

Awakn Life Sciences' Phase III Trial to Be Delivered in the UK National Health Service (NHS)

Phase III trial confirmed to cost CA\$3.75 million, with a UK Government agency funding 66% of this cost

Toronto, Ontario--(Newsfile Corp. - December 13, 2022) - Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954) ('Awakn'), a revenue-generating biotechnology company researching, developing, and commercializing therapeutics to treat addiction with a near-term focus on Alcohol Use Disorder (AUD), announces that its Phase III clinical trial exploring the use of ketamine-assisted therapy for the treatment of severe AUD will be delivered across seven NHS sites in the UK. The trial has also been approved for grant funding for 66% of the costs by the National Institute for Health and Care Research (NIHR), a UK government agency. It is currently forecast the trial will cost approximately CA\$3.75 million in total, with Awakn funding approximately CA\$1.25 million of that.

The University of Exeter (UoE) will conduct the trial, with Professor Celia Morgan, Professor of Psychopharmacology at UoE and Awakn's Head of Ketamine-Assisted Therapy leading it. 280 people will be recruited with severe AUD and participants will be randomly allocated into two groups. Half will be given ketamine in conjunction with the proprietary psychological therapy, developed for the Phase II trial. The other half will be given a very low dose of ketamine and a seven-session education package about the harmful effects of alcohol.

The Phase III which is intended to be a pivotal trial, follows on from the impressive results of the [Phase II a/b trial](#) announced in January 2022, which resulted in participants experiencing on average 86% abstinence at six-months post treatment, versus 2% pre-trial. The Phase III trial will focus on establishing further definitive evidence and move towards the novel treatment being licensed for this indication. Awakn, UoE and the NHS will be working with the UK Department of Health and Social Care and other key stakeholders throughout the trial to facilitate the uptake within the NHS post trial, should the results be positive. It is expected to be the largest ketamine-assisted therapy clinical trial to date and the only Phase III psychedelic clinical trial ever to receive government funding.

Professor Celia Morgan commented: *"More than two million UK adults have serious alcohol problems, yet only one in five of those get treatment. Unfortunately, three out of four people who quit alcohol will be back drinking heavily after a year. Alcohol-related harm is estimated to cost the NHS around £3.5 billion each year, and wider UK society around £40 billion. Alcohol problems affect not only the individual but families, friends and communities, and related deaths have increased still further since the pandemic. We urgently need new treatments. If this trial definitively establishes that ketamine and therapy works, we hope we can begin to see it used in NHS settings."*

Anthony Tennyson Awakn CEO added *"For this phase III to have the support and funding from the NIHR and for it to be delivered in the NHS is a great endorsement of this treatment's potential and a sign of how badly a new more effective treatment is needed to help the millions of people suffering from Alcohol addiction in the UK. We are very proud to be part of this important piece of work. With two Awakn clinics already open in the UK and more in Europe we are already seeing the incredible benefits of this treatment for our clients on an off-label basis."*

About Awakn Life Sciences Corp.

Awakn Life Sciences Corp. is a revenue-generating biotechnology company researching, developing, and commercializing therapeutics to treat substance and behavioral addictions. 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 effective 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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