AN2 Therapeutics commences Phase 3 Part of Phase 2/3 Clinical Trial Evaluating Epetraborole for Treatment-Refractory Mycobacterium avium complex (MAC) Lung Disease

September 13, 2023

Company announces Phase 2 part of the EBO-301 trial is now fully enrolled with 80 patients; Topline Phase 2 trial results expected in summer 2024

Over 100 sites across four countries (U.S., Japan, S. Korea & Australia) as epetraborole enters Phase 3 portion of EBO-301; expected to enroll ~230 patients

MENLO PARK, Calif.--(BUSINESS WIRE)--Sep. 13, 2023-- 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 that it has commenced the Phase 3 part of its Phase 2/3 clinical trial evaluating once-daily, oral epetraborole for treatment-refractory MAC lung disease after completing Phase 2 enrollment. The Phase 2/3 clinical trial is expected to support regulatory filings for approval in the U.S. and Japan. AN2 anticipates reporting Phase 2 topline data in summer 2024.

“Completing Phase 2 enrollment and initiating Phase 3 in this important clinical trial are significant milestones for AN2 and the patients we intend to serve. There is currently no approved oral therapy for MAC lung disease. Given epetraborole’s novel mechanism of action, encouraging clinical and non-clinical data to date, and convenient once daily oral dosing, we believe that if approved, epetraborole has the potential to become the backbone of therapy for patients suffering with often debilitating treatment-refractory MAC lung disease,” said Eric Easom, Co-Founder, President and Chief Executive Officer of AN2 Therapeutics. “We look forward to sharing topline results from the Phase 2 portion of the trial in summer 2024, at which time we expect to be well on our way to completing Phase 3 enrollment. We will provide more information on the projected Phase 3 enrollment timeline as we get closer to the Phase 2 topline readout.”

The FDA has granted epetraborole Fast Track designation for treatment-refractory MAC lung disease, Qualified Infectious Disease Product designation for treatment-refractory MAC lung disease, and orphan drug designation for the treatment of infections caused by nontuberculous mycobacteria (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. 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 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 Phase 3 (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. For more information, please visit: www.clinicaltrials.gov (NCT05327803).

About AN2 Therapeutics

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 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: the timing, progress, and anticipated results from AN2's Phase 2/3 pivotal clinical trial; anticipated timing of enrollment in Phase 3 portion of the Phase 2/3 pivotal trial of epetraborole in treatment-refractory MAC lung disease; anticipated timing of the data readout of the Phase 2 part of AN2’s pivotal Phase 2/3 trial; AN2's anticipated progress, business plans, business strategy and planned clinical trials; the potential clinical benefits and therapeutic potential of epetraborole; 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 continuing effects of the COVID-19 pandemic; macroeconomic conditions; AN2's ability to progress enrollment in its Phase 2/3 pivotal clinical trial of epetraborole; the ability of AN2 to effectively and timely make amendments to the Phase 2/3 pivotal trial design pursuant to additional FDA feedback; timely enrollment of patients in its current 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; and other risks, including those described under the heading “Risk Factors” in AN2's reports to be filed with the SEC, including AN2’s Report on Form 10-Q for the quarter ended June 30, 2023. 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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