XPhyto Epilepsy clinical trial planned in 2022 with its proprietary fast-dissolving CBD oral strips

written by Raj Shah | December 15, 2021

December 15, 2021 (Source) – XPhyto Therapeutics Corp. (CSE:XPHY / OTC:XPHYF / FSE:4XT) ("XPhyto" or the "Company") is pleased to provide an update on the development of its fast-dissolving CBD oral strips. With significant complexities involved in the planning and preparation for the pending human pilot study, the Company is pleased to announce that its European human CBD bioavailability study will commence in January 2022.

Prof. Dr. Beckert said, "the clinical trial of our CBD product is aiming to demonstrate the efficient and precise dosing of the treatment. If successful, this could make a significant difference to Epilepsy patients and we are excited to commence the trial next year."

XPhyto is developing a hybrid-generic CBD prescription drug formulation that employs the Company's proprietary oral dissolvable ("ODF") platform to deliver precise and efficient CBD dosages for the treatment of certain forms of childhood Epilepsy.

The US Food & Drug Administration (FDA) and European Medicines Agency (EMA) have approved CBD based medical products from other companies for the treatment of severe childhood forms of Epilepsy, including Dravet syndrome and Lennox-Gastaut syndrome. The currently approved and registered formulation of CBD is a lipophilic solution in sesame oil with a standard dosage of 750

mg/day. Due to low bioavailability (approximately 5%) the formulation could be considered highly inefficient compared to the XPhyto ODF platform.

For the purpose of carrying out XPhyto's clinical study, the following important and necessary items have been completed or received: Product Development Report, Investigational Medicinal Product Dossier, Permit for Clinical Study, manufacture of clinical product samples; Product Specification File; monitoring agreement; and Import Authorization to the location of the FDA-inspected Clinical Research Center. Pending success in the CBD pilot study, the Company expects to carry out a pivotal clinical study in 2H of 2022.

The Company's CBD-based Epilepsy treatment program is one of several dissolvable oral drug delivery programs. Oral thin film drug delivery is a large and growing international industry which provides an alternative to conventional solid and liquid oral dosage forms. Transparency Market Research estimates that the global market for thin film drug manufacturing will be worth US$15.98 billion by 2024, rising at a 9.0% CAGR between 2019 and 2024. XPhyto's additional oral thin film drug delivery programs include both cannabinoid and non-cannabinoid products for pain, neurology, and infectious disease. The Cannabidiol Market revenue is estimated to be worth over US$89 billion by 2026 according to Global Market Insights Inc.

Executive management of XPhyto's drug formulation business is led by Prof. Dr. Beckert, managing director of Vektor Pharma TF GmbH. Prof Dr. Beckert is a German-based scientist and experienced corporate executive who is leading XPhyto's drug formulation and diagnostics operations.

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.

XPhyto Therapeutics Corp.

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