aprea Therapeutics Provides ACESOT-1051 Program Update for WEE1 Inhibitor APR-1051: Accelerating and Expanding Enrollment. Clinical Data Presentation Planned for Q4 2026

July 30, 2026

- *Next clinical data update from the ongoing Phase 1 dose escalation ACESOT-1051 trial anticipated at a medical meeting in Q4 2026, providing a near-term opportunity to demonstrate continued clinical progress with APR-1051*
- *Enrollment in ACESOT-1051 is accelerating as the Company advances dose escalation and amasses the clinical data needed to inform dose selection and subsequent development*
- *Aprea plans to advance APR-1051 in uterine serous carcinoma (USC) and Cyclin E–overexpressing platinum-resistant ovarian cancer (PROC) while also evaluating combination regimens with standard of care in HPV-positive head and neck cancer and colorectal cancer, utilizing dose levels that have shown single-agent activity and cleared safety review*
- *The expanded development strategy builds on emerging single-agent activity and positions APR-1051 across biomarker-defined indications where WEE1 inhibition may address significant unmet medical need*

DOYLESTOWN, Pa., July 30, 2026 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) (“Aprea”, or the “Company”), a clinical-stage precision medicine oncology company focused on the discovery and development of targeted therapies for patients with biomarker-defined cancers, today provided an update on the ongoing Phase 1 dose escalation ACESOT-1051 trial of its oral WEE1 inhibitor APR-1051.

This latest corporate update builds on the positive progress in ACESOT-1051 to date in which APR-1051 demonstrated early signs of single-agent activity along with a favorable tolerability profile in patients with difficult-to-treat cancers.

Next Clinical Update and Accelerating Enrollment

Aprea expects to report the next clinical data update from ACESOT-1051 at a medical meeting in the fourth quarter of 2026. Enrollment is accelerating ahead of this anticipated clinical catalyst, with the number of active clinical sites expanding from three to ten. Aprea expects enrollment to reach 6 to 10 patients per month by Q4 of 2026, potentially increasing the pace of clinical data generation. The Company also plans to broaden the development by advancing APR-1051 into combination regimens, expanding the current study to include arms enrolling HPV-positive head and neck squamous cell carcinoma and colorectal cancer in combination with standard-of-care therapies.

“Expanding enrollment and adding combination regimens in HPV positive head and neck cancer and colorectal cancer will broaden the clinical dataset as we advance development of ACESOT-1051,” said Gene Kennedy, M.D., Chief Medical Advisor of Aprea. “We look forward to sharing the next set of data from the trial at a medical meeting in the fourth quarter of this year,”

As previously announced, the Company is expanding enrollment to include at least 50 patients with uterine serous carcinoma or cyclin E-overexpressing, platinum-resistant ovarian cancer. Completion of dose escalation and backfill expansion is anticipated in the second quarter of 2027. This expansion is intended to further characterize the clinical activity of APR-1051 in biomarker-defined tumor populations with a mechanistic rationale for WEE1 inhibition.

Planned Combination Development

Aprea’s plans to evaluate APR-1051 in combination settings are supported by preclinical synergy observed in relevant disease models. In HPV-positive head and neck squamous cell carcinoma, the Company plans to combine APR-1051 with immune checkpoint therapy. In colorectal cancer, the Company plans to combine APR-1051 with standard-of-care chemotherapy.

The Company intends to advance dose levels that have already cleared safety review and shown single-agent activity into the planned combination regimens. This provides an appropriate starting point to establish the preliminary safety and preliminary efficacy of these regimens. In preclinical models, APR-1051 has demonstrated antitumor activity in combination with chemotherapy and with immuno-oncology agents, providing a rationale for the planned clinical combinations.

About ACESOT-1051 and Trial Design

ACESOT-1051 is a multi-center, open-label Phase 1 study evaluating oral, single-agent APR-1051 administered once daily in 28-day cycles. Part 1 is a dose escalation and dose backfill expansion of up to 100 patients, using accelerated titration at lower

dose levels followed by a Bayesian optimal interval (BOIN) design. Part 2 is a dose selection optimization stage of up to 80 patients that will randomize patients 1:1 to two selected doses, to determine the recommended Phase 2 dose (RP2D).

Dose levels considered in the protocol range from 10 mg to 500 mg. Dose escalation is currently enrolling at the 300 mg cohort. Eligible patients are adults with advanced solid tumors harboring cancer-associated gene alterations, including uterine serous carcinoma regardless of biomarker status; cyclin E-overexpressing, platinum-resistant ovarian cancer (PROC); tumors harboring CCNE1, CCNE2, FBXW7, or PPP2R1A alterations; HPV-positive oropharyngeal, cervical, vaginal, or vulvar carcinoma; and KRAS- and TP53-mutated colorectal cancer.

The primary objectives are safety, dose-limiting toxicity, maximum tolerated or maximum administered dose, and RP2D. Secondary objectives include pharmacokinetics and antitumor activity assessed by RECIST/PCWG3.

The most recent update from the ACESOT-1051 trial was presented at the ASCO 2026 annual meeting; a copy of the poster can be found on the Aprea corporate website here.

For more information on ACESOT-1051, refer to ClinicalTrials.gov NCT06260514.

About Aprea Therapeutics

Aprea is a clinical-stage precision medicine oncology company focused on the discovery and development of targeted therapies for patients with biomarker-defined cancers. The Company is pioneering a new approach to treat cancer by exploiting vulnerabilities associated with cancer cell mutations. This approach was developed to kill tumors while minimizing the effect on normal, healthy cells. Aprea's technology has potential applications across multiple cancer types, enabling it to target a range of tumors, including ovarian, endometrial, colorectal and head and neck squamous cell carcinoma. 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 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 our clinical development programs, and our ability to predict clinical outcomes based on such preclinical and early clinical results, 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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