Aprea Therapeutics Presents Primary Analysis from Phase 2 Trial of Eprenetapopt + Azacitidine for Post-Transplant Maintenance Therapy in TP53 Mutant MDS and AML at the 2021 American Society of Hematology (ASH) Annual Meeting

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- 60% relapse free survival at 1 year post-transplant
- 79% overall survival at 1 year post-transplant
- Median overall survival of 20.6 months

BOSTON, Dec. 13, 2021 (GLOBE NEWSWIRE) -- Aprea Therapeutics, Inc. (Nasdaq: APRE), a biopharmaceutical company focused on developing and commercializing novel cancer therapeutics that reactivate mutant tumor suppressor protein, p53, today announced updated results from its Phase 2 trial evaluating eprenetapopt with azacitidine for post-transplant maintenance therapy in patients with *TP53* mutant MDS and AML at the 2021 ASH Annual Meeting.

In 33 patients enrolled in the trial, the relapse free survival (RFS) at 1 year post-transplant was 60% and the median RFS was 12.5 months. The overall survival (OS) at 1 year post-transplant was 79%, with a median OS of 20.6 months. Published studies evaluating post-transplant outcomes in *TP53* mutant MDS and AML patients have reported a 1-year post-transplant RFS of ~30% and a median OS of ~5-8 months. In addition, the post-transplant regimen of eprenetapopt and azacitidine was well tolerated among patients in the clinical trial. Given the encouraging data, the Company intends to explore opportunities to conduct future randomized clinical trials to further assess safety and efficacy of this combination in the post-transplant maintenance setting.

“This update of data at ASH, representing the primary analysis, highlights the very encouraging outcomes for these *TP53* mutant MDS and AML patients who received eprenetapopt and azacitidine as post-transplant maintenance therapy,” said trial principal investigator Asmita Mishra, M.D., of the H. Lee Moffitt Cancer Center and Research Institute. “As these patients characteristically have poor outcomes, even with transplantation, this post-transplant maintenance regimen is potentially paradigm-shifting and I look forward to investigating it further.”

Slides for this presentation can be accessed from “Presentations” in the News and Events section of the Company’s website at Link.

About Aprea Therapeutics, Inc.

Aprea Therapeutics, Inc. is a biopharmaceutical company headquartered in Boston, Massachusetts with research facilities in Stockholm, Sweden, focused on developing and commercializing novel cancer therapeutics that reactivate mutant tumor suppressor protein, p53. The Company’s lead product candidate is eprenetapopt (APR-246), a small molecule in clinical development for hematologic malignancies and solid tumors. A pivotal Phase 3 clinical trial of eprenetapopt and azacitidine for frontline treatment of *TP53* mutant MDS has been completed and failed to meet the primary statistical endpoint of complete remission. Eprenetapopt is currently on clinical hold in myeloid malignancies. Eprenetapopt has received Orphan Drug and Fast Track designations from the FDA for myelodysplastic syndromes (MDS), Orphan Drug and Fast Track designations from the FDA for acute myeloid leukemia (AML), and Orphan Drug designation from the European Commission for MDS and AML. APR-548, a next generation small molecule reactivator of mutant p53, is being developed for oral administration. 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.

About p53, eprenetapopt and APR-548

The p53 tumor suppressor gene is the most frequently mutated gene in human cancer, occurring in approximately 50% of all human tumors. These mutations are often associated with resistance to anti-cancer drugs and poor overall survival, representing a major unmet medical need in the treatment of cancer.

Eprenetapopt (APR-246) is a small molecule that has demonstrated reactivation of mutant and inactivated p53 protein – by restoring wild-type p53 conformation and function – thereby inducing programmed cell death in human cancer cells. Pre-clinical anti-tumor activity has been observed with eprenetapopt in a wide variety of solid and hematological cancers, including MDS, AML, and ovarian cancer, among others. Additionally, strong synergy has been seen with both traditional anti-cancer agents, such as chemotherapy, as well as newer mechanism-based anti-cancer drugs and

immuno-oncology checkpoint inhibitors.

APR-548 is a next-generation small molecule p53 reactivator. APR-548 has demonstrated high oral bioavailability, enhanced potency relative to eprenetapopt in *TP53* mutant cancer cell lines and has demonstrated in vivo tumor growth inhibition following oral dosing of tumor-bearing mice.

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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