



## APrea Therapeutics Announces Clinical Hold on Lymphoid Malignancy Program

August 12, 2021

BOSTON, Aug. 12, 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 that the U.S. Food and Drug Administration (FDA) has placed a clinical hold on its clinical trial evaluating eprenetapopt with acalabrutinib or with venetoclax and rituximab in lymphoid malignancies. No additional patients can be enrolled until the clinical hold is resolved, though patients on study deriving clinical benefit can continue to receive study treatment.

Subsequent to receiving notification of a partial clinical hold on its myeloid malignancies program, Aprea was informed by FDA of a clinical hold on its lymphoid malignancy study. The FDA's concerns referred to the safety and efficacy data from the Phase 3 MDS clinical trial. One CLL patient is currently on study treatment receiving eprenetapopt in combination with venetoclax and rituximab and has achieved complete remission (CR). Aprea intends to work closely with the FDA to address the specific questions raised, and seek to resolve the clinical hold as soon as possible.

### 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 and lymphoid malignancies. Eprenetapopt has received Breakthrough Therapy, 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](http://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," "seek" 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.

Corporate Contacts:

Scott M. Coiante

Sr. Vice President and Chief Financial Officer

617-463-9385

Gregory A. Korbel

Sr. Vice President and Chief Business Officer

617-463-9385



Source: Apria Therapeutics