

# Awakn Life Sciences Engages Orphan Insight Ltd. to Advance Market Access, Pricing, and Reimbursement Strategies for AWKN-P001 Targeting Severe Alcohol Use Disorder

Toronto, Ontario--(Newsfile Corp. - October 31, 2023) - Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954) ("Awakn"), a clinical-stage biotechnology company developing therapeutics to treat addiction with a near-term focus on Alcohol Use Disorder (AUD), announces it has engaged Orphan Insight Ltd ("Orphan Insight") to develop and advance market access, pricing, and reimbursement for Awakn's lead program AWKN-P001. AWKN-P001 targets Severe Alcohol Use Disorder (SAUD), the most chronic type of AUD, a condition affecting approximately 17 million individuals in the United States and the key European markets of UK, Germany, France, Italy, and Spain.

Founded in 2007, Orphan Insight is a consultancy specializing in UK healthcare market access and pricing strategies. Orphan Insight has supported many organisations in achieving market access in the UK, leading to the successful introduction of therapeutics for the treatment of diseases with significant unmet clinical need. Orphan Insight also will play a pivotal role in due course in negotiations with the UK Department of Health to ensure that AWKN-P001 becomes accessible to those in need.

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 very positive, achieving 86% abstinence in the 6 months post treatments vs. 2% abstinence pre-trial and a 50% reduction in Heavy Drinking Days (HDD) versus placebo.

In February 2023, Awakn announced that the 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.

In September 2023, Awakn announced that it had submitted the Clinical Trial Application (CTA) for a phase III trial of AWKN-P001 in the UK. The trial is being run by Awakn, The University of Exeter, and a partnership between the National Institute for Health and Care Research (NIHR) and the Medical Research Council. 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.

Anthony Tennyson, Awakn Life Sciences' CEO commented, "Our commitment to developing innovative addiction treatments goes beyond scientific discovery. We are also focused on ensuring these treatments reach the patients who need them most, and that's where Orphan Insight plays a crucial role. Their experience and strategic guidance will be invaluable in driving revenue and maximizing our reach."

Mark Barrett, Managing Director, Orphan Insight commented "The introduction of a life-changing therapeutic approach to the treatment of SAUD is massively important, and the UK has a real opportunity to lead the way in implementing this meaningful intervention to reduce the burden of a globally devastating condition."

## 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 Orphan Insight**

Founded in 2007, Orphan Insight has supported a number of organisations to navigate the market access landscape in the UK. Successful negotiations across a range of therapeutic areas have led to the introduction of therapies, including the first 'advanced therapeutic medicinal product', into the UK market for the treatment of diseases with significant unmet clinical need.

## **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.

This news release does not constitute an offer to sell, or a solicitation of an offer to buy, any securities in the United States. The Company's and Awakn's securities have not been and will not be registered under the United States Securities Act of 1933, as amended (the "**U.S. Securities Act**") or any state securities laws and may not be offered or sold within the United States or to U.S. Persons unless registered under the U.S. Securities Act and applicable state securities laws or an exemption from such registration is available.

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