August 21, 2023

Anebulo Receives Positive Feedback from FDA on Path to Advance Phase 3 Clinical Development of ANEB-001 and Completes Dosing of Phase 2 Extension

FDA provides favorable input on studies to support ANEB-001 approval

Part C Extension of Phase 2 trial completed exploring THC challenge dose of up to 60 mg

AUSTIN, Texas--(BUSINESS WIRE)-- **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB) (the "Company" or "Anebulo"), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication (ACI) and substance abuse, today announced positive feedback from the United States Food and Drug Administration (FDA) following a Type B meeting in July. The FDA indicated that a single well-controlled study of ANEB-001 in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers could potentially provide substantial evidence to support a new drug application.

"We're very pleased with the encouraging feedback we received from the FDA as it provides a viable path forward for designing and executing our Phase 3 trials with ANEB-001. Based on this constructive guidance and continuing dialog with the FDA, we are focusing on finalizing our registrational study designs. We look forward to providing further updates as we continue to advance this important program," said Simon Allen, CEO of Anebulo. "We plan to pursue the development path for ANEB-001 as efficiently as possible to bring this much-needed treatment for the growing number of patients who present to emergency departments every day with cannabinoid-related intoxication."

In addition to receiving the final minutes of the FDA meeting, Anebulo has also completed dosing in an open-label Part C extension of its Phase 2 clinical trial to evaluate the safety and efficacy of ANEB-001 at higher challenge doses of THC. Twenty healthy adult volunteers (2 cohorts of 10 subjects) participated in Part C of the study. Cohort 7 received a single oral dose of 40 mg of THC together with a single oral dose of 10 mg of ANEB-001. Cohort 8 received a single oral dose of 60 mg of THC together with a single oral dose of 20 mg of ANEB-001. In the earlier Part B of the study, a single oral dose of 40 mg THC without ANEB-001 was not well tolerated due to overt THC-related effects. However, the use of even higher THC challenge doses was considered acceptable by the IRB provided that all subjects would also receive ANEB-001. Part C of the study was therefore conducted as open-label without a placebo arm.

Subjective and objective assessments performed during the open-label Part C of the study were similar to those used in Parts A and B, with the addition of several new outcome measures intended to explore further evidence of clinically meaningful effects. Based on preliminary safety observations, THC challenge doses of 40 mg and 60 mg were well-

tolerated when dosed in combination with ANEB-001, and all treatment-related adverse events were mild and transient. Full safety, pharmacokinetic (PK), and pharmacodynamic data from the study, as well as results at higher doses of THC, are expected in 4Q 2023.

“Part C of this study was designed to provide insight into the potential efficacy and safety of ANEB-001 in real-world emergency situations, by challenging subjects with THC doses even higher than those that could be tested in Parts A and B,” said Ken Cundy, Ph.D., Chief Scientific Officer of Anebulo. “Higher THC doses in Part C of this study were administered by ensuring that all healthy subjects received ANEB-001 concurrently with the THC challenge. We are pleased to continue our very productive collaboration with our colleagues at the Centre for Human Drug Research in the Netherlands and look forward to announcing additional results of this open-label study.”

In addition to the Part C extension, Anebulo’s observational PK study in patients reporting to the emergency department with ACI is currently ongoing. Data gathered from these two studies are expected to improve our understanding of the range of THC exposures associated with ACI and the potential for treatment with ANEB-001.

About the Phase 2 study of ANEB-001

Parts A and B of the Phase 2 study were previously conducted in the Netherlands by the CHDR. A total of 134 healthy subjects were enrolled. All subjects received oral THC challenge doses. In total, 91 subjects received single oral doses of ANEB-001. Pharmacodynamic outcomes were assessed by mixed-effect model repeated measures analysis of covariance through 8 hours post-ANEB-001 dosing. Safety was assessed by continuous observation for 24 hours and followed up at 7 to 14 days after treatment. ANEB-001 was well tolerated in this study and there were no serious adverse events. At the 30 mg THC dose, prior to dosing ANEB-001 or placebo, subjects developed mild to moderate THC-related symptoms including moderate euphoria, nausea, and/or vomiting, and mild bradyphrenia, dizziness, paresthesia, and/or feeling emotional. After delayed dosing of 10 mg ANEB-001 or placebo following a 21 mg or 30 mg THC challenge dose, the adverse events considered possibly or probably related to ANEB-001 were mild except for one case of moderate nausea/vomiting at THC doses of 21 mg and 30 mg; the incidence of dizziness and euphoria was greater in the placebo treated subjects. Administration of a high-fat meal delayed the absorption of THC resulting in blunted effects of a 30 mg THC dose on many of the outcomes. However, delayed dosing of 10 mg ANB-001 still significantly reduced VAS feeling high in fed subjects ($p=0.0030$). Part C of the Phase 2 study was an open-label assessment of higher THC doses administered simultaneously with ANEB-001. The Dutch Ethics Committee has allowed these higher THC doses to be administered to healthy subjects provided that all subjects also receive treatment with ANEB-001.

