January 3, 2022

Anebulo Pharmaceuticals Announces Initiation of Phase 2 Clinical Study Evaluating ANEB-001 for the Treatment of Acute Cannabinoid Intoxication

Affirms expectations for initial topline results in 1H 2022

Recent FDA pre-IND meeting provides valuable guidance on U.S. regulatory path; company expects to submit IND in 1Q 2022

AUSTIN, Texas--(BUSINESS WIRE)-- **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and substance abuse, announces that the first patient has been dosed in a Phase 2 proof-of-concept clinical study investigating ANEB-001 as a potential treatment for acute cannabinoid intoxication.

In addition, Anebulo recently held a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) during which the company received valuable guidance regarding the clinical development of ANEB-001 in the U.S. Importantly, the FDA noted that a challenge model whereby subjects are exposed to THC in a controlled clinical setting may be acceptable to investigate primary efficacy, which would allow for the more efficient development of ANEB-001. Further, the FDA suggested that Anebulo submit a model-informed drug development (MIDD) paired-meeting request.

“The initiation of our Phase 2 study in the Netherlands represents a significant milestone for Anebulo. We continue to anticipate reporting initial topline results from Part A of this trial in the first half of 2022, as we closely monitor the impact of COVID-19. Despite the recently announced national lockdown in the Netherlands, our CRO is continuing to screen and enroll patients,” stated Daniel Schneeberger, M.D., Chief Executive Officer of Anebulo.

“Additionally, we are pleased with the guidance provided by the FDA regarding ANEB-001’s clinical and regulatory path in the U.S. We were able to rapidly incorporate the FDA’s feedback into the design of the current Phase 2 trial to make the data generated in Europe as relevant as possible for a potential future NDA submission. We expect to file an IND with the FDA during the first quarter of 2022,” he added. “There is a large and growing need to treat acute cannabinoid intoxication with 1.7 million cannabinoid-related emergency department visits in the U.S. in 2018, and we believe ANEB-001 holds potential to reverse symptoms safely and rapidly.”

The Phase 2 clinical trial is a randomized, double-blind, placebo-controlled study at a single site in the Netherlands to evaluate ANEB-001 in the inhibition of THC-induced effects. The new trial design anticipates enrolling a total of 60 patients in Part A, randomized 1:1:1 between 50mg of ANEB-001, 100mg of ANEB-001 and placebo. All participants will receive

10.5mg of THC as a challenge drug. The goal of Part A is to deliver clinical proof-of-concept that ANEB-001 can reverse the effects of THC. Part B will enroll additional cohorts and further explore the relationship between THC and ANEB-001 dose levels and clinical efficacy, and provide additional datapoints for pharmacokinetic/pharmacodynamic models. Anebulo believes the ability to quickly adapt the protocol and test additional hypotheses will save time and reduce development risk while designing future trials in 2022.

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. Its lead product candidate, ANEB-001, is intended to reverse 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) with good oral bioavailability and brain penetration (rat brain:plasma ratio of approximately 1.5). Clinical trials completed to date have shown that ANEB-001 is rapidly absorbed, well tolerated, and may lead to weight loss, an effect that is consistent with CB1 antagonism in the central nervous system. For further information about Anebulo, please visit www.anebulo.com.

Forward-Looking Statements

This press release contains 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. These forward-looking statements, along with terms such as “anticipate,” “expect,” “intend,” “may,” “will,” “should” and other comparable terms, involve risks and uncertainties because they relate to events and depend on circumstances that will occur in the future. Those statements include statements regarding the intent, belief or current expectations of Anebulo Pharmaceuticals and members of its management, as well as the assumptions on which such statements are based. Prospective investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, including risks attendant to developing, testing and commercializing the company’s product candidates, and those described in Anebulo Pharmaceutical’s most recent annual report on Form 10-K and in other periodic reports filed with the SEC, and that actual results may differ materially from those contemplated by such forward-looking statements. Except as required by federal securities law, Anebulo Pharmaceuticals undertakes no obligation to update or revise forward-looking statements to reflect changed conditions.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20220103005125/en/

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

LHA Investor Relations
Yvonne Briggs
(310) 691-7100

ybriggs@lhai.com

Source: Anebulo Pharmaceuticals, Inc.