Psyence Group Receives Phase IIa Clinical Trial Approval from the UK Medicines and Healthcare Products Regulatory Agency (MHRA)

TORONTO, September 19, 2022 - Psyence Group Inc. (CSE: PSYG | OTCQB: PSYGF) ("Psyence" or the "Company"), a life science biotechnology company pioneering the use of natural psychedelics in mental health and well-being, is delighted to announce that it has received approval for its Phase IIa clinical trial from the Medicines and Healthcare products Regulatory Agency (MHRA), the UK equivalent regulatory body to Canada's Health Canada and the US's FDA. The clinical trial will assess the efficacy and safety of psilocybin-assisted psychotherapy versus psychotherapy alone for the treatment of adjustment disorder due to an incurable cancer diagnosis.

Psyence has partnered with a leading psychedelic Contract Research Organisation (CRO), Clerkenwell Health, to design and deliver the clinical trial. Clerkenwell has experience in conducting psychedelic research and the trial will be conducted at two centers in the United Kingdom.

"The UK's MHRA's approval to conduct this clinical trial in the field of palliative care, has the real potential to allow Psyence to create a paradigm shift in the treatment of patients with an incurable illness, in order to improve quality of end-of-life and the standard of care," says **Dr. Neil Maresky, Psyence Chief Executive Officer**. "It is a privilege to conduct research with psilocybin that may result in significant improvements in patients' lives. We are thrilled that we can now progress this important trial."

An estimated 40 million people require palliative care annually, with 75% of these patients exhibiting a high burden of depression, anxiety or psychosocial distress after diagnosis.

Adjustment disorder is a serious condition affecting 40% of patients with a terminal diagnosis. It severely affects the patient's and their family's quality of life and, as such, can lead to over utilisation of healthcare resources and medications.

"Developing therapies, such as psilocybin, that reduce patients' stress and anxiety resulting in better quality of life for their remaining time can be very impactful. The current management of adjustment disorder in palliative care has a low rate of success indicating a big unmet medical need," **Dr. Maresky** says.

"We are very excited about being involved with this study, one of very few looking at this indication. Clerkenwell Health brings utmost rigour to the performance of clinical trials, especially needed at this stage of psilocybin research," says **Tom McDonald, Clerkenwell Health Chief Executive Officer**. "The study will likely enter the first patient by the end of this year or sooner and is expected to run for approximately 18 months when the primary endpoint will be available."

Psyence aims to commence this study by the end of the year.

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ABOUT PSYENCE GROUP: www.psyence.com

Psyence is a life science biotechnology company listed on the Canadian Securities Exchange and (CSE: PSYG) and quoted on the OTCQB (OTCQB: PSYGF), with a focus on natural psychedelics. Psyence works with natural psilocybin products for the healing of psychological trauma and its mental health consequences in the context of palliative care.

Our name "Psyence" combines the words psychedelic and science to affirm our commitment to producing psychedelic medicines developed through evidence-based research.

Informed by nature and guided by science, we built and operate one of the world's first federally licensed commercial psilocybin mushroom cultivation and production facilities in Lesotho, Southern Africa. Our team brings international experience in both business and science and includes experts in mycology, neurology, palliative care, and drug development. We work to develop advanced natural psilocybin products for clinical research and development.

Our key divisions, Psyence Production, Psyence Therapeutics, and Psyence Function, anchor an international collaboration, with operations in Canada, the United Kingdom, South Africa and Lesotho, and a presence in the United States and Australia.

Contact Information:

Katherine Murphy, Investor Relations

Email: ir@psyence.com

Media Inquiries: media@psyence.com General Information: info@psyence.com

FORWARD LOOKING STATEMENTS:

Certain statements in this news release related to Psyence Group Inc and its subsidiaries (collectively the are forward-looking statements and are prospective in nature. Forwardlooking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as "may", "should", "could", "intend", "estimate", "plan", "anticipate", "expect", "believe" or "continue", or the negative thereof similar variations. Forward-looking statements in this news release include statements regarding the successful commencement of clinical trials in the UK, the efficacy and results of such clinical trials and the general improvement of patient well-being. These forward-looking statements are based on a number of assumptions, including the assumptions that the Company's applications for human clinical trials will be successful. There are numerous risks and uncertainties that could cause actual results and the Company's plans and objectives to differ materially from those expressed in the forward-looking information. These risks and uncertainties include demand for the Company's securities being less than anticipated, fluctuations in the price the Company's common shares, and the Company not raising the amount expected, or any funds at all. Actual results and future events could differ materially from those anticipated in such information. These and all subsequent written and oral forward-looking information are based on estimates and opinions of management on the dates they are made and are expressly qualified in their entirety by this notice. Except as required by law, the Company does not intend to update these forward-looking statements.

The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The efficacy of psilocybin, psilocybin analogues, or other psychedelic compounds or nutraceutical products remains the subject of ongoing research. There is no assurance that the use of psilocybin, psilocybin analogues, or other psychedelic compounds or nutraceuticals can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. The Company

has not conducted clinical trials for the use of its proposed products. Any references to quality, consistency, efficacy, and safety of potential products do not imply that the Company verified such in clinical trials or that the Company will complete such trials. If the Company cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.