AN2 Therapeutics Receives U.S. FDA IND Clearance to Proceed with Planned Phase 2 Global Study of Oral Epetraborole in Polycythemia Vera

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MENLO PARK, Calif.--(BUSINESS WIRE)--Nov. 2, 2026-- AN2 Therapeutics, Inc. (Nasdaq: ANTX), a clinical stage biopharmaceutical company focused on the discovery and development of novel small molecule therapeutics derived from its boron chemistry platform, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for epetraborole in polycythemia vera (PV). The Company has now received regulatory clearance in all planned jurisdictions (Australia, India, and the U.S.) for the global study and expects to initiate the trial in the fourth quarter of 2026.

"We're pleased to receive FDA IND clearance and the necessary authorizations globally to advance epetraborole into Phase 2 clinical development for polycythemia vera," said Cameron Trenor, M.D., Chief Medical Officer of AN2 Therapeutics. "Extensive preclinical and human data generated to date indicate that epetraborole has the potential to produce early, controlled, sustained and dose-dependent control of hematocrit, providing a strong rationale for clinical development in PV. We anticipate initiating the Phase 2 trial in the fourth quarter of 2026."

About the Phase 2 Study of Oral Epetraborole in PV

The planned Phase 2 study consists of an open-label epetraborole sentinel cohort, an open-label dose optimization cohort for dose selection (Part 1), followed by a double-blind, randomized, placebo-controlled cohort (Part 2), and an optional open-label extension cohort (Part 3). The study is designed to assess the efficacy of oral epetraborole in phlebotomy-dependent adults with PV and its effect on key hematological variables, to optimize a dose regimen on a by-patient level, to assess safety and tolerability, and and to assess patient-reported outcomes (PROs) using validated PRO instruments.

About Polycythemia Vera (PV)

PV is a blood cancer characterized by overproduction of red blood cells in the bone marrow. This overproduction increases hematocrit which can lead to serious medical complications, including arterial and venous thromboembolic events. If untreated, PV can be life-threatening. Despite available therapies, many patients experience uncontrolled hematocrit levels and persistent symptom burden, requiring long term management to maintain adequate disease control. PV is estimated to affect approximately 155,000 people in the U.S.

About AN2 Therapeutics

AN2 Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on the discovery and development of novel small-molecule therapeutics derived from our boron chemistry platform. Our development pipeline spans hematologic diseases, infectious diseases, and oncology with three Phase 2 programs expected to be active in 2026, as well as preclinical and research programs focused on targets in oncology, bone disorders, and infectious diseases. We are committed to delivering high-impact drugs to patients that address critical unmet needs and improve health outcomes.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "believe," "estimate," "predict," "potential," or "continue," or the negative of these terms or other similar expressions. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: epetraborole as a potential oral treatment for PV and the rationale for development based on preclinical and clinical data generated to date; the anticipated timeline for initiating the Phase 2 trial in PV; the potential of the Company's boron chemistry platform and advancement of the Company's development programs; the jurisdictions where enrollment may occur; 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: AN2's ability to implement its plans for its Phase 2 trial in PV; timely enrollment of patients in AN2's clinical trials and investigator-initiated clinical trials; AN2's ability to procure sufficient supply of its product candidates for its clinical trials; the potential for results from clinical trials to differ from preclinical, early clinical, preliminary, or expected results; the ability of particular preclinical models in non-human primates to predict safety and efficacy in humans; 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; 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 Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other reports filed with the U.S. Securities and Exchange Commission (SEC). These filings, when made, are available on the investor relations section of AN2's website at www.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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