XPhyto Reports Development Update for its Drug Delivery Business

written by Raj Shah | October 12, 2021
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- ***Rotigotine transdermal skin patch optimization and pivotal study planning underway***
- ***Rotigotine patch manufacturing, sales and marketing in preparation***
- ***Cannabinoid oral dissolvable film (ODF) programs advanced, CBD ODF ready for pilot study***
- ***Prioritization of additional near-term drug formulation programs underway***

XPhyto Therapeutics Corp. (CSE:XPHY)(OTCQB:XPHYF)(FSE:4XT) ("XPhyto" or the "Company") is pleased to announce that its drug formulation and development business continues to advance multiple generic and hybrid-generic programs for neurotherapeutics. XPhyto's drug formulation business is focused on scalable, low-cost development opportunities that present expedited pathways to regulatory approval. Products in the Company's development pipeline are for the treatment of large and growing markets with the potential for significant improvements in patient outcomes.

"XPhyto's strategy is to advance its thin-film technology platform to develop innovative formulations of generic and hybrid-generic drugs. In 2021, we have completed the pilot study for our lead program and are expecting to complete pilot studies for our three cannabinoid drug formulation programs in Q4 2021 and Q1 2022," said Hugh Rogers, XPhyto CEO & Director. "We are

also looking to expand our near-term product pipeline beyond neurotherapeutics and are expecting considerable synergies with other XPhyto business lines by applying our drug delivery expertise to psychedelic compounds and to delivering biosensors via our proprietary oral dissolvable platform."

Based on its human bioavailability pilot study completed in March 2021, XPhyto has advanced its generic Rotigotine transdermal product to formula optimization. The optimization process, expected to be completed in Q4 2021, is carried out to finalize the product in anticipation of a pivotal clinical study in Q2 2022. Data generated from the pivotal trial is expected to form the basis for the Company's European product regulatory application. Preparation for contract manufacturing, sales and marketing is being done simultaneously to ensure rapid and efficient market launch, subject to a successful pivotal trial.

Rotigotine is a non-ergoline dopamine agonist approved for the treatment of Parkinson's disease and restless legs syndrome in Europe and the United States. Rotigotine, the active pharmaceutical ingredient, is a generic "off-patent" drug that is typically formulated as a once-daily transdermal patch which provides a slow and constant supply of the drug over the course of 24 hours.

According to Research and Markets, the global transdermal skin patches market reached a value of nearly US$6.5 billion in 2020, having increased at a compound annual growth rate (CAGR) of 3.9% since 2015. The market is expected to grow to US$7.9 billion in 2025 and reach US$9.39 billion in 2030.

XPhyto is currently advancing three hybrid-generic oral dissolvable ("ODF") cannabinoid products: CBD, THC, and 1:1 CBD:THC. The chemical similarities between the three related ODF formulas have led to research and development efficiencies as

knowledge gained in each program has been utilized in the others, including patentable technological advancements in the Company's ODF platform. Due to the harmonization of regulations between certain jurisdictions within the EU and changing documentation requirements, XPhyto's contract research organization ("CRO") is awaiting approval for the import of clinical materials to carry out human bioavailability pilot studies planned for 2021. Import approval is expected in November 2021 with the CBD pilot study to commence immediately thereafter. Study planning and clinical product manufacturing is complete.

The US Food & Drug Administration (FDA) and European Medicines Agency (EMA) have approved CBD-based medicines for the treatment of severe childhood forms of epilepsy, specifically Dravet syndrome and Lennox-Gastaut syndrome. THC-based medicines have been approved for the treatment of nausea associated with cancer chemotherapy and for the treatment of anorexia associated with weight loss in AIDS patients. The registered formulation for CBD is a lipophilic solution in sesame oil and for THC it is a soft gelatin capsule filled with THC in a sesame oil carrier. Alternatively, XPhyto's medical cannabinoid programs are focused on the development of precise and efficient oral dissolvable drug formulations for prescription use.

XPhyto's strategy is to develop a portfolio of generic and hybrid-generic drug products. The Company is reviewing its development pipeline for selection of its next near-term drug formulation candidate. As the Company looks to expand its near-term product pipeline it is reviewing numerous transdermal and oral dissolvable opportunities. The Company is also advancing its psychedelic medicine program and expects to make announcements with respect to API production and drug formulation in due course.

XPhyto’s drug formulation business is carried out primarily by its 100% owned, German subsidiary, Vektor Pharma TF GmbH (“Vektor”). Vektor is a German drug manufacturer, developer, and research organization located in the district of Biberach, Baden-Württemberg, Germany. For over a decade, the company and its team have been leaders in the design, testing and manufacture of thin film drug formulations, particularly transdermal patches and sub-lingual (oral) strips for the delivery of active pharmaceutical ingredients for the treatment of pain and neurological conditions.

About XPhyto Therapeutics Corp.
XPhyto Therapeutics Corp. is a bioscience accelerator focused on next-generation drug delivery, diagnostic, and new active pharmaceutical ingredient investment opportunities, including: precision transdermal and oral dissolvable drug formulations; rapid, low-cost infectious disease and oral health screening tests; and standardization of emerging active pharmaceutical ingredients for neurological applications, including psychedelic compounds and cannabinoids. The Company has research and development operations in North America and Europe, with an operational focus in Germany, and is currently focused on regulatory approval and commercialization of medical products for European markets.

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SOURCE: XPhyto Therapeutics Corp.