Aprea Therapeutics Announces Agreement with MD Anderson Cancer Center to Explore APR-1051 as a Potential Treatment for Head and Neck Squamous Cell Carcinoma (HNSCC)

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DOYLESTOWN, Pa., March 11, 2025 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE) ("Aprea", or the "Company"), a clinical-stage biopharmaceutical company developing innovative treatments that exploit specific cancer cell vulnerabilities while minimizing damage to healthy cells, announced today that it has entered into a Material Transfer Agreement (MTA) with MD Anderson Cancer Center. Under the agreement, Aprea will supply its proprietary WEE1 kinase inhibitor, APR-1051, to support preclinical research aimed at exploring its potential in treating HPV+ and HPV- head and neck squamous cell carcinoma (HNSCC) expressing genomic markers of replication stress.

The agreement will enable the research group at MD Anderson to conduct a series of pre-clinical experiments designed to generate preliminary efficacy and mechanistic data to support future clinical trials and treatment regimens. The goal of this research is to further characterize the therapeutic potential of APR-1051 in HNSCC and generate insights that could support future clinical development strategies. The studies will include combining APR-1051 with immune checkpoint inhibitors (ICIs) to treat both HPV+ and HPV- HNSCC tumors harboring genomic markers of replication stress. The project is being overseen by Professors Jeffrey N. Myers, M.D., Ph.D., F.A.C.S., and Abdullah A. Osman, Ph.D., both from the Department of Head and Neck Surgery, MD Anderson Cancer Center. Prof. Myers is the leading expert on head and neck cancers.

"This agreement with MD Anderson Cancer Center underscores our commitment to leveraging strong academic partnerships to advance our pipeline of DDR inhibitors" said Oren Gilad, Ph.D., President and Chief Executive Officer of Aprea. "HNSCC represents a major global health burden, and prior work conducted at MD Anderson, and published by Professors Myers, Osman and their colleagues, suggests that WEE1 kinase may present a promising therapeutic target. We look forward to the insights that will emerge from this important research."

Head and neck cancers, particularly those associated with HPV infection, present significant clinical challenges. WEE1 kinase inhibition represents a novel therapeutic strategy by targeting the effectiveness of DNA damage response, potentially enhancing the sensitivity of cancer cells to existing treatments.

A high proportion of HNSCC cases are attributable to HPV. An estimated 70% of the 20,000 cases of OPSCC (HNSCC that occurs in the oropharynx) seen annually in the US are attributable to HPV. Although these HPV+ tumors generally have a better prognosis than their HPV- counterparts, standard of care chemotherapy and radiation is very toxic and surviving patients often face a lifetime of difficulties. The group at MD Anderson was the first to observe that HPV+ HNSCC tumor lines are very sensitive to WEE1 kinase inhibition both in vitro and in vivo. Their findings were published in a paper in Clinical Cancer Research in 2015. The researchers also showed in their previous experiments that a subset of HPV- HNSCC tumors may also be susceptible to this mechanism.

Under the terms of the agreement, Aprea will retain all rights, title, and interest in APR-1051.

APR-1051 is a potent and selective small molecule that has been designed to potentially solve tolerability challenges of the WEE1 class and may achieve greater clinical activity than other programs currently in development. The candidate is currently being tested in the ongoing ACESOT-1051 (A Multi-Center Evaluation of WEE1 Inhibitor in Patients with Advanced Solid Tumors, APR-1051) clinical trial. This Phase 1 clinical trial is evaluating single-agent APR-1051 in patients advanced solid tumors harboring cancer-associated gene alterations.

About Aprea
Aprea is pioneering a new approach to treat cancer by exploiting vulnerabilities associated with cancer cell mutations. This approach was developed to kill tumors but to minimize the effect on normal, healthy cells, decreasing the risk of toxicity that is frequently associated with chemotherapy and other treatments. Aprea's technology has potential applications across multiple cancer types, enabling it to target a range of tumors, including ovarian, colorectal, prostate, and breast cancers. 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 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.

Investor Contact:

Mike Moyer
LifeSci Advisors
mmoyer@lifesciadvisors.com