About ANEB-001

Our lead product candidate is ANEB-001, a potent, small molecule cannabinoid receptor antagonist, under development to address the unmet medical need for a specific antidote for ACI. ANEB-001 is an orally bioavailable, readily absorbed treatment candidate that we anticipate will rapidly reverse key symptoms of ACI. 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, positive Part B data on September 26, 2022, completed dosing of all subjects in mid-December 2022, and announced preliminary Phase 2 Part B data on January 9, 2023. On March 28, 2023, we announced complete results from Part A and Part B of our Phase 2 clinical trial. We met with the FDA in July for a Type B meeting to discuss these data and the potential path forward to approval and received formal minutes on August 17, 2023. In addition, an observational study in patients presenting to Emergency Departments with ACI is currently ongoing. The study will determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected subjective assessments.

About Acute Cannabinoid Intoxication

Symptoms of ACI can include increased somnolence, impaired cognition and perception, disorientation, anxiety, and acute psychosis. A diagnosis of cannabinoid intoxication includes a recent history of cannabinoid use, and clinically considerable behavioral or psychological changes, such as anxiety, panic attacks, euphoria, impaired judgment and motor skills, and elevated heart rate, which have taken place since cannabinoid exposure.

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, has completed dosing in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) evaluating its utility in blocking and reversing the negative effects of acute cannabinoid intoxication. ANEB-001 is a competitive antagonist at the human cannabinoid receptor type 1 (CB1). For further information about Anebulo, please visit www.anebulo.com.

About The Centre for Human Drug Research

The Centre for Human Drug Research (CHDR), located in Leiden, the Netherlands, operates as an independent institute that specializes in early-stage clinical drug research. By merging groundbreaking methodologies, advanced technologies, and exceptional facilities, CHDR enables its clients to maximize their success. CHDR prioritizes the well-being and safety of its participants while actively contributing to the education of medical and clinical research communities. For more information about CHDR, please visit www.chdr.nl.

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," "designed," "expect," "may," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: the potential for a single well-controlled study of ANEB-001 in ACI patients presenting to the emergency department combined with a larger THC challenge study in volunteers to provide substantial evidence to support a new drug application; the path forward for designing and executing Phase 3 trials with ANEB-001 and whether it is viable and our plans for pursuing Phase 3 development in an efficient matter;

the expected timing for results from the open-label Part C extension of our Phase 2 clinical trial; the timing of future updates on the advancement of ANEB-001; future results that may be implied by prior results; the potential for ANEB-001 to address an unmet medical need for a specific antidote for ACI; and Anebulo's expectation that ANEB-001 will rapidly reverse key symptoms of ACI. 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; the ability to obtain regulatory approval; the Type B meeting minutes should not be relied on as an indication that ANEB-001 will ultimately be approved; the timing and success of clinical trials and potential safety and other complications thereof; any negative effects on the Company's business and product development plans caused by or associated with health crises or geopolitical issues; and Anebulo's need for additional capital. These and other risks are described under the "Risk Factors" heading of Anebulo's Quarterly Report on Form 10-Q for the quarter ended March 31, 2023, as filed with the SEC on May 11, 2023. 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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Media Contact
Ignacio Guerrero-Ros, Ph.D.
Russo Partners
(646) 942-5604
ignacio.guerrero-ros@russopartnersllc.com

Investor Relations
Adanna Alexander, Ph.D. or Harrison Seidner, Ph.D.
(646) 942-5603
(646) 942-5599
Adanna@RussoPR.com
Harrison.seidner@russopartnersllc.com

Anebulo Pharmaceuticals, Inc.
Sandra Gardiner
Acting Chief Financial Officer
(512) 598-0931
Sandra@anebulo.com

Source: Anebulo Pharmaceuticals, Inc.