

# Anebulo Pharmaceuticals Announces Completion of Manufacturing of ANEB-001 Capsules for Upcoming Phase 2 Clinical Trial

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 addiction, today announced the completion of finished product manufacturing of its lead drug ANEB-001 for use in the Company's upcoming Phase 2 clinical study. In compliance with all current Good Manufacturing Practice requirements, ANEB-001's active pharmaceutical ingredient was delivered to its contract manufacturer and filled into 10mg and 50mg capsules for finished product.

"Completion of manufacturing ANEB-001 capsules is a critical step in advancing the development of our drug candidate for the treatment of acute cannabis intoxication," stated Daniel Schneeberger, M.D., Chief Executive Officer of Anebulo. "With more than 1.7 million cannabinoid-related emergency department visits in 2018 and the number of visits growing by an estimated 15% annually, we believe ANEB-001 addresses a significant unmet need. We are on track to commence our Phase 2 proof-of-concept study in the coming weeks, which is ahead of schedule, and expect initial topline results from the first cohort in the first half of next year."

### **About ANEB-001**

Anebulo believes ANEB-001 is an asset with a well-understood mechanism of action. ANEB-001 is a competitive antagonist at the human CB1 receptor with an affinity of 0.6nM with good oral bioavailability and brain penetration (brain:plasma ratio = 1.5). ANEB-001 has been shown to antagonize THC-induced hypolocomotion in mice, a CB1 receptor-mediated response.

ANEB-001 is being developed to be administered as an oral treatment, reaches potentially therapeutic blood levels within 30 minutes and is believed to rapidly reverse the signs and symptoms of cannabinoid overdose in as little as one hour. Anebulo believes there is a low likelihood of drug-drug interactions as preclinical testing demonstrated that ANEB-001 does not inhibit the metabolic cytochromes 1A2, 2C9, 2C19, 2D6 and 3A4 at pharmacologically relevant concentrations. No product is approved for acute cannabinoid intoxication and Anebulo is not aware of any competing products to reverse the symptoms of cannabinoid intoxication that are further along in the development process than ANEB-001.

# **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 addiction. Its lead product candidate, ANEB-001, is intended to reverse the negative effects of acute cannabinoid intoxication within one hour of administration. Clinical trials completed to date have shown that ANEB-001 is rapidly absorbed, well tolerated and leads to weight loss, an effect that is consistent with central cannabinoid receptor type 1 antagonism. 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 recent registration statement on Form S-1 and in 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.

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### 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

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