



PharmaTher and TSRL Enter into Co-Development Agreement For Microneedle Patch Delivery Technology for Psychedelics and Antivirals

TORONTO, June 01, 2021 (GLOBE NEWSWIRE) -- PharmaTher Holdings Ltd. (the "Company" or "PharmaTher") (OTCQB: PHRRF) (CSE: PHRM), a clinical-stage psychedelics biotech company and TSRL, Inc. ("TSRL"), a company focused on developing microneedle patches for the delivery of antivirals for the treatment of influenza, are pleased to announce that PharmaTher and TSRL (collectively the "Companies") entered into a Co-Development Agreement to jointly develop a microneedle array patch with the aim to control the manufacturing and supply of microneedle patches for the Companies respective clinical and commercial drug programs.

PharmaTher and TSRL share the commitment to commercialize a patented hydrogel-forming microneedle patch delivery technology licensed from Queens University of Belfast. PharmaTher is focused on incorporating psychedelics (i.e. ketamine, psilocybin, DMT, MDMA and LSD) and TSRL is focused on incorporating antiviral medications (i.e. Zanamivir, other antiviral therapeutics and vaccines) in a microneedle patch with the potential to improve on the safety (i.e. fewer side effects), efficacy (i.e. bioavailability, optimized dosing regimen including continuous system delivery) and compliance (i.e. storage, distribution and self-administration) of these compounds that currently must be taken orally, inhaled, injected and intravenously.

TSRL is comprised of a team of pharma industry veterans with deep drug development expertise, ranging from discovery and preclinical development to clinical, regulatory, and IP strategy development. TSRL's facility is based in Ann Arbor, Michigan, and is positioned as a preclinical accelerator for anti-infective therapeutic product concepts, with an emphasis on improving dosing regimens and outcomes of approved product with suboptimal market uptake. TSRL has performed in-house optimization of the Zanamivir drug-device combination product, and initiated tech transfer for scale-up and manufacturing to toxicology and clinical supplies to a GMP contract research lab. TSRL has successfully conducted a pre-IND meeting with the US FDA and achieved agreement with the agency on their proposed 505(b)2 product development plans.

Fabio Chianelli, CEO of PharmaTher commented: "We are very excited to collaborate with TSRL as they have de-risked certain technical and manufacturing aspects of the microneedle patch and by sharing our resources it will allow PharmaTher to expedite the clinical and commercial development of the microneedle patch with ketamine and other psychedelics. Also, the collaboration will ensure control over the manufacturing and supply of microneedle patches for not only both of our respective product programs, but also it may unlock future commercial partnering opportunities with pharmaceutical companies seeking a microneedle patch delivery system."

Dr. Elke Lipka, CEO of TSRL commented: "We are delighted to join forces with PharmaTher, as this collaboration will allow us to execute our respective lean development strategies for the manufacturing of the microneedle array and ultimately the array/drug reservoir combination product. In addition to increased cost effectiveness, there is substantial strategic overlap between our two organization with respect to the regulatory strategy for our product candidates. Microneedle-enabled drug delivery is at the cusp of becoming one of the most promising approaches to achieve carefully tuned systemic delivery of therapeutics and vaccine."

Microneedle-enhanced intradermal delivery is an elegant, efficient and painless method for increasing the skin permeation of many drugs, including psychedelics, antiviral therapeutics and vaccines.

Transdermal delivery systems offer a number of advantages over inhalation and IV administration. Our approach consists of a 2-part system comprised of a drug-loaded reservoir that is placed on top of the hydrogel microneedle array. After administration into the skin (i.e. intradermal delivery), the microneedles become hydrated and swell, creating pores for the reservoir to release the drug content into the tissue over the treatment course. Upon removal, the needles are intact, yet rounded, and do not need to be disposed of as sharps. The drug directly enters the systemic circulation, circumventing absorption and first-pass barriers typical for oral delivery. Our studies show that with transdermal delivery, systemic drug concentrations are reached within minutes after administration and are maintained over multiple days. This system addresses a major unmet need by offering greater ease of administration, inclusion of patients with pre-existing conditions that exempt them from oral or inhalation dosing. It avoids syringe needles, eliminating pain and patient visits to a clinician. We also anticipate that patient compliance will be improved with a self-administered transdermal patch.

About TSRL, Inc.

TSRL, Inc. collaborates with partners in academia and industry to develop anti-infective therapeutics and drug delivery technologies. In these collaborations, TSRL provides infrastructure, drug development expertise, and access to non-dilutive funding. TSRL's portfolio holds promising lead-stage anti-infective therapeutics. More information about TSRL and portfolio technologies are available at [TSRLinc.com](https://www.tsrlinc.com).

About PharmaTher Holdings Ltd.

PharmaTher Holdings Ltd. (OTCQB: PHRRF) (CSE: PHRM) is a clinical-stage psychedelics biotech company focused on the research, development and commercialization of novel uses, formulations and delivery methods of psychedelics to treat mental illness, neurological and pain disorders. PharmaTher is currently conducting an FDA approved phase 2 clinical study with

ketamine to treat Parkinson's disease and is developing a novel microneedle patch for the intradermal delivery of psychedelics.

Learn more at: PharmaTher.com and follow us on [Twitter](#) and [LinkedIn](#).

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