Amygdala Neurosciences Selects ANS-858 for Clinical Development as a Novel ALDH2 Inhibitor for Substance Use Disorder

The discovery and preclinical efficacy of ANS-858, a proprietary, selective, reversible, orally bioavailable ALDH2 inhibitor will be presented at 48th Annual Scientific Meeting of the Research Society on Alcohol.

SAN FRANCISCO, CA – April 2, 2025 –

Amygdala Neurosciences, Inc., a biopharmaceutical company dedicated to the research and development of novel therapies for addiction and compulsive overeating disorders, has announced a significant milestone in its drug development pipeline. The company has selected ANS-858 as its lead clinical candidate. This marks a crucial step forward in bringing a potentially transformative treatment to patients suffering from these debilitating conditions.

ANS-858 is a new, proprietary, small molecule inhibitor of aldehyde dehydrogenase 2 (ALDH2). By inhibiting ALDH2, ANS-858 aims to reduce the rewarding effects associated with alcohol and other substances, thereby mitigating the risk of relapse and offering a path toward abstinence while also reducing anxiety.

The selection of ANS-858 follows an extensive preclinical evaluation demonstrating strong efficacy, selectivity, and a favorable safety profile. ALDH2 inhibition represents a promising mechanism for reducing consumption of addictive drugs by affecting the mesolimbic dopamine reward pathway to reduce cravings. Unlike traditional therapies, ANS-858 is designed to provide greater tolerability, improved dosing flexibility, and optimized pharmacokinetics.

“Amygdala Neurosciences is committed to advancing the treatment landscape for substance use disorder, a condition with significant unmet medical need,” said Brent K Blackburn, PhD, CEO. “The selection of ANS-858 for clinical development marks a key milestone in our mission to develop safe and effective therapeutics for individuals struggling with SUD. Our team is preparing to initiate first-in-human clinical trials to evaluate ANS-858’s potential in reducing addictive drug consumption and promoting recovery.”

One in five adult Americans, or 48 million people, have a diagnosis of a substance use disorder. Alcohol use disorder affects over 28 million adults in the United States, yet current treatment options remain limited. There are 1.2 million patients with cocaine use disorder, where no medical treatment options are available. ANS-858 is designed to provide a targeted, pharmacological approach to modulating dopamine biosynthesis in the brain without affecting basal levels, offering a novel alternative to existing therapies.

Amygdala Neurosciences plans to submit an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) and advance ANS-858 into Phase 1 clinical trial.

Amygdala Neurosciences to present at the Research Society on Alcohol.

The Annual Scientific Meeting of the Research Society on Alcohol (RSA) aims to bring together alcohol researchers from various disciplines to share their latest findings and stay updated on new research developments. It fosters both professional and personal interactions in a collaborative environment. The meeting is being held in New Orleans, LA, June 21-25, 2025.

About ANS-858

ANS-858, a proprietary new chemical entity, works in the brain's 'neural interface between motivation and action' to reduce the dopamine surge responsible for craving. Inhibition of ALDH2 has been shown to reduce drug seeking behavior in preclinical studies against multiple addictive agents and has the potential for use as pharmacotherapy for substance use disorders (SUD), binge-eating, and anxiety. Amygdala Neurosciences is developing ANS-858 for the safe treatment of SUD that includes alcohol and cocaine use disorders.

About Amygdala Neurosciences, Inc.

Amygdala Neurosciences is developing ANS-858 to curb craving. Its mission is to treat individuals who experience harmful cravings associated with chemicals of addiction and food. The company was formed based on technology discovered and developed by members of the companies' leadership team while at CV Therapeutics and acquired from Gilead Sciences.

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For more information, please visit **amygns.com** or contact mailroom@amygns.com.

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