



19 October 2021

Press Releases

# First patient dosed in Phase IIA DMT-assisted therapy clinical trial

LONDON, Oct. 19, 2021 – Small Pharma Inc. (TSXV: DMT) (the “Company” or “Small Pharma”), a neuropharmaceutical company focused on psychedelic-assisted therapies, today announced that the first patient has been dosed in the Company’s Phase IIA clinical trial for its lead N,N-dimethyltryptamine (“DMT”) candidate, SPL026, which, in combination with psychotherapy, is intended to serve as a possible treatment of Major Depressive Disorder (“MDD”).

Dr. Carol Routledge, Chief Medical and Scientific Officer of Small Pharma noted:

The world’s first regulated clinical trial for DMT-assisted therapy targeting MDD is underway and we continue to make rapid progress. This is a key study for our DMT-assisted therapy portfolio as we assess the effectiveness of our lead candidate to treat MDD. There has been strong interest in trial recruitment to date, as such, we expect reporting of topline results to remain on track for the first half of next year. We believe that DMT-assisted therapy has the potential to offer a new therapeutic treatment for MDD, a disorder that devastates the lives of millions of people every year.”

The first of 42 patients with MDD have now been dosed in the blinded, randomized, placebo-controlled, proof-of-concept Phase IIA study of SPL026 in combination with psychotherapy. The Phase IIA portion of the Phase I/IIa study, being held at two UK clinical trial sites – Hammersmith Medicines Research and MAC Clinical Research – will assess the efficacy of one versus two doses of SPL026 in combination with psychotherapy in patients with MDD, while furthering the Company’s safety and tolerability dataset. Efficacy will be assessed using the Montgomery-Asberg Depression Rating scale to measure any potential reduction in the patients’ depression. Topline results are anticipated in the first half of 2022.

## About Small Pharma

Small Pharma is a neuropharmaceutical company specialised in IP-led development of novel treatments for mental health conditions, with a focus on depression. Small Pharma initiated a clinical program into DMT-assisted therapy in February 2021. This program includes a Phase I/IIa trial on the Company’s lead candidate alongside development of a robust pipeline of proprietary preclinical assets.

## About DMT

DMT is a naturally occurring psychedelic tryptamine found in plants and in the brain of mammals. Scientific evidence suggests DMT offers the potential for rapid-acting and long-lasting antidepressant effects. DMT is differentiated by its short psychedelic experience (< 30mins) which



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This press release contains statements that constitute “forward-looking information” (“forward-looking information”) within the meaning of the applicable Canadian securities legislation. All statements, other than statements of historical fact, are forward-looking information and are based on expectations, estimates and projections as at the date of this news release. Any statement that discusses predictions, expectations, beliefs, plans, projections, objectives, assumptions, future events or performance (often but not always using phrases such as “expects”, or “does not expect”, “is expected”, “anticipates” or “does not anticipate”, “plans”, “budget”, “scheduled”, “forecasts”, “estimates”, “believes” or “intends” or variations of such words and phrases or stating that certain actions, events or results “may” or “could”, “would”, “might” or “will” be taken to occur or be achieved) are not statements of historical fact and may be forward-looking information. Forward-looking statements in this news release include statements regarding the Company’s placebo-controlled, proof-of-concept Phase IIa study of SPL026 and the Company’s ability to develop solutions to effectively address depression through DMT-based therapies. In disclosing the forward-looking information contained in this press release, the Company has made certain assumptions. Although the Company believes that the expectations reflected in such forward-looking information are reasonable, it can give no assurance that the expectations of any forward-looking information will prove to be correct. Known and unknown risks, uncertainties, and other factors which may cause the actual results and future events to differ materially from those expressed or implied by such forward-looking information. Such factors include, but are not limited to: compliance with extensive government regulations; domestic and foreign laws and regulations adversely affecting the Company’s business and results of operations; the impact of COVID-19; and general business, economic, competitive, political and social uncertainties. Accordingly, readers should not place undue reliance on the forward-looking information contained in this press release. Except as required by law, the Company disclaims any intention and assumes no obligation to update or revise any forward-looking information to reflect actual results, whether as a result of new information, future events, changes in assumptions, changes in factors affecting such forward-looking information or otherwise.

Small Pharma makes no medical, treatment or health benefit claims about its proposed products. The Medicines and Healthcare products Regulatory Agency (“MHRA”) or other similar regulatory authorities have not evaluated claims regarding DMT-assisted therapies and other next generation psychoactive compounds. The efficacy of such therapies have not been confirmed by MHRA-approved research. There is no assurance that such DMT-assisted therapies and other psychoactive compounds can diagnose, treat, cure or prevent any disease or condition. Vigorous scientific research and clinical trials are needed. Any references to quality, consistency, efficacy and safety of potential therapies do not imply that Small Pharma verified such in clinical trials or that Small Pharma will complete such trials. If Small Pharma cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on Small Pharma’s performance and operations.

*The TSX Venture Exchange (the “TSXV”) has neither approved nor disapproved the contents of this news release. Neither the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.*

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