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Anebulo Pharmaceuticals Announces Completion of Dosing and Preliminary Data from Part B of its Phase 2 Study of ANEB-001 for Acute Cannabinoid Intoxication

- Preliminary data showed ANEB-001 reduced effects of a 30 mg dose of THC
- Delayed dosing of ANEB-001 rapidly reversed pre-existing THC effects
- Full PK, PD, and safety data expected by end of 1Q2023
- Company targeting an End of Phase 2A meeting with FDA in the first half of 2023

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 completion of dosing in its randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating ANEB-001 as a potential treatment for ACI in healthy subjects challenged with oral THC. Part B of the Phase 2 trial was an adaptive design that included six cohorts of up to 15 healthy adults to examine different doses of THC and ANEB-001, and the impact of delayed dosing of ANEB-001 or placebo. In total, Parts A and B of the Phase 2 study enrolled 134 healthy subjects.

Data from Part A of the study showed positive protective effects of a single oral dose of 50 or 100 mg ANEB-001 when co-administered with an oral challenge dose of 10.5 mg THC. In Part B of the study, subjects were challenged with substantially higher oral doses of THC (21, 30 or 40 mg) and treated with lower doses of ANEB-001 (10 or 30 mg) or matching placebo. Delayed dosing of ANEB-001 was also examined by introducing a one-hour pause between the THC challenge and treatment with the ANEB-001 or placebo. The final cohort of the study included administration of a high fat meal prior to the THC challenge. Additional analyses await the final unblinded data.

Based on preliminary pharmacodynamic data for Part B of the study, a single low oral dose of ANEB-001 (10 mg) administered 1 hour after THC appeared to rapidly reverse key psychotropic effects of THC doses as high as 30 mg, including reduction in feeling high and improvement in alertness and body sway. ANEB-001 also appeared to reduce the time required for effects to normalize back to baseline. Only 5 subjects were challenged with 40 mg THC due to poor THC tolerability. Final analyses await the unblinded data expected by end of 1Q2023.

"Completing the dosing in this Phase 2 trial represents an important milestone for the company. Preliminary data showed that a single 10 mg dose of ANEB-001 reduced key symptoms of ACI induced with 30 mg of THC," said Simon Allen, Chief Executive Officer of Anebulo. "Further, we successfully demonstrated rapid reversal of key ACI symptoms even

after a one-hour delay between the THC challenge and ANEB-001 dosing. We believe the final data from this study, together with data from our planned observational study in ACI subjects, will provide support for the design of a registrational trial. We anticipate discussing the final data from this study with FDA at an End of Phase 2A meeting in the first half of this year.”

The Phase 2 study was conducted in the Netherlands by the Centre for Human Drug Research (“CHDR”). A total of 134 healthy subjects were enrolled. The safety data for the study are still blinded. 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 euphoria, bradyphrenia, paresthesia, and feeling emotional. After dosing ANEB-001 or placebo, the adverse events considered possibly or probably related to ANEB-001, THC, or placebo were mild except for one case of moderate nausea/vomiting. Administration of a high fat meal delayed the THC effects and the reversal of feeling high by ANEB-001.

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, 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, and completed dosing of all subjects in mid-December 2022.

About Acute Cannabinoid Intoxication

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 the Centre for Human Drug Research

The 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, has completed dosing in a Phase 2 clinical trial (www.clinicaltrials.gov/ct2/show/NCT05282797) evaluating its utility in 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.

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: the Phase 2 Study for ANEB-001 and the design, timing and potential benefits thereof; expected timing for full PK, PD and safety data from Anebulo’s Phase 2 Study of ANEB-001 by the end of the first quarter of 2023; the targeted timing for an End of Phase 2A meeting with the FDA in the first half of 2023; future results that may be implied by prior results; Anebulo’s belief that the data from its Phase 2 Study of ANEB-001, together with data from its planned observational study in ACI subjects, will provide support for the design of a registrational trial; 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; 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; any negative effects on the Company’s business and product development plans caused by or associated with COVID-19 or geopolitical issues; and Anebulo’s need for additional capital. These and other risks are described under the “Risk Factors” heading of Anebulo’s most recent quarterly report on Form 10-Q filed with the Securities and Exchange Commission on November 10, 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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