# Awakn Life Sciences Signs Collaboration Agreement with University of Exeter for Upcoming Phase III Trial

## Phase III Trial Will Assess Ketamine-Assisted Therapy for the Treatment of Severe Alcohol Use Disorder

Toronto, Ontario--(Newsfile Corp. - April 18, 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 that it has signed a collaboration agreement with the University of Exeter (UoE) putting in place a framework for the upcoming Phase III trial exploring the use of ketamine-assisted therapy to treat Severe AUD. The agreement formalizes the design, budget, and Awakn's contribution to the cost of the trial.

The trial will be a Phase III, 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 GBP £800,000 towards the costs of the trial, with the National Institute for Health and Care Research (NIHR), the Medical Research Council (MRC), and the University of Exeter contributing the balance of the costs.

The trial will be the largest ketamine-assisted psychological therapy clinical trial to date and the only Phase III psychedelic clinical trial to receive government funding. If the results of the Phase III are positive, Awakn plans in due course to apply for marketing authorization for ketamine-assisted therapy to treat severe AUD.

Professor Celia Morgan, Professor of Psychopharmacology at UoE and Awakn's Head of Ketamine-Assisted Therapy, will lead the trial, which follows on from the impressive results of the <u>Phase II a/b trial</u> announced in January 2022, which resulted in participants experiencing on average 86% abstinence at six-months post treatment, versus 2% pre-trial.

In February 2023, Awakn received an <u>Innovation passport</u> as part of the Innovative Licensing and Access Pathway (ILAP) from the Medicine's Health and Regulatory Authority (MHRA) the UK regulatory body, which aims to accelerate time to market for research programs, much like the FDA's fast track designation. ILAP will allow Awakn a working collaboration with access to specialist advice from the MHRA and its partners, including the National Institute of Health and Care Excellence (NICE).

Anthony Tennyson, Awakn CEO, added, "We are delighted to formalize an even stronger working collaboration and agreement with the University of Exeter, particularly when this gives such a clear roadmap for our Phase III. We have been working side by side for several years now and they are a world leading institute for research and a partner we are very happy to work with. We share the same vision of providing a new, more effective treatment for AUD, available to the millions of people who are in such desperate need for it."

#### About Awakn Life Sciences Corp.

Awakn Life Sciences Corp. is a biotechnology company developing therapeutics to treat addiction. Awakn has a near-term focus on Alcohol Use Disorder (AUD), a condition affecting 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.

#### 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 <u>www.sedar.com</u>. 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.

#### **Investor Enquiries:**

Anthony Tennyson, CEO, Awakn Life Sciences anthony.tennyson@awaknlifesciences.com

### Media Enquiries:

Gordo Whittaker, CMO, Awakn Life Sciences gordo@awaknlifesciences.com



To view the source version of this press release, please visit <u>https://www.newsfilecorp.com/release/162831</u>