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Anebulo Pharmaceuticals Announces Positive Interim Data for ANEB-001 from Part B of its Phase 2 Clinical Trial for Acute Cannabinoid Intoxication

- **Lower doses of ANEB-001 reduced the negative effects of higher doses of THC**
- **Currently exploring delayed dosing to better understand real-world conditions**

AUSTIN, Texas--(BUSINESS WIRE)-- **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication (ACI) and substance addiction (the "Company" or "Anebulo"), today announced positive interim data from the first two cohorts of Part B of its ongoing Phase 2 clinical trial evaluating ANEB-001 as a treatment for ACI.

The first two cohorts were challenged with 21 mg of THC, dosed orally (twice the THC dose used in Part A). Subjects then received 30mg (cohort 1) or 10mg (cohort 2) oral doses of ANEB-001, or matching placebo. The interim data available from Part B include pharmacokinetics, key pharmacodynamic outcomes, and blinded safety data. Based on these data, subjects challenged with a higher 21 mg oral THC dose and treated with placebo showed greater central nervous system (CNS) effects than observed in Part A with 10.5 mg THC. The effects included a substantial increase in feeling high and body sway, decreased alertness, and slightly increased heart rate compared to baseline. In contrast, treatment of subjects with 10 mg or 30 mg ANEB-001 led to significant and sustained reductions in the visual analog scale (VAS) feeling high score ($p < 0.001$), improvement in the VAS alertness scale ($p < 0.01$), and a reduction in THC-induced body sway ($p < 0.01$), compared to placebo.

In addition, 100% of subjects given 21 mg THC with placebo in Cohorts 1 and 2 met the VAS threshold for feeling high (>20 mm on the 100 mm VAS scale) compared to only 1 subject per group treated with ANEB-001 at 10 mg or 30 mg doses. Although the THC-induced increase in heart rate in this study was small, there was a trend towards improvement with ANEB-001 compared to placebo. The 10 mg and 30 mg ANEB-001 doses had similar effects to previous higher doses used in Part A, despite doubling the THC dose. Pharmacokinetic data from Part A and the first two cohorts of Part B confirmed rapid absorption and dose-related plasma exposure for oral ANEB-001.

"These new Part B data showed that 10mg of ANEB-001 reversed key symptoms of ACI, comparing favorably to our Part A data showing similar effects with 50mg and 100mg. The 10mg data is even more impressive considering we doubled the THC challenge to 21mg in that cohort," said Simon Allen, Chief Executive Officer of Anebulo. "Using lower doses of ANEB-001 to reduce ACI symptoms should allow us to optimize tolerability, while providing an even more favorable cost of goods if ANEB-001 is approved. We are currently exploring the effects of delayed dosing to better understand real-world conditions. In this circumstance,

we challenge subjects with THC one hour before administering ANEB-001. With no FDA approved therapeutic, ACI often requires lengthy emergency department stays with expensive follow-on interventions for neuropsychiatric complications such as anxiety and acute psychosis. We believe ANEB-001 will play a critical role in reducing the burden of ACI for the patient and the healthcare system."

The Phase 2 study is being conducted in healthy adult occasional cannabis users at the Centre for Human Drug Research (CHDR) in the Netherlands. Results of Part A of the study, announced in July 2022, showed positive effects of 50 mg or 100 mg of ANEB-001 in reducing the effects of a 10.5 mg oral THC dose. Part B of the study is an adaptive study design intended to evaluate lower doses of ANEB-001 at higher levels of THC. We intend to enroll a total of at least 6 cohorts in Part B, with up to 15 subjects per cohort, randomized 2:1 to active versus placebo.

Based on Part A and interim Part B results, the Company is continuing Part B of the study at CHDR to further evaluate the dose response and the effects of separating the doses of THC and ANEB-001. Enrollment of the third cohort of Part B is ongoing. Anebulo is currently collaborating with the Model-Informed Drug Development (MIDD) group at FDA to develop a PK/PD model that will be designed to predict optimal doses for treatment of ACI subjects. Preparations are ongoing for an observational study in ACI subjects in the emergency department setting to further support the PK/PD model and ANEB-001 development. Based on blinded safety data, adverse events in Cohorts 1 and 2 were mild and transient, except for two cases of moderate dizziness in Cohort 1 likely attributable to THC.

