

# Awakn Life Sciences Receives Regulatory and Ethical Approval for Phase III Clinical Trial of AWKN-P001

## AWKN-P001 is a N-methyl-D-aspartate Receptor-Modulating Drug Used in Combination with Psycho-Social Support for the Treatment of Severe Alcohol Use Disorder

Toronto, Ontario--(Newsfile Corp. - November 15, 2023) - Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954), a clinical-stage biotechnology company developing therapeutics to treat addiction with a near-term focus on Alcohol Use Disorder (AUD), announces today that it has received clinical trial authorization from the Medicines and Healthcare products Regulatory Agency (MHRA) and ethical approval from the Health Research Authority in the UK for a phase III clinical trial for its lead program AWKN-P001 for the treatment of Severe Alcohol Use Disorder (SAUD).

SAUD, the most acute type of alcohol use disorder, affecting approximately 12.5 million people in the US and the key European markets of Germany, UK, France, Italy, and Spain.

AWKN-P001 is a novel combined therapeutic of a N-methyl-D-aspartate receptor-modulating drug (ketamine) used in combination with psycho-social support to treat SAUD. Results from AWKN-P001 phase II study were very positive, achieving 86% abstinence in the 6 months post treatments vs. 2% abstinence pre-trial, and 25% abstinence in current standard of care.

The trial is being funded by Awakn, The University of Exeter, and a partnership between the National Institute for Health and Care Research (NIHR) and the Medical Research Council (MRC). The phase III trial will be a n=280, two-armed randomized placebo-controlled trial. It will be delivered in the UK across ten UK National Health Service (NHS) sites. Awakn will contribute approx. GBP £800,000 towards the costs of the trial, with the NIHR, the MRC, and the University of Exeter contributing the balance of the costs.

The MHRA and Health Research Authority's approval and continued support reflects their confidence in the rigorous research, ethical standards and promise of this trial. Enrollment for the phase III is due to start in Q1 2024.

Prof. Celia Morgan, Head of Ketamine-Assisted Therapy at Awakn and Principal Investigator of the trial commented, *"We are thrilled to have received the green light to proceed with this landmark trial, which will be the largest and most rigorous study of ketamine-assisted therapy for Alcohol addiction to date. We believe that ketamine, when combined with psychological support, has the potential to offer a new treatment paradigm for millions of people who suffer from alcohol addiction, and another vote of confidence from these organizations is an amazing and critical step in the process."*

Anthony Tennyson, Awakn CEO, commented, *"This regulatory and ethical approval is not only a testament to our commitment to scientific rigor and patient well-being, but also a pivotal step in our commercial journey. It opens new horizons for Awakn, as we move one step closer to delivering a potentially transformative therapy to the market. Our Phase 3 clinical trial represents a crucial bridge between cutting-edge science and a commercially viable solution for addressing severe alcohol use disorder."*

**About Awakn Life Sciences Corp.**

Awakn Life Sciences Corp. is a clinical-stage biotechnology company developing therapeutics targeting addiction. Awakn has a near-term focus on Alcohol Use Disorder (AUD), a condition affecting approximately 51 million people in the US and key European international markets and 285m people globally 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 commercializing our R&D pipeline across multiple channels.

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## **About National Institute for Health and Care Research (NIHR)**

The mission of the National Institute for Health and Care Research (NIHR) is to improve the health and wealth of the nation through research. We do this by:

- Funding high quality, timely research that benefits the NHS, public health and social care;
- Investing in world-class expertise, facilities and a skilled delivery workforce to translate discoveries into improved treatments and services;
- Partnering with patients, service users, carers and communities, improving the relevance, quality and impact of our research;
- Attracting, training and supporting the best researchers to tackle complex health and social care challenges;
- Collaborating with other public funders, charities and industry to help shape a cohesive and globally competitive research system;
- Funding applied global health research and training to meet the needs of the poorest people in low and middle income countries.

NIHR is funded by the Department of Health and Social Care. Its work in low and middle income countries is principally funded through UK Aid from the UK government.

## **Notice Regarding Forward-Looking Information**

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.

Although the Company believes that the expectations expressed in such statements are based on reasonable assumptions, such statements are not guarantees of future performance and actual results or developments may differ materially from those in the statements. There are certain factors that could cause actual results to differ materially from those in the forward-looking information. These include, but are not limited to: COVID-19; fluctuations in general macroeconomic conditions; the business plans and strategies of the Company; the ability of the Company to comply with all applicable governmental regulations in a highly regulated business; the inherent risks in investing in target companies or projects which have limited or no operating history and are engaged in activities currently considered illegal in some jurisdictions; changes in laws; limited operating history; reliance on management; requirements for additional financing; competition; fluctuations in securities markets; inconsistent public opinion and perception regarding the medical-use of psychedelic drugs; expectations regarding the size of the addiction market; and regulatory or political change. Readers are cautioned that the foregoing list of factors is not exhaustive of the factors that may affect forward-looking statements. Accordingly, readers

should not place undue reliance on forward-looking statements. The forward-looking statements in this news release speak only as of the date of this news release or as of the date or dates specified in such statements.

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.sedar.com](http://www.sedar.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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