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Anebulo Pharmaceuticals Announces Positive Regulatory Update for Selonabant in Acute Cannabis-Induced Toxicity in Children and Capital Raise

AUSTIN, Texas--(BUSINESS WIRE)-- **Anebulo Pharmaceuticals, Inc.** (Nasdaq: ANEB), a clinical-stage biopharmaceutical company developing novel solutions for people suffering from acute cannabinoid-induced toxicities (the "Company" or "Anebulo"), today announced a positive regulatory update and the close of a capital raise.

- In a Phase 2 proof-of-concept study, Anebulo enrolled 134 adult subjects challenged with oral delta-9-tetrahydrocannabinoil ("THC"), oral selonabant blocked or reversed key CNS effects of THC, establishing the clinical path for intravenous selonabant for a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of acute cannabis-induced toxicity in children
- Anebulo met with FDA to discuss the development of intravenous selonabant and the initial plan for clinical testing
- FDA acknowledged the unmet need for a treatment for children exposed to cannabis toxicity, and proposed a close, ongoing collaboration to efficiently advance the selonabant program for the pediatric indication
- Anebulo plans to begin its Phase I SAD study of IV selonabant in healthy adults in 1H25
- Anebulo entered into a definitive stock purchase agreement with 22NW, a company controlled by one of its directors, Nantahala Capital and an additional existing investor for the issuance and sale of 15.2 million shares of common stock for gross proceeds of $15 million in a private placement offering priced at-the-market under Nasdaq rules
- In exchange for purchasing $10 million of shares of common stock in the private placement, Anebulo intends to modify the Loan and Security Agreement (LSA) that was entered into with 22NW and JFL Capital Management by reducing the maximum loan size to approximately $3 million, which reduces the LSA to just under the securitization threshold, and the removal of any securitization

"We are grateful to have the continued support from current investors. Having secured such meaningful financing without having to issue stock at a discount to the market or include warrant coverage is indicative of the confidence these highly respected institutional investors have in the company's future," commented Richie Cunningham, Chief Executive Officer of Anebulo.

Cunningham continued, "In recent interactions, FDA confirmed our belief that there is an unmet need for a treatment for children exposed to cannabis toxicity and suggested a close collaboration with Anebulo to facilitate an efficient development plan for this important pediatric condition. If approved, we believe selonabant has the potential to offer a much-

needed targeted therapy for rapidly reversing the serious and life-threatening consequences of acute cannabis-induced toxicity in children. To validate this market opportunity, we hired a top five pharmaceutical consulting firm to complete a market assessment. This team of experts evaluated and confirmed acute cannabis induced toxicity in children as a viable commercial opportunity. In addition, based on an incidence less than 200,000 cases per year we also believe this to be a rare pediatric condition."

The private placement is expected to close no later than December 24th, subject to the satisfaction of customary closing conditions. The private placement is being conducted in accordance with applicable Nasdaq rules and was priced at $0.99 per share to satisfy the "Minimum Price" requirement (as defined in the Nasdaq rule).

In connection with the close of the private placement, the Company will amend its LSA that was entered into in November 2023. The LSA allowed the Company to borrow up to $10 million, and to date, no funds have been borrowed. The amended loan agreement will reduce the borrowing limit to approximately $3 million and will be unsecured.

About Selonabant (ANEB-001)

The Company's lead product candidate is selonabant (ANEB-001), a potent, small molecule antagonist of the cannabinoid receptor type-1 ("CB1"), under development to address the unmet medical need for a specific antidote for acute cannabis-induced toxicity, including acute cannabinoid intoxication ("ACI") in adults and unintentional cannabis poisoning in pediatric subjects. The Company anticipates that selonabant will rapidly reverse key symptoms of cannabis toxicity. Selonabant has been successfully formulated for oral administration in clinical studies and as a potential IV treatment. In a Phase 2 proof-of-concept study in adult subjects challenged with oral delta-9-tetrahydrocannabinol ("THC") (www.clinicaltrials.gov/ct2/show/NCT05282797), oral selonabant blocked or reversed key CNS effects of THC. Selonabant was well tolerated in this study and there were no serious adverse events. In the open-label extension of the study, THC challenge doses of 40 mg and 60 mg were well-tolerated when dosed in combination with oral selonabant, and all treatment-related adverse events were mild and transient. The prior Phase 1 and Phase 2 studies of oral selonabant have together enrolled a total of 250 subjects, of which 189 received selonabant. Selonabant is protected by two issued patents covering various methods of use of the compound and composition of matter of the crystalline form of selonabant. Anebulo also has multiple pending applications covering various methods of use of the compound and delivery systems. An observational study in patients presenting to Emergency Departments with cannabis toxicity is currently ongoing. The study is intended to determine concentrations of cannabinoids and metabolites in plasma and gather information on signs and symptoms, patients' disposition and selected subjective assessments.

About Anebulo Pharmaceuticals, Inc.

Anebulo Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company developing novel solutions for people suffering from acute cannabinoid intoxication and unintentional cannabis intoxication. Its lead product candidate, selonabant, has completed a Phase 2 clinical trial evaluating its utility in blocking and reversing the negative effects of acute cannabinoid intoxication in healthy adults challenged with oral THC. Rather than proceeding directly with Phase 3 studies of oral selonabant in adults with ACI, the Company is prioritizing the advancement of a selonabant IV formulation as a potential treatment for pediatric patients

with acute cannabis-induced toxicity, which it believes offers the potential for a faster timeline to approval relative to the adult oral product. Anebulo is currently scaling up the intravenous formulation for initial clinical safety studies. Selonabant is a competitive antagonist at the human CB1 receptor. 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,” “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: plans to begin its Phase I SAD study of IV selonabant in healthy adults in 1H25; plans to amend the LSA; the unmet need for a treatment for children exposed to cannabis toxicity; the potential for selonabant to offer a much-needed targeted therapy for rapidly reversing the serious and life-threatening consequences of acute cannabis-induced toxicity in children; acute cannabis induced toxicity in children being a viable commercial market opportunity and a rare pediatric condition; the closing of the private placement on December 24, 2024; selonabant rapidly reversing key symptoms of cannabis toxicity; the observational study determining concentrations of cannabinoids and metabolites in plasma and gathering information on signs and symptoms, patients’ disposition and selected subjective assessments; and advancement of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, offering the potential for a faster timeline to approval relative to the adult oral product. 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: the Company’s ability to close its private placement as anticipated; pursue its regulatory strategy including; commencement of the Phase 1 SAD study of IV selonabant in healthy adults in 1H25, having acute cannabis induced toxicity in children treated as a rare pediatric condition; its ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, the Company’s ability to obtain or maintain the capital or grants necessary to fund its research and development activities, its ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to the ability to promote or commercialize product candidates for specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of Anebulo’s products, the Company’s ability to maintain its license agreements, the continued maintenance and growth of its patent estate and the Company’s ability to retain its key employees or maintain its Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statements included in the Company’s Annual Report on Form 10-K for the year ended June 30, 2024, and its subsequent filings with the Securities and Exchange Commission, including subsequent periodic reports on Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. 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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