About ANEB-001

Our lead product candidate is ANEB-001, a potent, small molecule cannabinoid receptor antagonist, to address the unmet medical need for a specific antidote for ACI. ANEB-001 is an orally bioavailable, rapidly absorbed treatment candidate that we anticipate will reverse the symptoms of ACI, in most cases within 1 hour of administration. ANEB-001 is protected by one issued patent and rights to one patent application covering various methods of use of the compound and delivery systems. We began a Phase 2 proof-of-concept trial for ANEB-001 in December 2021 in the Netherlands and announced positive Phase 2 Part A proof-of-concept topline data on July 5, 2022 and positive Part B data on September 26, 2022.

About Acute Cannabinoid Intoxication (ACI)

Symptoms of ACI can include increased somnolence, impaired cognition and perception, disorientation, anxiety, and acute psychosis. According to DSM-5, a diagnosis of cannabinoid intoxication should include recent history of cannabinoid use, clinically considerable behavioral or psychological changes, such as euphoria, impaired judgment and motor skills, which have taken place since cannabinoid exposure.

About Visual Analogue Scale (VAS)

VAS is a validated tool commonly used to help rate the intensity of certain subjective sensations and feelings, such as feeling high. For example, for rating feeling high, the visual analog scale is typically a straight line with one end meaning not high and the other end meaning extremely high. A subject marks a point on the line that matches how high they feel.

About CHDR

The Centre for Human Drug Research (CHDR) is an independent institute that specializes in cutting-edge early-stage clinical drug research. Combining innovative methods and technologies, state-of-the-art facilities, and talented, motivated researchers helps CHDR maximize their clients' success. In addition, CHDR places the highest priority on their subjects' comfort and safety, and they play an active role in helping educate the medical and clinical research communities.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance abuse disorder. Its lead product candidate, ANEB-001, is currently in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) to evaluate its utility in reversing the negative effects of acute cannabinoid intoxication within one hour of administration. ANEB-001 is a competitive antagonist at the human cannabinoid receptor type 1 (CB1). For further information about Anebulo, please visit www.anebulo.com.

Forward-Looking Statements

Statements contained in this press release that are not statements of historical fact are forward-looking statements as defined in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, these forward-looking statements can be identified by words such as "anticipate," "believe," "designed," "expect," "intend," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: our belief that using lower doses of ANEB-001 to reduce ACI symptoms should allow us to optimize safety and tolerability, while providing an even more favorable cost of goods if ANEB-001 is approved; our belief that ANEB-001 will play a critical role in reducing the burden of ACI for the patient and the healthcare system; the PK/PD model we are developing in collaboration with MIDD and its expected design and capabilities; are planned observational study in ACI subjects in the emergency department setting and its expected benefits; statements related to the remainder of Part B of the Phase 2 study; You are cautioned that any such forward-looking statements are not guarantees of future performance and are subject to a number of risks, uncertainties and assumptions, including, but not limited to: initial and interim results from clinical studies are not necessarily indicative of results that may be observed in the future; clinical trial site challenges that may impact the expected timing of the Company's ongoing clinical trials, including challenges related to the ongoing COVID-19 pandemic; the timing and success of clinical trials and potential safety and other complications thereof; future supply or manufacturing issues; our ability to successfully commercialize and distribute ANEB-001, if approved; any negative effects on the Company's business and product development plans caused by or associated with COVID-19 or geopolitical issues; and our need for additional capital. These and other risks are described in under the "Risk Factors" heading of Anebulo's most recent annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on September 9, 2022. All forward-looking statements made in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Except as required by law, Anebulo undertakes no obligation to update or revise forward-looking statements to reflect

new information, future events, changed conditions or otherwise after the date of this press release.

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Anebulo Pharmaceuticals, Inc.
Scott Anderson
Head of Investor Relations and Public Relations
(858) 229-7063
scott@anebulo.com

Rex Merchant
Chief Financial Officer
(512) 598-0931
IR@anebulo.com

Source: Anebulo Pharmaceuticals, Inc.