21 October 2021
Press Releases

Small Pharma granted fast-track designation from UK regulator for DMT-assisted therapy for Major Depressive Disorder

LONDON, Oct. 21, 2021 — Small Pharma Inc. (TSXV: DMT) (the "**Company**" or "**Small Pharma**"), a neuropharmaceutical company focused on psychedelic-assisted therapies, is pleased to announce that following discussions with the U.K. Medicines and Healthcare products Regulatory Agency (the "**MHRA**"), Small Pharma has been granted an Innovation Passport Designation for SPL026, the lead product candidate from its pipeline of N,N-dimethyltryptamine ("**DMT**") assisted therapies for the treatment of major depressive disorder ("**MDD**").

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

> Similar to the FDA's fast-track in the United States, the U.K.'s MHRA Innovation Passport provides us with access to specialist advice throughout the drug development process and has the potential to enable a speedier, more efficient development process for SPL026, the lead candidate in our psychedelic-assisted therapy approach for the treatment of MDD. SPL026 entered clinical trials at the beginning of 2021 and this designation marks an important step forward towards an accelerated drug approval pathway for bringing the benefits of SPL026 to market for patients suffering with MDD."

The Innovation Passport is an innovative medicine designation that provides access to the Innovative Licensing and Access Pathway (the "**ILAP**"). The ILAP accelerates time to market and facilitates patient access to emerging and novel treatments. The ILAP provides a single integrated platform for sustained collaborative working among the MHRA, its partners and the medicine developer, which allows for enhanced coordination and monitoring of important product development activities culminating in market authorisation. Under the ILAP, Small Pharma will have access to a toolkit to support all stages of the design, development and approvals process, as well as identify key areas for future

ultimately enable quicker patient access to these potential medicines. Key partnering stakeholders include the MHRA, the U.K.'s public body responsible for evidence-based evaluations of novel treatments, the National Institute for Health and Care Excellence, as well as the NHS England, the Scottish Medicines Consortium, NHS Improvement Health Research Authority, and the National Institute for Health Research.

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 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 MDD, in collaboration with Imperial College London.

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next-generation psychedelic compounds. The efficacy of such therapies have not been confirmed by FDA/EMA 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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