

# Awakn Announces Positive Outcome of Pre-IND Meeting with FDA for AWKN-002 in Alcohol Use Disorder

Toronto, Ontario--(Newsfile Corp. - January 20, 2025) - **Awakn Life Sciences Corp.** (CSE: AWKN) (OTC Pink: AWKNF) (FSE: 954) ("Awakn" or the "Company"), a clinical-stage biotechnology company developing therapeutics for substance use and mental health disorders, announces a positive outcome from its Pre-Investigational New Drug (Pre-IND) meeting with the U.S. Food and Drug Administration (FDA), which took place on December 16, 2024. The meeting addressed the continued development of AWKN-002, a proprietary oral thin film (OTF) formulation of esketamine designed for sublingual and buccal administration in combination with structured alcohol education, being developed for moderate to severe alcohol use disorder (AUD).

The Pre-IND meeting provided an opportunity for the Company to discuss its Investigational New Drug (IND) development plan and receive FDA guidance on nonclinical and clinical study requirements for its new drug candidate. During the meeting, the FDA provided constructive feedback and expressed support for Awakn's proposed development strategy. Notably, the FDA confirmed that no additional clinical data are required prior to initiating a Phase 2b trial for AWKN-002 in patients with moderate to severe AUD.

The FDA also agreed that AWKN-002 can be reviewed under the 505(b)(2) New Drug Application (NDA) approval pathway, which allows the use of data from an approved esketamine product to support the development of AWKN-002 for AUD treatment once a scientific bridge between AWKN-002 and the reference product has been established.

**Anthony Tennyson, Chief Executive Officer of Awakn, stated,** "We are pleased with the outcome of our Pre-IND meeting with the FDA. The FDA's support for our development strategy, particularly their confirmation that we can proceed to Phase 2b once a suitable scientific bridge to the product has been established, marks a significant milestone for Awakn. This feedback provides us with a clear and efficient path forward in the development of AWKN-002, a novel treatment for AUD, an area of substantial unmet medical need."

**Prof. David Nutt, Chief Research Officer of Awakn, added,** "The FDA's recognition of our development strategy, and their willingness to support progression to Phase 2b, further validates the potential of AWKN-002 as a therapeutic for AUD. We look forward to continuing our work to bring this promising treatment to patients in need."

Awakn is planning to submit its IND application and initiate the Phase 2b clinical trial for AWKN-002 in patients with AUD once a scientific bridge to the reference product has been suitably established.

## 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 million<sup>1</sup> 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 treatment<sup>2</sup>. 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 US<sup>3</sup>.

## 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 with the Company estimating a current affected population of 40 million in the US and 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 to the business of the Company. All forward-looking statements, including those herein are qualified by this cautionary statement.

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Investors are cautioned that any such statements are not guarantees of future performance and actual results or developments may differ materially from those projected in the forward-looking information. For more information on the Company, investors are encouraged to review the Company's public filings on SEDAR at [www.sedarplus.com](http://www.sedarplus.com). The Company disclaims any intention or obligation to update or revise any forward-looking information, whether as a result of new information, future events or otherwise, other than as required by law.

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

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

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



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