Awakn Life Sciences Announces Positive Results from Phase II A/B Ketamine-Assisted Therapy for Treatment of Alcohol Use Disorder Trial

written by Raj Shah | January 11, 2022

Primary and Secondary Endpoints Achieved, Including 86% Abstinence Over 6 Months Post Treatment and No Serious Adverse Events

January 11, 2022 (Source) – Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954) ('Awakn'), a biotechnology company developing and delivering psychedelic therapeutics (medicines and therapies) to treat addiction, is delighted to announce ground-breaking positive data from their Phase II A/B trial. It was the first controlled trial in the world to investigate Ketamine-Assisted Therapy for the treatment of Alcohol Use Disorder (AUD), the results have been published in the American Journal of Psychiatry. The trial was conducted by University of Exeter (UoE) and led by Professor Celia Morgan, Awakn's Head of Ketamine-Assisted Therapy for Addiction and Professor of Psychopharmacology at UoE. Awakn acquired the intellectual property (IP) to the therapy under license for use in further research, its clinics in Europe, and its partnerships globally.

The positive Phase II trial outcome and Awakn's newly formed partnership with the UK National Healthcare Service (NHS) and UoE, paved the way to progress this trial into Phase III. With the ultimate aim of securing regulatory approval for Ketamine-

Assisted Therapy to treat AUD in the UK through the NHS and potentially in other territories.

The double-blind placebo-controlled trial included 96 patients with severe AUD, who were randomised to one of four groups: 1) three ketamine infusions (0.8 mg/kg IV over 40 minutes) plus proprietary manualized therapy (KARE); 2) three saline infusions plus KARE therapy; 3) three ketamine infusions plus alcohol education; and 4) three saline infusions plus alcohol education.

The primary outcomes of the trial were 1) Days abstinent in the 6 months after treatment, 2) Relapse at 6 month follow up. The findings showed that ketamine combined with KARE therapy, resulted in total abstinence in 162 of 180 days in the following 6-month period, achieving an increase in abstinence from around 2% prior to the trial to 86% post trial. The results for relapse at 6 months, showed that the Ketamine plus KARE group's risk of relapse, was 2.7 times less than the placebo plus alcohol education group.

"Alcohol Use Disorder is a pervasive and persistent public health issue, affecting at least 390 million people globally. Treatment rates are low and relapse rates post treatment tend to be high. We urgently need new and more effective treatments," said Prof. Morgan. "We found that controlled, low doses of ketamine combined with manualized psychological therapy can significantly increase post treatment abstinence rates. This is extremely encouraging, as we normally see three out of four people returning to heavy drinking within twelve months of treatment. The data we've collected from this study paves the way for a paradigm shift in how AUD is treated."

The secondary outcomes of the study identified further encouraging results including improved liver function across several different markers, a statistically significant decrease

in depression after 3 months and an increase in the ability to experience pleasure.

In addition to the primary and secondary endpoints, Prof. Morgan identified further significant results in the reduction in heavy drinking days. At six months post trial, there was an average of 12 heavy drinking days in the Ketamine plus KARE group, this is a large reduction compared to other trials in this area and it is widely believed the real-world data is far higher than this. Within the KARE group there was also a significant decrease in the risk of mortality, 1 in 8 patients would have died within 12 months without treatment, that number decreased to 1 in 80 following the treatment.

In total, the trial demonstrated that three subanesthetic infusions of ketamine support abstinence from alcohol and that abstinence may be further enhanced when ketamine treatment is combined with therapy. No serious adverse events took place during the trial.

Anthony Tennyson, Awakn's Chief Executive, added, "We are so pleased to see such encouraging results in an area of treatment that has been stagnant for so long, leaving so many people with little or sub-par options available to them. We will continue to support this research and future clinical trials as we push to bring a radical shift in the alcohol addiction treatment industry."

See following link for presentation of KARE results – Awakn Life Sciences – KARE Presentation.

Awakn will hold a conference call to go through the results in further detail.

Conference Call Details:
Date: Wednesday, January 12, 2022

Time: 8:00 a.m. Eastern Time
Toll-free Dial-in Number: 1-877-407-0789
International Dial-in Number: 1-201-689-8562
Conference ID: 13725796

Participant Link: https://viavid.webcasts.com/starthere.jsp?ei=1518205&tp_key=b24ddb9685.

A telephone replay will be available through Wednesday January 26, 2022. To access the replay, please dial 1-844-512-2921 (domestic) or 1-412-317-6671 (international). At the system prompt, please enter the code 13725796 followed by the # sign. You will then be prompted for your name, company, and phone number. Playback will then automatically begin.

About Awakn Life Sciences Corp.

Awakn Life Sciences is a biotechnology company developing and delivering psychedelic therapeutics (medicines and therapies) to better treat addiction. Awakn's team consists of world leading chemists, scientists, psychiatrists, and psychologists who are developing and advancing the next generation of psychedelic drugs, therapies, and enabling technologies to treat addiction. Awakn will deliver these evidence backed psychedelic therapies in clinics in the UK and Europe and through licensing partnerships globally.

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