March 28, 2023

Anebulo Pharmaceuticals Announces Positive Complete Phase 2 Clinical Data Demonstrating Potential of ANEB-001 as a Treatment for Acute Cannabinoid Intoxication

- **ANEB-001 statistically significantly reduced VAS Feeling High in all cohorts (p= <0.0001 at the 30 mg THC dose level)**
- **A single 10 mg oral dose of ANEB-001 reduced key symptoms of Accute Cannabinoid Intoxication induced in healthy volunteers by 30 mg challenge dose of oral THC**
- **Delayed dosing of ANEB-001 rapidly reversed pre-existing THC effects**
- **ANEB-001 was well tolerated**
- **Targeting End of Phase 2A (EOP2A) meeting with FDA by mid 2023**

AUSTIN, Texas, March 28, 2023 /PRNewswire/ -- **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 addiction, today announced complete results from its randomized, double-blind, placebo-controlled Phase 2 clinical trial evaluating ANEB-001 as a potential treatment for ACI in healthy volunteers challenged with oral delta-9-tetrahydrocannabinol ("THC"). Part B of the study 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.

"The positive results of the Phase 2 proof of concept study are very encouraging and will have significant clinical implications for the unmet need of patients presenting to emergency departments with ACI," said Simon Allen, Chief Executive Officer of Anebulo. "We believe the complete data from this study, together with data from our observational study in ACI subjects and our PK/PD modeling efforts, will provide support for the design of a registrational trial. We are in the process of requesting an End of Phase 2A meeting with FDA to discuss the final data from this study. We expect the meeting to occur within 75 days from the date of the request but acknowledge that it could be longer."

Final ANEB-001 Part 2 Proof of Concept Study Results

Data from Part A of the study previously 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 a 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 the administration of a high-fat meal prior to the THC challenge.

Based on the final data for Part B of the study, a single low oral dose of ANEB-001 (10 mg) administered 1 hour after a THC challenge rapidly and statistically significantly reversed key psychotropic effects of THC doses as high as 30 mg, including a reduction in the visual analog scale (VAS) for feeling high ($p=<0.0001$) and improvement in VAS alertness ($p=0.0042$) and reduced body sway ($p=0.0196$). In a pre-specified pooled analysis of data for the combined 21 mg or 30 mg THC dose levels, a single 10 mg of ANEB-001 administered one hour after THC achieved statistical significance on all primary outcomes, including a reduction in VAS feeling high ($p=<0.0001$), improvement in VAS alertness ($p=0.0024$), reduced body sway ($p=0.0014$), and reduction in heart rate ($p=0.0125$). ANEB-001 also reduced the time required for the THC effects to normalize back to baseline.

"With these final data from the Phase 2 proof of concept study we have shown favorable tolerability and efficacy data of ANEB-001 in rapidly reversing the effects of a THC challenge, reinforcing the preliminary data previously reported," said Ken Cundy, Ph.D., Chief Scientific Officer of Anebulo. "These positive data showed that delayed ANEB-001 treatment after a THC challenge produced statistically significant improvements in all key outcomes, as well as improvements in other exploratory outcomes, demonstrating the therapeutic potential of ANEB-001 for the treatment of ACI. This successful study is the result of the hard work of the Anebulo team and our colleagues at the Centre for Human Drug Research ("CHDR") in the Netherlands. We look forward to presenting additional details from the study at a future scientific meeting."

The Phase 2 study was 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 (MMRM) analysis of covariance (ANCOVA) through 8 hours post-ANEB-001 dosing. Safety was assessed by continuous observation through 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 ($p=0.0030$).

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 a Phase 2 clinical trial (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 and follow us on LinkedIn.

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, completed dosing of all subjects in mid-December 2022, announced preliminary Phase 2 Part B data on January 9, 2023, and announced complete Phase 2 data on March 28, 2023.

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 a recent history of cannabinoid use, and 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 its 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.

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," "targeting," "expect," "will," "should" and other comparable terms. Forward-looking statements include statements regarding Anebulo's intentions, beliefs, projections, outlook, analyses or current expectations regarding: the targeted timing for an End of Phase 2A meeting with the FDA by mid 2023; the expected timing for a response from the FDA on the request for an End of Phase 2A meeting; the timing for presenting further details of the

Phase 2 clinical trial; the potential for ANEB-0001 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; the timing and success of clinical trials and potential safety and other complications thereof; 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 December 31, 2022, as filed with the SEC on February 10, 2023, and other filings Anebulo makes with the Securities and Exchange Commission from time to time (which are available at http://www.sec.gov). 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.

Media Contact

Ignacio Guerrero-Ros, Ph.D.
Russo Partners
646-942-5604
ignacio.guerrero-ros@russopartnersllc.com

Investor Contact

Adanna Alexander, Ph.D.
Russo Partners
646-942-5603
adanna.alexander@russopartnersllc.com

View original content to download multimedia:https://www.prnewswire.com/news-releases/anebulo-pharmaceuticals-announces-positive-complete-phase-2-clinical-data-demonstrating-potential-of-aneb-001-as-a-treatment-for-acute-cannabinoid-intoxication-301783031.html

SOURCE Anebulo Pharmaceuticals, Inc.