September 25, 2025

# Anebulo Pharmaceuticals Announces First Patients Dosed in Phase 1 Single Ascending Dose Study of Intravenous Selonabant, under Development for Acute Cannabis-Induced Toxicity

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 announces the first subjects dosed in its Phase 1 single ascending dose (“SAD”) study of intravenous (IV) selonabant in healthy young adults. The study is supported by a collaborative grant from the National Institute on Drug Abuse (NIDA).

- First Subjects Dosed in Phase 1 SAD Study of Intravenous Selonabant
- Second year of NIDA collaborative grant ($994,300) awarded

“This important milestone brings Anebulo closer to its goal of providing the first emergency antidote for acute cannabis-induced toxicity,” commented Richie Cunningham, Chief Executive Officer of Anebulo. “Anebulo previously evaluated selonabant as an oral treatment in a Phase 2 clinical trial, demonstrating potential for blocking and reversing the negative effects of acute cannabinoid intoxication (ACI) in healthy adults challenged with oral THC. The Company has since prioritized the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, which it believes is a more serious condition that offers the potential for a faster timeline to approval relative to the adult oral product. In particular, acute cannabis exposure in children can result in serious and potentially life-threatening consequences, including CNS depression, respiratory depression, coma, and in rare cases death. Research has shown that children are much more sensitive to the toxic effects of cannabis, due in part to age-related differences in the abundance and distribution of cannabis receptors in their brains. As a consequence, cannabis ingestion in children can result in much more serious outcomes than in adults, and a much greater risk of hospitalization and admission to intensive care.”

Cunningham continued, “In addition to the continuing support from NIDA, our interactions with the Food and Drug Administration have confirmed our belief that there is a significant and growing unmet need for a treatment for children exposed to cannabis toxicity. FDA has suggested a close collaboration with Anebulo to facilitate development of selonabant 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.”

**About the Phase 1 Clinical Trial**

The phase 1 clinical trial is a randomized, double-blind, placebo-controlled, single ascending dose (SAD) study of intravenous selonabant. The study will investigate the safety, tolerability, and pharmacokinetics of selonabant administered intravenously in healthy adult subjects aged 18 to 25 years. The study is supported by the National Institute on Drug Abuse (NIDA) of the National Institutes of Health (NIH) under award number U01DA059995.

**About Selonabant**

Selonabant is a competitive antagonist at the human CB1 receptor, the primary receptor involved in the psychotropic effects of cannabis and certain other cannabinoids. Anebulo previously evaluated selonabant as an oral treatment in a Phase 2 clinical trial (NCT05282797), demonstrating potential for blocking and reversing the negative effects of acute cannabinoid intoxication (ACI) in healthy adults challenged with oral THC. The Company has since prioritized the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, which it believes is a more serious condition that offers the potential for a faster timeline to approval relative to the adult oral product.

**About Anebulo Pharmaceuticals, Inc.**

Anebulo Pharmaceuticals, Inc. is a clinical-stage pharmaceutical company developing novel solutions for people suffering from acute cannabis-induced toxicity. For further information about Anebulo, please visit www.anebulo.com.

**Forward-Looking Statements**

This press release may contain forward-looking statements that are being made pursuant to the Private Securities Litigation Reform Act of 1995, which provides a “safe harbor” for forward-looking statements to encourage companies to provide prospective information so long as those statements are accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those discussed in the statement. Such forward-looking statements include statements regarding providing the first emergency antidote for acute cannabis-induced toxicity, the advancement of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, the significant and growing unmet need for a treatment for children exposed to cannabis toxicity, and the potential of selonabant to offer a targeted therapy for rapidly reversing the serious and life-threatening consequences of acute cannabis-induced toxicity in children. 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, Anebulo’s ability to pursue its regulatory strategy; the ability of selonabant to rapidly reverse key symptoms of cannabis toxicity, including acute cannabis-induced toxicity in children; the ability of a selonabant IV formulation as a potential treatment for pediatric patients with acute cannabis-induced toxicity, Anebulo’s ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, Anebulo’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, Anebulo’s ability to maintain its license agreements,

the continued maintenance and growth of its patent estate and Anebulo's ability to retain its key employees. These risks should not be construed as exhaustive and should be read together with the other cautionary statements included in Anebulo's Annual Report on Form 10-K for the year ended June 30, 2024, and its subsequent filings with the Securities and Exchange Commission. 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. 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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Source: Anebulo Pharmaceuticals, Inc.