AN2 Therapeutics Initiates Pivotal Phase 2/3 Trial Evaluating Epetraborole for Treatment-Refractory MAC Lung Disease

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- *AN2 is developing epetraborole as a once-daily, orally administered treatment with a novel mechanism of action for patients with NTM lung disease, with an initial focus on treatment-refractory MAC lung disease*
- *Phase 2/3 pivotal trial expected to support regulatory approval for treatment-refractory MAC lung disease; Plan to use LPAD pathway*

MENLO PARK, Calif., June 29, 2022 (GLOBE NEWSWIRE) -- 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 it has screened its first patient in its pivotal Phase 2/3 clinical trial evaluating once-daily, oral epetraborole for treatment-refractory *Mycobacterium avium* complex (MAC) lung disease, the most common form of nontuberculous mycobacterial (NTM) lung disease.

“Initiating this pivotal Phase 2/3 trial marks an important step towards delivering a new treatment option to patients with treatment-refractory MAC lung disease, an area which has seen little innovation,” said Eric Easom, President and Chief Executive Officer of AN2 Therapeutics. “As a once-daily oral therapy, epetraborole has the potential to become an important component of a multi-drug treatment regimen for patients with treatment-refractory MAC lung disease. We look forward to sharing clinical data from the Phase 2 portion of this trial in mid-2023, when we expect to get our first clinical readout on the impact of epetraborole added to a standard of care regimen.”

AN2 Therapeutics believes that compelling data from this pivotal Phase 2/3 clinical trial could allow the company to seek approval for epetraborole with the U.S. Food and Drug Administration (FDA) using the Limited Population Pathway for Antibacterial and Antifungal drugs (LPAD) and in other geographies. Under the LPAD pathway, the FDA may approve and review new antibacterial drugs to treat serious bacterial diseases in patients with an unmet medical need and for which effective bacterial drugs are limited or lacking, potentially resulting in a New Drug Application submission based on streamlined development. Epetraborole has been granted Qualified Infectious Disease Product and Fast Track status by the FDA for treatment-refractory MAC lung disease, as well as orphan drug designation for the treatment of infections caused by NTM.

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. In total, this multi-center trial is expected to enroll approximately 314 patients across North America, Europe and potentially other geographies. The Phase 2 part of the trial (n=80) will assess the clinical response using various patient-reported outcome tools as well as to determine the safety, efficacy and pharmacokinetics of epetraborole plus an optimized background regimen (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 the Phase 3 part of the trial (n≈ 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. The Company expects to report topline data from the Phase 2 part of the trial in mid-2023 and from the Phase 3 part in mid-2024, pending any sample size adjustments. 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. AN2 is developing epetraborole, a once-daily, oral treatment with a novel mechanism of action for patients with 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.

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: AN2's anticipated progress, business plans, business strategy and planned clinical trials; AN2's plans to initiate its Phase 2/3 pivotal clinical trial and the timing thereof; the potential clinical benefits and therapeutic potential of epetraborole; the timing of initial data from AN2's Phase 2/3 pivotal clinical trial; the ability of AN2’s Phase 2/3 pivotal clinical trial to support regulatory approval; and other statements that are not historical fact. These statements are based on AN2's current plans, objectives, estimates, expectations 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 those described under the heading “Risk Factors” in AN2's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022 filed with the U.S. Securities and Exchange Commission (SEC). These filings, when available, are available on the investor relations section of our 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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