

Awakn Announces First Patient Screened in Phase 3 Clinical Trial of AWKN-001 for Severe Alcohol Use Disorder

Toronto, Ontario--(Newsfile Corp. - August 9, 2024) - Awakn Life Sciences Corp. (CSE: AWKN) (OTCQB: AWKNF) (FSE: 954) ("Awakn" or the "Company"), a clinical-stage biotechnology company developing therapeutics for substance use and mental health disorders, with a near-term focus on Alcohol Use Disorder ("AUD"), announces that the first patient has been screened in the landmark 'MORE-KARE' Phase 3 trial of AWKN-001 for severe AUD.

AWKN-001 is an investigational, novel medication-assisted treatment for severe AUD, consisting of an N-methyl-D-aspartate receptor-modulating drug (ketamine) delivered intravenously (IV) in combination with manualized psycho-social support for severe AUD.

The MORE-KARE study, or the Multicentre Investigation of Ketamine for Reduction of Alcohol Relapse, 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 Exeter Clinical Trials Unit.

The Phase 3 trial aims to evaluate the effectiveness of a single treatment cycle of AWKN-001. Participants will be randomly allocated into a trial arm, receiving different doses of ketamine infusion along with psycho-social support sessions from a trial therapist. The specific dose and type of psychological support for each participant will be randomly assigned by a computer. Both participants and the research team will be blinded to the assigned dose/support.

The primary endpoint is the reduction in heavy drinking days (HDD) over a six-month period post-treatment. Secondary endpoints include continuous abstinence and the percentage of HDD at the six-month follow-up. The effectiveness of the treatment will be assessed using drink diaries and daily self-administered breathalyser tests, with follow-up visits at three and six months.

This study is the largest of its kind investigating ketamine-assisted therapy for AUD. The total trial cost is estimated at £2.4 million / CAD 4.2 million, with Awakn contributing £0.8 million / CAD 1.4 million. The trial is being conducted at eight National Health Service (NHS) sites across the UK.

Trial lead Professor Celia Morgan, from the University of Exeter, said: "More than half a million UK adults have serious alcohol problems that require help, yet only one in five of those get treatment. Current treatments have low success rates - we know that three out of four people who quit alcohol will be back drinking heavily after a year. This new trial is helping to fill the gap in the urgent search for new treatments. We're excited that the NIHR and Awakn Life Sciences have funded this study, which is the largest study of ketamine combined with psychological therapy to take place anywhere in the world."

Awakn's Chief Scientific Officer, Professor David Nutt, added: "This trial could potentially revolutionize the treatment landscape for severe AUD, offering hope to those who currently have limited options. We're excited to see the impact of combining ketamine with structured psychological support."

About AWKN-001

AWKN-001 is an investigational, novel medication-assisted treatment for severe AUD, consisting of an N-methyl-D-aspartate receptor-modulating drug (ketamine) delivered intravenously (IV) in combination with manualized psycho-social support in the UK market only.

A phase 2 trial was successfully completed with efficacy proven, achieving 86% abstinence on average over the 6 months post-treatment versus 2% pre-trial and a 50% reduction in HDD versus placebo.

A phase 3 clinical trial ("MORE KARE") is being run by the University of Exeter with participant recruitment due to start in Q3 2024. This trial is co-funded by the Efficacy and Mechanism Evaluation (EME) Programme - a partnership between the UK's National Institute for Health Research (NIHR) and the Medical Research Council (MRC) - and Awakn Life Sciences Corp.

About Alcohol Use Disorder

AUD is a chronic, relapsing brain health disorder characterised by compulsive alcohol use, loss of control over drinking, and negative emotional states when not using alcohol. AUD affects approximately 29^[1] million adults in the US and approximately 40 million^[2,3,4,5,6] in the 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^[7]. This creates a significant unmet medical need and a substantial public health concern, with enormous economic cost of approximately \$249 billion in the US^[8], rising to approximately US\$472 billion^[9,10,11,12,13] when including key European markets.

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^[1] adults in the US and approximately 40 million^[2,3,4,5,6] 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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About University of Exeter

The University of Exeter is the sponsor of this clinical trial with overall trial management, data management and statistical analysis provided in collaboration with the Exeter Clinical Trials Unit (University of Exeter). At the University of Exeter, we combine teaching excellence and high levels of student satisfaction with world class research at our campuses in Exeter and Cornwall. We are a member of the Russell Group of leading research-intensive universities.

About 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: 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. 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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