# AN2 Therapeutics Announces FDA Clearance to Proceed with 90-Patient Investigator-Initiated Trial (IIT) of Epetraborole in Patients with M. abscessus Lung Disease

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*AN2 aims to advance oral treatment option for patients currently reliant on complex, off-label IV therapies*

*Led by nontuberculous mycobacteria (NTM) expert Dr. Kevin Winthrop, trial will focus on early-stage, treatment-naive patients, a key difference from AN2's previous studies in mycobacterium avium complex (MAC)*

*Patient enrollment expected to be initiated in 1Q 2026*

MENLO PARK, Calif.--(BUSINESS WIRE)--Jan. 12, 2026-- AN2 Therapeutics, Inc. (Nasdaq: ANTX), a biopharmaceutical company advancing novel small molecule therapeutics derived from its boron chemistry platform, today announced that the U.S. Food and Drug Administration has cleared Oregon Health & Science University's (OHSU) Investigational New Drug (IND) application to proceed with an IIT that will evaluate the safety, efficacy, and pharmacokinetics of epetraborole in patients with *Mycobacterium abscessus* lung disease (*M. abscessus*). The multicenter, randomized, double-blind, placebo-controlled, prospective clinical study will be led by Dr. Kevin Winthrop, Professor of Public Health and Infectious Diseases at OHSU, in collaboration with other investigators across an estimated 10-15 sites in the U.S.

"Current treatment for *M. abscessus* relies on off-label, complex intravenous drug regimens that are difficult to tolerate, provide modest efficacy and are burdensome to patients," said Dr. Winthrop. "Patients need oral therapies that are efficacious and well tolerated, and epetraborole has the potential to address this unmet need in *M. abscessus* patients. Currently there are no FDA-approved therapeutics for this difficult to treat chronic lung infection, and the pathogen is resistant to most oral antibiotics. There is a pressing need for effective new treatment options."

Dr. Winthrop continued: "While the epetraborole trial in MAC focused on patients with advanced disease, for *M. abscessus*, enrolling a population with treatment-naïve disease should allow us to evaluate the potential impact of this novel candidate in a related patient population with a similarly urgent need for new therapies. Launching this study is an important step toward potentially delivering a treatment option that could advance care for patients and families facing this devastating condition."

"The IND clearance is a significant milestone as we evaluate epetraborole as potentially the first FDA-approved therapy for patients with *M. abscessus*," said Eric Easom, Co-Founder, Chairman, President and CEO of AN2 Therapeutics. "Partnering with Dr. Kevin Winthrop, a leading global expert in nontuberculous mycobacterial lung disease at OHSU, will be instrumental as we support this investigator-initiated trial across an estimated 10-15 sites in the U.S. With an estimated 120,000–150,000 people in the U.S. living with NTM lung disease, 10–15% caused by *M. abscessus,* this program represents both a significant unmet need and a meaningful market opportunity. Positive data from this study could establish human proof of concept and inform the design of a subsequent pivotal trial."

**About the IIT of epetraborole in *M. abscessus***

This investigator-initiated, proof-of-concept study is a randomized, double-blind, placebo-controlled, multicenter, prospective trial to assess the efficacy, safety, and pharmacokinetics of epetraborole in patients with *M. abscessus*.

The study will enroll approximately 90 patients across 10-15 sites in the U.S. The results are expected to provide data to support further development of epetraborole for patients with *M. abscessus*.

**About AN2 Therapeutics**

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 lung disease caused by *M. abscessus* and melioidosis, along with programs focused on targets in oncology and infectious diseases. We are committed to delivering high-impact drugs to patients that address critical unmet needs and improve health outcomes. 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, including, but not limited to, statements regarding the potential of epetraborole to treat *M. abscessus* and to show efficacy as an oral therapy or once-daily therapy; statements regarding conducting future trials, including pivotal trials; the design and implementation of trials, including the anticipated number of sites and patients in the planned IIT; and epetraborole's potential in early-stage, treatment-naïve patients. Forward-looking statements are based on AN2's current expectations and involve risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. These risks and uncertainties include, among others, risk inherent in IITs, including reliance on third-party investigators and institutions for study conduct, availability and timing of external funding and operational support, site activation and retention, patient identification and enrollment pace, screen-failure rates, protocol adherence, and limited control over trial execution and data quality; the translation of preclinical data to outcomes in clinical trials; the ability to successfully initiate and complete clinical studies, obtain regulatory approvals, and commercialize any resulting products; the timing and success of clinical trials; the unmet need and market opportunity in *M. abscessus*; and other risks described in AN2's filings with the Securities and Exchange Commission, including under the heading "Risk Factors" in AN2's most recent quarterly report on Form 10-Q and other filings. AN2 undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.

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**Company Contact:**
Lucy O. Day
Chief Financial Officer
l.day@an2therapeutics.com

**Investor and Media Contact:**
Anne Bowdidge
ir@an2therapeutics.com

Source: AN2 Therapeutics, Inc.