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Press Releases

World's First clinical trial for DMT-assisted therapy in Major Depressive Disorder Shows Consistent Quality of Psychedelic Response in Phase I

In the Phase I clinical trial, participants were administered SPL026 and underwent a 20-minute psychedelic experience

Phase I full dataset demonstrates consistent dose related effects on the intensity and quality of the psychedelic experience

February 22, 2022 – London, United Kingdom – Small Pharma Inc. (TSXV: DMT) (OTCQB: DMTTF) (the "**Company**" or "**Small Pharma**"), a neuropharmaceutical company focused on psychedelic-assisted N,N-dimethyltryptamine ("**DMT**") therapies for mental health, is pleased to share the analysis of Phase I data from the combined Phase I/IIa clinical trial of SPL026 with psychotherapy for the treatment of Major Depressive Disorder ("**MDD**").

In the dose-escalating, placebo-controlled Phase I study, 32 healthy psychedelic naïve volunteers across four dose cohorts received either SPL026 in combination with psychotherapy (n=24) or placebo (n=8). This analysis provides additional insight into dose-related effects on the primary outcomes of safety and tolerability as well as on pharmacodynamic measures, including the treatment experience and subject well-being.

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

> The analysis of the unblinded data set supports our choice to explore the antidepressant potential of our selected dose of SPL026 in the Phase IIa trial. Given the subjectivity of the psychedelic experience, it was exciting to see a close correlation between levels of drug in the body and pharmacodynamic endpoints. As for the subjects' experience, most reported that it was pleasurable, not too challenging, and most importantly, nobody expressed any regrets. Additionally, the strong safety profile and rapid clearance of SPL026 from the body provides the potential for a scalable treatment with limited monitoring needs post dosing."

Key Results

- No drug-related serious adverse events and minimal short-lived adverse events reported on dosing day.
- Of 20 drug-related adverse events, all were mild (85%) or moderate (15%) and resolved rapidly and independently.
- No statistically significant negative effects on anxiety and well-being identified at any point during the three-month follow-up.
- Data show a clear correlation between quality of psychedelic experience and dosing levels, starting at 9mg and up to 21.5mg, across all four cohorts.
    - Participant-reported scores, using a 0 to 100 scale, on the richness of the psychedelic experience demonstrated increasing values of 48 (9mg), 79, 79, 88 (21.5mg) across the four increasing doses. A dose correlation was seen across most patient-reported scores.
    - Therapist assessment of the predicted therapeutic benefit of SPL026 demonstrated a positive relationship with dose.
- In the majority of participants, there was a strong correlation between levels of N,N-dimethyltryptamine ("**DMT**") in the body and the quality and intensity of the psychedelic experience.
- IV administration of SPL026 offers a short-lived, well-tolerated psychedelic experience of ~20 minutes, enabling a dosing session to last only ~30 minutes.
- Pharmacokinetic sampling supported rapid clearance out of the body, showing near undetectable DMT levels in the blood by 60 minutes at all investigated doses.

The data confirms the selected dose of SPL026 taken forward into Phase IIa most consistently delivers the target treatment profile across

> Psychedelic-assisted therapies have the potential to completely change the treatment paradigm of mental health conditions. The additional insights from Small Pharma's Phase I study show promising results at this stage of the development. The dosing time of 30 minutes, in comparison with up to 6 hours seen with alternative approaches, has the potential to offer a real benefit in terms of treatment regimen for both patients and providers."

The blinded, randomized, placebo-controlled, proof-of-concept Phase IIa study of SPL026 in combination with psychotherapy in 42 patients with MDD remains on track to deliver topline results in the first half of 2022. This study will assess the efficacy of one dose of SPL026 versus a placebo, and one versus two doses of SPL026 in combination with psychotherapy in patients with MDD while bolstering existing safety and tolerability data.

About Small Pharma

Small Pharma is a neuropharmaceutical company specialized 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 its lead candidate, SPL026, 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 allows for short treatment sessions and offers the potential for convenient supervised treatments within patient clinics. Small Pharma is advancing a pipeline of DMT-based therapies and is leading the world's first DMT clinical trial for depression, in collaboration with Imperial College London.

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this news release include statements regarding the Company's continued progress in Phase I/IIa clinical trial of SPL026, the anticipated timing for the readout of topline data for the Company's Phase IIa trial, the Company's advancement of pre-clinical trials into new clinical trials, including the anticipated commencement and timing of the Company's Phase IIb trial of SPL026, the Company's success in launching a clinical program into DMT-assisted therapy, the Company's ability to develop solutions to effectively address depression through DMT-based therapies, the potential of DMT-assisted therapies to transform the lives of patients suffering with MDD, the ILAP providing potential access to speedier time to market and facilitation of patient access to emerging and novel treatments, and the Company's development of a robust pipeline of proprietary preclinical assets. 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 U.K. 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 has 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.

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