

Awakn Life Sciences Provides Update on R&D Programs, Progressing Novel Therapeutics for Alcohol Use Disorder and PTSD

Toronto, Ontario--(Newsfile Corp. - January 27, 2025) - Awakn Life Sciences Corp. (CSE: AWKN) (OTC Pink: AWKNF) (FSE: 954) ("Awakn" or the "Company"), a clinical-stage biotechnology company focused on developing therapeutics for substance use and mental health disorders, is pleased to provide an update on its research and development (R&D) programs.

Awakn currently has three main R&D programs:

1. AWKN-001

An investigational, novel combination therapy, consisting of an N-methyl-D-aspartate receptor-modulating drug (ketamine) delivered intravenously (IV) in combination with manualized relapse prevention cognitive behavioral therapy (CBT) for the treatment of severe Alcohol Use Disorder (AUD) in the UK and potentially the EU.

- **Current Status:** AWKN-001 is in Phase 3 in the UK. The trial is co-funded by a partnership between the UK's Medical Research Council (MRC) and the National Institute for Health and Care Research (NIHR), and Awakn Life Sciences Corp. It is managed by the University of Exeter Clinical Trials Unit. Awakn's costs for this trial are capped at GB£800,000 / CA\$1.4m.
- **Regulatory Path and Exclusivity:** Awakn is targeting a Regulation 52b hybrid application in the UK for AWKN-001. If successful, this could provide 8 years of market exclusivity, with an additional 2 years of supplementary protection, preventing competitors from marketing a similar product for the same indication.

2. AWKN-002

A proprietary oral thin film (OTF) formulation of esketamine for sublingual and buccal administration, developed in combination with structured alcohol education for moderate to severe Alcohol Use Disorder (AUD) in the U.S.

- **Current Status:** Awakn has in-licensed a Phase 1 program from LTS Lohmann Therapie-Systeme AG and completed two mechanistic studies in AUD with AWKN-002. These studies were used to file method-of-use patents. Awakn also completed a Pre-Investigational New Drug (Pre-IND) meeting with the U.S. Food and Drug Administration (FDA), which confirmed that AWKN-002 can be reviewed under the 505(b)(2) NDA pathway. The FDA further confirmed that no additional clinical data are needed to proceed with a Phase 2b trial in patients with moderate to severe AUD.
- **Regulatory Path and Exclusivity:** Awakn plans to submit an IND Application for AWKN-002 in H2 2025, followed by a Clinical Trial Application ("CTA") for a Phase 2b trial in H1 2026. In due course, Awakn will submit a NDA under the 505(b)(2) pathway. The reference product for Awakn's NDA will be J&J's Spravato®, which is forecast to achieve US\$1bn in sales in 2024. Subject to successful clinical trial outcomes and FDA approval, AWKN-002 could be granted up to 5 years of market exclusivity in the US for the treatment of AUD, provided its patents are granted and recognised in the US Orange Book. Awakn anticipates that the Phase 2b clinical trial application will be made in 2026.

3. AWKN-SND-14

A series of serotonin, dopamine, and noradrenaline modulators under pre-clinical investigation for

trauma-related mental health disorders, including Post-Traumatic Stress Disorder (PTSD). This program was previously referred to as Awakn's aminoindane new chemical entity program.

- **Program Focus:** AWKN-SND-14 is designed to promote pro-social behavior with a potentially improved safety profile compared to current investigational PTSD treatments. By enhancing trust, empathy, and social bonding-critical elements in addressing PTSD-AWKN-SND-14 aims to help individuals rebuild relationships, overcome isolation, and engage more effectively in therapy.

Anthony Tennyson, CEO of Awakn, commented: "We are excited about the progress across our key R&D programs, particularly in the areas of Alcohol Use Disorder and PTSD. With the advancements we've made in AWKN-001 and AWKN-002, we're on track to deliver transformative therapies for patients in need of more effective solutions."

Prof. David Nutt, Chief Research Officer of Awakn, added: "Our ongoing work with AWKN-SND-14 is especially promising, as it targets the underlying mechanisms of PTSD. We're optimistic about its potential to offer a safer, more effective option for individuals suffering from trauma-related disorders."

About AUD

Alcohol Use Disorder (AUD) is a chronic, relapsing brain health disorder characterized by compulsive alcohol use, loss of control over drinking, and negative emotional states when not using alcohol. It affects individuals across diverse demographics and can lead to a wide range of physical, psychological, and social consequences. AUD affects approximately 29 million¹ adults in the US with the Company estimating a current affected population of 40 million in the US and US and key European markets. Despite this high prevalence treatment success rates are very low with up to 75% of patients with AUD returning to harmful drinking within 12 months of treatment². This high prevalence rate and low treatment success rate create a significant unmet medical need, a significant public health concern, and an enormous economic cost \$249 billion in the US³.

About PTSD

PTSD is a debilitating mental health condition characterized by persistent and distressing symptoms resulting from exposure to traumatic events. Individuals with PTSD often experience intrusive memories, flashbacks, nightmares, hypervigilance, and avoidance behaviors, leading to significant impairment in daily functioning and overall well-being. Despite its prevalence, with an estimated 13⁴ million adults in the US and with the Company estimating a current affected population of 20 million in the US and key European markets affected by PTSD, the condition remains underdiagnosed and underserved. Current treatment options often fall short in providing adequate relief, leaving many individuals without effective therapeutic solutions

About Awakn Life Sciences Corp.

Awakn Life Sciences Corp. is a clinical-stage biotechnology company developing therapeutics targeting substance use and mental health disorders. Awakn has a near-term focus on AUD, a condition affecting approximately 29 million adults in the US and approximately 40 million in the US and key European markets for which the current standard of care is inadequate. Our goal is to provide breakthrough therapeutics to addiction sufferers in desperate need and our strategy is focused on commercialising our R&D pipeline across multiple channels.

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This news release contains certain forward-looking information and forward-looking statements, as defined in applicable securities laws (collectively referred to herein as "forward-looking statements").

Forward-looking statements reflect current expectations or beliefs regarding future events or the Company's future performance. All statements other than statements of historical fact are forward-looking statements. Often, but not always, forward-looking statements can be identified by the use of words such as "plans", "expects", "is expected", "budget", "scheduled", "estimates", "continues", "forecasts", "projects", "predicts", "intends", "anticipates", "targets" or "believes", or variations of, or the negatives of, such words and phrases or state that certain actions, events or results "may", "could", "would", "should", "might" or "will" be taken, occur or be achieved, including statements relating the business of the Company. All forward-looking statements, including those herein are qualified by this cautionary statement.

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¹ Substance Abuse and Mental Health Administration, 2022 National Survey on Drug Use and Health (NSDUH).

² Treatment rates for alcohol use disorders: a systematic review and meta-analysis, (Mekonen et al., 2021).

³ National Institute for Alcoholism and Alcohol Abuse (NIAAA), Economic Burden of Alcohol Misuse in the United States

⁴ US VA National Center for PTSD. US Department of Veterans Affairs.



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