

Awakn Life Sciences Submits Clinical Trial Application for Phase III 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. - September 6, 2023) - Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954) ("Awakn"), a biotechnology company developing therapeutics to treat addiction with a near-term focus on Alcohol Use Disorder (AUD), announces today it has submitted the Clinical Trial Application (CTA) for a phase III 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, affects approx. 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 an 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 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 run by Awakn, The University of Exeter, and a partnership between the National Institute of Health and Care Research (NIHR) and the Medical Research Council (MRC). The phase III trial will be an 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.

Awakn and its partners are expecting feedback in the coming months on the CTA, and subject to ethical and regulatory approval, first trial participants will be treated in late Q4 2023 or early Q1 2024.

Furthermore, in February 2023 UK Medicines and Healthcare products Regulatory Agency (MHRA) awarded an Innovation Passport to AWKN-P001. The Innovation Passport is the entry point for the MHRA's Innovative Licensing and Access Pathway (ILAP), the UK's version of the FDA break through designation. The goal of ILAP is to accelerate the time to market in the U.K. Awakn now intends to utilize its ILAP access to seek input from the regulators including the MHRA and the National Institute of Health and Care Excellence (NICE) regarding market access for AWKN-P001 in the UK.

Anthony Tennyson, Awakn CEO commented, "We are pleased to be working with our partners in the NIHR, MRC, and the University of Exeter on this program as we together progress AWKN-P001 closer to potentially treating the first participant in the phase III trial. We are also pleased to have secured ILAP designation for AWKN-P001 with which we will look to initiate discussions in the near-term with the MHRA and NICE on our target development plan and market access in parallel to the executing the phase III."

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 40 million people in the US and key 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.

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.sedarplus.ca. 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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