## Psyence Partners with iNGENū for Palliative Care Clinical Trial in Australia

**Vancouver, British Columbia, March 21, 2023** – <u>Psyence Group Inc</u> (<u>CSE:PSYG</u> | <u>OTCQB: PSYGF</u>), a life science biotechnology company pioneering the use of natural psilocybin in mental health and wellbeing, is pleased to announce that its newly incorporated wholly owned Australian subsidiary, **Psyence Australia Pty Ltd**, has partnered with **iNGENū Pty Ltd** (iNGENū) to conduct Psyence's previously announced clinical trial in palliative care. iNGENū is an Australian based, globally focused Contract Research Organization (CRO) with extensive experience working in the psychedelic pharmaceutical drug development and clinical research industry.

iNGENū will be responsible for jointly designing Psyence's Phase IIb clinical trial, using a natural psilocybin drug candidate PEX010, in the palliative care setting. The trial will be carried out in accordance with the requirements of the Therapeutic Goods Administration of the Commonwealth of Australia as well as other international guidelines that relate to clinical investigations and the conduct of clinical research.

"We are delighted to be in a position to initiate Psyence's first clinical trial in palliative care and are working tirelessly to execute the initial phases of setting up this study," said **Dr. Neil Maresky, Chief Executive Officer of Psyence**. "By partnering with iNGENu, we will benefit from their experience as a leading psychedelic CRO. In addition, the Australian Federal Government's Research & Development tax incentive program, which can provide up to a 43.5% rebate on our research and development expenses in Australia, makes it a very cost-effective endeavour".

"It is a privilege to serve as the chosen CRO for Psyence and be part of their investigative team using psychedelic assisted psychotherapy in such an innovative fashion," **Dr. Sud Agarwal, Chief Executive Officer of iNGENū.** "Being able to help this vulnerable patient group who are suffering major mental health issues secondary to their cancer diagnosis, will be very rewarding professionally."

Psyence's Phase IIb study is a planned randomised, placebo-controlled, double-blind study. It will evaluate the use of psilocybin assisted psychotherapy vs psychotherapy alone. It will use FDA-recommended primary endpoints to test natural psilocybin (PEX010) in over 75 patients with adjustment disorder due to a recent terminal cancer diagnosis. PEX010 (25mg) is standardized to provide 25 mg of psilocybin per oral capsule and has previously received authorization from the FDA and Health Canada to enter into phase 1 and phase 2 human clinical trials. Upon successful completion of the study, Psyence aspires to conduct a multinational Phase III registrational study.

## About Psyence Group, Inc.

Psyence is a life science biotechnology company listed on the Canadian Securities Exchange (CSE: PSYG) and quoted on the OTCQB (OTCQB: PSYGF), with a focus on natural psychedelics. The Psyence Biomed Division 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 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, Southern Africa, and a presence in the United States and Australia.

Learn more at <u>www.psyence.com</u> and on <u>Twitter</u>, <u>Instagram</u> and <u>LinkedIn</u>.

## About iNGENū CRO Pty Ltd

iNGENū is a globally focused Contract Research Organization working exclusively in the cannabinoid and psychedelic space. Our core values: subject matter expertise – globally unmatched expertise in psychedelic drug development; client-centric culture – a highly transparent and collaborative style of partnering with sponsors; and an agile and lean approach to drug development. The Australian advantage is the ability to perform high quality (FDA-eligible) clinical trials prior to opening an IND, accessing 43.5% research and development rebate from the Australian Government, and rapid start-up of clinical trials in under 12 weeks.

Learn more at www.ingenucro.com.au

MEDIA <u>PSYENCE GROUP</u> Katherine Murphy <u>ir@psyence.com</u> Media Inquiries: <u>media@psyence.com</u> General Information: info@psyence.com

MEDIA iNGENū hello@ingenuCRO.com.au www.ingenuCRO.com.au

## FORWARD LOOKING STATEMENTS PSYENCE

Certain statements in this news release related to Psyence Group Inc and its subsidiaries (collectively the "Company") are forward-looking statements and are prospective in nature. Forward-looking 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 or similar variations. Forward-looking statements in this news release include statements regarding the future success of the partnership with iNGENū, the receipt of all such approvals as may be required to commence the clinical trials referred to in this news release, the procurement of the necessary FDA approvals to execute on Psyence's strategy, the expediting of a Phase III registrational clinical trial, and Psyence's ability to deliver its intended drug product to patients. These forward-looking statements are based on a number of assumptions, including the assumptions that Psyence will obtain all such regulatory and other approvals as may be required to pursue its clinical trials on the drug product referred to in the news release, the results of such clinical trials will be positive, and Psyence will be able to commercialize Filament's natural psilocybin drug candidate, PEX010 (25 mg). 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.