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Press Releases

Small Pharma Expands Potential of Commercial Portfolio with DMT-based Psychedelic Assets

Lead DMT-assisted therapy candidate SPL026's clinical development program strengthened with the addition of two clinical trials planned for 2022

SPL028, a deuterated DMT candidate with Composition of Matter patent protection in the UK, moves towards Phase I clinical trial in H2 2022 on positive preclinical data

March 10, 2022 – London, United Kingdom – Small Pharma Inc. (TSXV: DMT) (OTCQB: DMTTF) (the "**Company**" or "**Small Pharma**"), a neuroscience company focused on psychedelic-assisted therapies for mental health, announces research and development updates on two N,N-dimethyltryptamine ("**DMT**") based candidates, SPL028 and SPL026. Small Pharma's pipeline of short duration psychedelics have the potential to offer effective, accessible and practical in-clinic treatments with patients and clinicians in mind for a range of mental health conditions. Two additional trials have been added to SPL026's development program while the SPL028 program moves towards a Phase I clinical trial in H2 2022.

SPL026 Update

Following the success of its lead DMT candidate SPL026's Phase I trial, Small Pharma is expanding its development program with the addition of a drug interaction study, planned for 2022. This study will assess the impact of antidepressants on the safety, tolerability, pharmacokinetics and pharmacodynamics of SPL026 with psychotherapy. These endpoints will be assessed in patients with Major Depressive Disorder ("**MDD**"),

Small Pharma is also planning a further Phase I study of SPL026 with healthy volunteers in 2022 to compare the treatment profile of intramuscular ("**IM**") versus intravenous ("**IV**") modes of administration. IM injection would offer a simple injectable form that could further enhance convenience and accessibility for patients and clinicians.

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

> **We want to maximize access to DMT therapy for the greatest number of patients. We recognize that for some MDD patients, coming off antidepressants can be a difficult process. Additionally, we are looking to explore optimized treatment routes. By continuing our research in these new avenues, our ambition is to identify the best potential treatment options for patients with major depression."**

SPL028 Update

Small Pharma has advanced its proprietary deuterated DMT candidate SPL028 through preclinical studies. The goal is to deliver a treatment with an extended psychedelic experience, as compared to SPL026, but still significantly shorter than the experience of other psychedelics, such as psilocybin and LSD. Through SPL028, Small Pharma is exploring whether an extended duration could offer a DMT treatment tailored for other mental health conditions. Additionally, the pharmacokinetic profile of SPL028 offers the opportunity for optimizing alternative routes of administration beyond IV.

The final candidate of SPL028 was selected after screening a range of deuterated DMT compounds through in vitro and in vivo studies. Importantly, preclinical studies suggest that SPL028 offers a similar safety and pharmacological profile to SPL026, while being differentiated by its pharmacokinetics, to offer a potentially extended psychedelic experience as compared to SPL026.

- **Safety profile:** SPL028 has the potential for a similar safety profile to SPL026 in the clinic.
  - In vitro and ex vivo binding: data suggest a similar binding affinity across a range of receptors including 5-HT receptor subtypes (5HT2A included), which are believed to induce psychoactive effects.
  - Toxicology: SPL028 found to be safe and well-tolerated in vivo at all doses tested, demonstrating significant safety margins for progressing into first-in-human trials.
- **Behavioral effects:** Similar but prolonged behaviors induced by SPL028 in a number of preclinical models were observed in vivo, suggesting the potential for a similar but longer psychedelic experience as compared to SPL026.
- **Pharmacokinetic profile:** In vitro data of SPL028 demonstrated a reduction in clearance rate and significant extension in half-life compared to SPL026. Following IM administration in vivo, SPL028 demonstrated a marked decrease in clearance from the body, resulting in higher blood concentrations for an extended period of time versus SPL026.

Dr. Carol Routledge continued,

> **The rapid effects of DMT, as highlighted in recent Phase I data, offers the flexibility to engineer alternative DMT candidates that could deliver extended yet convenient and accessible in-clinic treatment options for a broader range of mental health conditions. SPL028's promising preclinical data demonstrates its similarities to DMT from a safety and behavioural perspective, allowing for a potentially expedited route to the clinic."**

In H2 2022 Small Pharma intends to initiate a Phase I study of SPL028 with psychotherapy among healthy volunteers to assess safety, tolerability, pharmacodynamics and pharmacokinetics of IM and IV administration. This study will allow Small Pharma to better understand the profile of SPL028 as a therapeutic candidate and identify the optimal route of administration in a clinical setting.

About Small Pharma

Small Pharma is a neuroscience company specialized in discovering and developing novel treatments for mental health conditions, with a current 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 (< 30 mins), which allows for short treatment sessions and offers the potential for convenient supervised treatments within patient clinics. Small Pharma is

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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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