AN2 to Voluntarily Pause Enrollment in Phase 3 Part of Phase 2/3 Pivotal Clinical Trial Evaluating Epetraborole for Treatment-Refractory Mycobacterium Avium Complex (MAC) Lung Disease

February 12, 2024

-Enrolled patients allowed to continue on study-

MENLO PARK, Calif.--(BUSINESS WIRE)--Feb. 12, 2024-- AN2 Therapeutics, Inc. (Nasdaq: ANTX), a clinical-stage biopharmaceutical company focused on developing treatments for rare, chronic, and serious infectious diseases with high unmet needs, today announced the company's decision to voluntarily pause Phase 3 enrollment in the seamless Phase 2/3 clinical trial (EBO-301) evaluating epetraborole in treatment-refractory MAC lung disease, pending further data review. The double-blind, placebo-controlled trial has two arms comparing epetraborole plus optimized background regimen (OBR) versus placebo plus OBR. The voluntary pause was instituted following a blinded aggregate analysis of the ongoing Phase 2 study, including pooled patients from both treatment arms, which showed potentially lower than expected efficacy. The decision was not due to safety concerns. The Phase 2 part of the trial is intended to inform the Phase 3 part of the trial. The company continues to expect to announce topline data from the Phase 2 part of the trial in summer 2024.

The company's decision to pause enrollment enables time to further evaluate study data and for the independent Data Safety Monitoring Board (DSMB) to conduct an unblinded assessment and recommend next steps, which could include changes to the Phase 3 part of the study protocol. The Phase 2 part of the trial completed enrollment in September 2023 with 80 patients. The Phase 3 part of the trial has enrolled nearly 100 patients to date, a faster enrollment rate than previously anticipated. Patients already enrolled in the Phase 2/3 trial will be allowed to continue on study.

"Developing new therapies for patients suffering with treatment-refractory MAC lung disease, a disease with limited treatment options and low response rates to existing therapies, is a complex undertaking. In light of recently available blinded aggregate data, we believe our voluntary decision to pause enrollment in the Phase 3 part of the study will provide us the opportunity to further evaluate study data, and determine the best path forward," said Eric Easom, Co-Founder, President and Chief Executive Officer of AN2 Therapeutics. "We plan to provide further details regarding the epetraborole Phase 2/3 clinical trial in the second quarter of 2024 following completion of our analysis."

About the Epetraborole Pivotal Phase 2/3 Trial (EBO-301)

This double-blind, placebo-controlled superiority trial uses an adaptive design to evaluate the safety and efficacy of epetraborole in patients with treatment-refractory MAC lung disease. The Phase 2 part of the trial (n=80) assesses clinical response using various patient-reported outcome tools as well as the safety, efficacy and pharmacokinetics of epetraborole plus an OBR, when compared to a placebo plus an OBR. The Phase 2 findings will be utilized to inform the clinical response measures evaluated in the Phase 3 part of the trial and confirm the final sample size. The primary objective in Phase 3 (n=at least 234) will be to determine if epetraborole plus an OBR, consisting of two or more standard-of-care drugs, is superior to placebo plus an OBR. For more information, please visit: www.clinicaltrials.gov (NCT05327803).

About AN2 Therapeutics, Inc.

AN2 Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing treatments for rare, chronic, and serious infectious diseases with high unmet needs. Our initial candidate is epetraborole, which we are studying as a once-daily, oral treatment with a novel mechanism of action for patients with nontuberculous mycobacteria (NTM) lung disease, a rare, chronic, and progressive infectious disease caused by bacteria known as mycobacteria, that leads to irreversible lung damage and can be fatal. For more information, please visit our website at www.an2therapeutics.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: timing of topline data, further evaluation of study data and DSMB review; potential changes to the Phase 3 study protocol; continuation of enrolled patients in the Phase 2/3 trial; timing of completion of AN2's analysis of study data; and other statements that are not historical fact. These statements are based on AN2's current estimates, expectations, plans, objectives, and intentions, are not guarantees of future performance and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, but are not limited to, risks and uncertainties related to: the recommendations of the DSMB following its review of blinded data; the number of patients who remain enrolled in the Phase 2/3 trial; the ability of AN2 to resume enrollment in the Phase 2/3 trial, in the event the determination to resume enrollment is made; the ability of AN2 to effectively and timely make amendments to the Phase 2/3 pivotal trial design based on its analysis of the Phase 2 portion of the study and/or pursuant to additional FDA feedback; possible changes to AN2's plans or priorities as it assesses study data; potential for protocol modifications, redesign or study termination; timely enrollment of patients in AN2's existing and future clinical trials; AN2's ability to procure sufficient supply of its product candidate for its existing and future clinical trials; the potential for results from clinical trials to differ from preclinical, early clinical, preliminary, or expected results; significant adverse events, toxicities, or other undesirable side effects associated with AN2's product candidate; the significant uncertainty associated with AN2's product candidate ever receiving any regulatory approvals; AN2's ability to obtain, maintain, or protect intellectual property rights related to its current and future product candidates; implementation of AN2's strategic plans for its business and current and future product candidates; the sufficiency of AN2's capital resources and need for additional capital to achieve its goals; global macroeconomic conditions and global conflicts; and other risks, including those described under the heading "Risk Factors" in AN2's reports filed with the U.S. Securities and Exchange Commission (SEC), including AN2's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023. These filings, when made, are available on the investor relations section of AN2's website at investor.an2therapeutics.com and on the SEC's website at www.sec.gov. Forward-looking statements contained in this press release are made as of this date, and AN2 undertakes no duty to update such information except as required under applicable law.

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