

Awakn Life Sciences Granted Fast-Track Designation from UK Regulator for Ketamine-Assisted Therapy for Alcohol Use Disorder

Designation Aims to Accelerate Time to Market

Toronto, Ontario--(Newsfile Corp. - February 7, 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 today the U.K. Medicines and Healthcare products Regulatory Agency (MHRA) has granted Awakn an Innovation Passport as part of the Innovative Licensing and Access Pathway (ILAP) for its proprietary ketamine-assisted therapy for the treatment of Severe Alcohol Use Disorder.

Alcohol use disorders affect 285 million people globally, of these circa. 25% or 70m people suffer with Severe Alcohol Use Disorder.

ILAP aims to accelerate time to market, facilitating patient access. Similar to the FDA's fast-track program in the United States, the U.K.'s MHRA Innovation Passport provides Awakn with access to specialist advice from the MHRA and its partners, including the National Institute of Health and Care Excellence (NICE). Throughout the therapeutic development process this has the potential to enable a more efficient, and ultimately a faster route to marketing authorization.

The ILAP provides a single integrated platform for sustained collaborative working among the MHRA, several key bodies and the therapeutics developer, allowing for earlier engagement, enhanced coordination and monitoring of important product development activities culminating in market authorisation. This also has the potential to allow the National Health Service (NHS) to adopt potential treatments faster and ultimately enable quicker patient access to these potential medicines. Under the ILAP, Awakn will have access to a toolkit to support all stages of the design, development, and approvals process, as well as identify key areas for future agency engagement.

Anthony Tennyson, Awakn CEO, commented, "Ensuring our therapeutics reach people who need them most is our key priority as a company. Having an innovation passport gives us the opportunity working with the regulators to find the most efficient pathway to marketing authorization and ultimately and most importantly to those people who desperately need it. We are very grateful to the MHRA and its partners for identifying the vast potential in our treatment."

Professor Celia Morgan, Awakn's Head of Ketamine-Assisted Therapy, added, "The award of Innovation Passport status validates development of our highly innovative therapeutic approach of using ketamine-assisted psychotherapy to treat severe alcohol use disorder and our desire to bring this therapeutic approach to patients as rapidly as possible. This will enable us to build optimally on the excellent phase II proof of concept study as we work in partnership towards marketing authorization. We look forward to working closely with the MHRA, NICE and partners to accelerate our planned phase 3 clinical trial, to be undertaken in collaboration with the NIHR, MRC, NHS, and Exeter University."

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 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.

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
<https://www.newsfilecorp.com/release/153858>