Awakn Life Sciences Receives UK State Funding to Identify Optimal Pathway to Market in UK & US for Its Lead Clinical Development Program – Ketamine-Assisted Therapy for Alcohol Use Disorder

written by Raj Shah | July 5, 2022

Awakn Provides Business Update on Progressing its Lead Program from Phase II b to Phase III

July 5, 2022 (Source) – Awakn Life Sciences Corp. (NEO: AWKN) (OTCQB: AWKNF) (FSE: 954), a revenue-generating biotechnology company researching, developing and commercializing therapeutics to treat addiction with a near-term focus on Alcohol Use Disorder (AUD), is pleased to announce it has secured funding from Innovate UK to identify the quickest and most cost-effective route to market in both the UK and the US for Awakn's lead program – proprietary ketamine-assisted therapy for treating AUD. Innovate UK is the UK's national innovation agency which provided the funding in an initiative delivered jointly by CPI and ABHI.

Awakn's activities will be delivered in collaboration with Veristat, a global Clinical Research Organization (CRO) that specialises in accelerating client therapies through the clinical development process into regulatory approval and commercialization. Veristat supported marketing applications for

12% of all US Food and Drug Administration (FDA) Novel Drug Approvals in 2021.

Awakn's Chief Scientific Officer, Shaun McNulty commented: "Our Phase II a/b 'KARE' study, led by Professor Celia Morgan, showed that ketamine-assisted therapy has the potential to revolutionize the treatment of AUD. This funding enables Awakn, working closely with Veristat, to bring a much-needed effective treatment approach to the market as soon as possible. Delivering this innovative therapeutic approach as rapidly as possible to patients in the UK and the US is critical to address this major unmet medical need."

Anthony Tennyson Awakn's CEO added: "Securing these funds from Innovate UK is a major endorsement of our efforts and approach to developing new and effective treatments for addictions. Our Lead program has all the right components to make a lasting difference for the very significant number of people who are suffering from AUD. We are also delighted to be working with a partner of the calibre of Veristat and to have the ability to benefit from their significant expertise. The addiction treatment market opportunity is, unfortunately, large and growing, and Awakn is uniquely positioned to offer proven therapeutics supported by data to sufferers for whom the current standard of care is inadequate and relapse rates are unacceptably high.

Project Kestrel

Awakn is also providing a business update on its lead program. Awakn has renamed its lead program to Project Kestrel. Project Kestrel will aim to deliver marketing authorization/regulatory approval for ketamine-assisted therapy to treat AUD in both the UK and the US with clear Intellectual Property (IP) surrounding the treatment. Project Kestrel builds on Awakn's

successful Phase II a/b 'KARE' clinical trial and efficacy data released in January 2022, which demonstrated safety and efficacy as a new treatment option for AUD patients.

Awakn has started planning and intends to initiate a Phase III trial in the UK in 2022 as a prelude to initiating a further Phase III trial in the US thereafter. Both are designed to provide the key data necessary to bring Project Kestrel to the market as soon as possible. Awakn has also applied for a grant to the National Institute for Health and Care Research (NIHR) in the UK to cover two-thirds of the cost of the planned UK Phase III trial and a decision on this application is anticipated shortly.

The outputs from Project Kestrel will benefit all of Awakn's Research and Development project portfolio by defining a clear regulatory pathway for drug-assisted therapies to treat not only AUD but also a broad range of other behavioral addictions which Awakn is developing therapies for.

About Awakn Life Sciences Corp.

Awakn Life Sciences Corp. is a revenue-generating biotechnology company researching, developing, and commercialising therapeutics to treat substance and behavioral addictions. Awakn has a near-term focus on Alcohol Use Disorder (AUD), a condition affecting 400m 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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About Project Kestrel

Project Kestrel is the lead clinical development program of Awakn Life Sciences. Project Kestrel is supported by Awakn's Phase II a/b 'KARE' clinical trial which examined ketamine-assisted therapy for the treatment of Alcohol Use Disorder (AUD). The trial resulted in patients experiencing on average 86% abstinence at 6 months post treatment versus 2% before the trial which means that study participants went from being sober on average 7 days a year to being sober on average 314 days a year. Awakn is planning to initiate a Phase III trial in the UK in 2022 and plans to seek regulatory approval in the UK and the US in due course.

About Veristat

Veristat, a scientific-minded global clinical research organization (CRO), enables sponsors to solve the unique and complex challenges associated with accelerating therapies through clinical development to regulatory approval. With more than 27 years of experience in clinical trial planning and execution, Veristat is equipped to support any development program. The company has prepared nearly 100 marketing applications for approval with global regulatory authorities in the last 10 years.

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