AN2 Therapeutics Provides Update on EBO-301 Phase 2/3 Study Evaluating Epetraborole for Treatment-Refractory Mycobacterium avium Complex (MAC) Lung Disease

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EBO-301 study to be discontinued following topline results from Phase 2 part of the study in treatment-refractory patients with MAC lung disease

AN2 plans to shift focus to internal boron chemistry platform and ongoing pipeline programs

Company restructuring and cost savings associated with discontinuation of the EBO-301 study expected to extend cash runway through 2027

MENLO PARK, Calif.--(BUSINESS WIRE)--Aug. 8, 2024-- AN2 Therapeutics, Inc. (Nasdaq: ANTX), a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from its boron chemistry platform today announced topline results from the Phase 2 part of the EBO-301 Phase 2/3 study evaluating epetraborole on top of an optimized background regimen (OBR) in treatment-refractory MAC lung disease.

The Phase 2 part of the study met its primary objective of demonstrating the potential validation of a novel patient-reported outcome (PRO) tool and a higher PRO-based clinical response rate in the epetraborole + OBR arm (39.5%) vs. placebo + OBR (25.0%; treatment difference 13.9%, p=0.19). However, sputum culture conversion at Month 6, a key secondary endpoint, was similar between treatment arms (13.2% in epetraborole + OBR vs. 10.0% placebo + OBR; treatment difference 3.4%, p=0.64).

In February, the Company voluntarily paused new patient enrollment in the Phase 3 part of the study due to potentially lower-than-expected efficacy observed in blinded aggregate data. Based on the topline data announced today, the Company will terminate the Phase 2 (80 patients) and Phase 3 parts of the EBO-301 trial (97 patients enrolled prior to pause). Oral epetraborole 500 mg daily was generally well-tolerated and the study was not terminated due to safety concerns.

“These results are deeply disappointing as there is a high unmet need for new therapies in treatment-refractory MAC lung disease,” said Eric Easom, Co-founder, Chairman, President and CEO. “We sincerely thank the patients, investigators, study site staff and AN2 employees who were part of the journey to investigate the prospects of epetraborole in this very difficult-to-treat patient population.”

“In the coming months, we will further evaluate the results from the EBO-301 study and make informed decisions regarding potential future development of epetraborole for NTM lung disease in other patient populations. In the near-term, we plan to accelerate our R&D efforts on our boron chemistry platform where we believe we have several promising programs in infectious diseases and oncology. We plan to embark on a strategic restructuring and expect to extend our cash runway through 2027, focusing our cash resources on advancing our pipeline through multiple milestones,” said Easom.

AN2’s core technology approach is based on the use of boron chemistry for its research and development initiatives. Boron has a distinctive ability to bind with biological targets through a reversible covalent bond and the potential to address biological targets that have been difficult to inhibit using traditional carbon-based molecules.

Pipeline Programs/ Milestones

- **Chagas Disease:** The Company plans to initiate Phase 1 clinical development of its product candidate aimed to cure chronic Chagas disease, a disease that affects an estimated 6-7 million people worldwide including approximately 300,000 in the U.S. and causes severe cardiac disease and death.
- **Melioidosis:** The Company plans to initiate a Phase 2 study with epetraborole in melioidosis, a deadly bacterial infection and global bioterrorism threat, with a goal of significantly reducing the 3-month mortality rate of ~50%.
- **Early-Stage Pipeline:** Additional research programs are underway and focused on targets in infectious diseases and oncology with high unmet needs. The Company anticipates multiple development compounds within its cash runway.
- **Global Health:** The Company will continue its efforts to tackle global health disease areas through non-dilutive funding, including tuberculosis and malaria, funded by the Gates Foundation.

About AN2 Therapeutics, Inc.

AN2 Therapeutics, Inc. is a biopharmaceutical company focused on discovering and developing novel small molecule therapeutics derived from its boron chemistry platform. AN2 has a pipeline of boron-based compounds in development for Chagas disease, NTM, and melioidosis, along with early-stage programs focused on targets in infectious diseases and oncology. 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 Company's plans to shift its focus to its internal boron chemistry platform and ongoing pipeline programs; strategic restructuring; cash runway; further evaluation of the results from the EBO-301 study and any future development of epetraborole for NTM lung disease; acceleration of R&D efforts on the Company's boron chemistry platform; potential for the identification of development compounds in infectious disease or oncology; 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: potential disruptions related to AN2's restructuring plans and its ability to implement its plans for its internal boron chemistry platform and ongoing pipeline programs; timely enrollment of patients in AN2's existing and future clinical trials; AN2's ability to procure sufficient supply of its product candidates 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 candidates; the significant uncertainty associated with AN2's product candidates ever receiving any regulatory approvals; continued funding by the National Institute of Allergy and Infectious Disease (NIAID) of the Company's development program for melioidosis; 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 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 March 31, 2024. 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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Lucy O. Day
Chief Financial Officer
l.day@an2therapeutics.com

Anne Bowdidge
Investor Relations
abowdidge@an2therapeutics.com

Source: AN2 Therapeutics, Inc.