XPhyto Announces Drug Formulation Strategy and 2021 Milestones Innovation to Impact

written by Raj Shah | January 28, 2021
January 28, 2021 (Source) –

- ***Construction of commercial drug manufacturing facility in Germany***
- ***Four clinical studies in neurological indications in 2021***
- ***Development of oral biosensor and contract development & manufacturing***
- ***Psychedelic transdermal and sublingual drug formulation development***

XPhyto Therapeutics Corp. (**CSE:XPHY)(OTCQB:XPHYF)(FSE:4XT**) ("**XPhyto**" or the "**Company**") is pleased to announce its drug formulation and delivery business strategy and milestones for 2021. As a bioscience accelerator at the leading-edge of the life science industry, XPhyto targets growth through commercialization of its product pipeline and focused investment in impact driven innovation with the potential for meaningful value creation.

Further to XPhyto's press release dated January 18, 2021, the Company's core milestones for this year include the commercialization of infectious disease diagnostics, the clinical validation of transdermal and sublingual drug formulations and continued investment in psychedelic medicine.

Regarding XPhyto's drug formulation business, the Company is

pleased to set out the strategy and milestones for 2021 of its wholly owned German subsidiary, Vektor Pharma TF GmbH ("Vektor"). Vektor will position itself for commercial manufacturing, pipeline development and drug formulations for critical mental health conditions.

"2021 is expected to be a transformative year for Vektor. We will be building on significant momentum from 2020 as we advance our drug formulation, contract development, and psychedelic business," said Prof. Dr. Thomas Beckert, managing director of Vektor Pharma TF GmbH. "The addition of scalable in-house manufacturing capability creates the potential for significant growth across virtually all of our development and commercialization programs."

Vektor is a German narcotics manufacturer, developer, and researcher 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 ("API") for the treatment of pain and neurological conditions.

Commercial Manufacturing Facility

In anticipation of Vektor's drug product commercialization schedule, and due to significant interest in contract manufacturing, Vektor is planning to build a new commercial drug manufacturing facility in Germany in 2021. Vektor has secured a property in the district of Biberach, near its current laboratory, and is currently in the due diligence process to ensure suitability of the land for construction and use as a commercial drug manufacturing and laboratory site. The estimated maximum capacity of laboratory and manufacturing space that could be constructed on the property is 3,000 m^2 (32,000 ft^2).

The Company is reviewing scalable construction options to synchronize manufacturing capacity and demand with the Company's projected growth and timelines.

As a vertically integrated drug formulation research, development and commercial production company, Vektor is well positioned to maximize the value of its physical and intellectual assets by way of: 1) development, manufacture and distribution of XPhyto products; and 2) contract development and/or manufacture of products for third-parties. The addition of in-house, scalable commercial drug manufacturing capability is expected to add significant value and optionality to XPhyto's drug formulation business.

Clinical Studies

XPhyto's drug formulation business is focused on neurological indications with strong market demand and the potential for improved patient outcomes. In 2020, XPhyto reported significant advancements in four drug formulation development programs. In 2021, the Company is planning to complete one clinical pilot study in each quarter as follows:

Q1) Rotigotine – transdermal patch in Parkinson's disease;
Q2) CBD – oral/sublingual strip in treatment resistant Epilepsy;
Q3) THC – oral/sublingual strip in anorexia/nausea; and
Q4) CBD:THC (1:1) – oral/sublingual strip in Multiple Sclerosis associated spasticity.

Each study is planned to be carried out over an approximately two-week period as an open label, randomized, crossover, two-period, two-sequence, single dose pilot study to assess the relative bioavailability of each product. Pending positive results, the Company plans to advance the products toward a final pivotal study and application for regulatory approval.

The Company is currently in discussions with multiple potential

commercial partners, licensors and distributors and will be reviewing monetization opportunities on a continued basis. In-house commercial manufacturing is expected to provide additional value to potential purchasers, partners and licensors, and ultimately to XPhyto.

Development of Oral Biosensors and Contract Development & Manufacturing

XPhyto's diagnostic portfolio includes several novel peptide-based oral screening tests, under licence from 3a-diagnostics GmbH, for the detection of infectious diseases including influenza A, and oral health indications, such as peri-implantitis. In 2020, XPhyto confirmed successful activation of its peptide-based biosensor program when delivered using Vektor's sublingual drug delivery platform. In 2021, XPhyto plans to continue development and validation of its biosensor products and plans to bring at least one biosensor product to market in Europe by yearend. In-house commercial manufacturing capacity, as set out above, is expected to maximize profitability of the biosensor commercialization.

Since its inception, Vektor has worked for major and emerging drug companies to develop new and generic dosage formulations based on its sublingual and transdermal drug delivery platforms. Vektor has produced generic drug formulations of Fentanyl, Rivastigmine, and Clonidine, as well as novel formulations of drugs in Parkinson's disease, restless leg syndrome, incontinence, local pain and abuse-resistant pain medications. Further, Vektor is currently engaged in the development of a sublingual drug formulation for a major European generic drug company.

Vektor provides its clients with a versatile and rapidly adjustable sublingual and transdermal dosage platform to create new delivery options for generic and novel APIs. With the

addition of in-house commercial manufacturing capacity, Vektor is building a vertically integrated thin film company to significantly grow its contract development and manufacturing business.

Psychedelic Transdermal and Sublingual Drug Formulations

Psychedelic compounds are a promising new class of API with potential for the treatment of mental health conditions such as depression, anxiety, addiction, and trauma-related stress disorder. Psychedelics could provide a major improvement over currently available therapeutics for a global market with unmet medical need.

Vektor will begin planning and development work for the incorporation of various psychedelic compounds into its drug formulations. This is facilitated by Vektor's drug delivery platforms in combination with, XPhyto's agreements for the development of industrial scale biotechnology processes for the production of psilocybin in Germany, and for the research and development of a broad range of psychedelic compounds, including psilocybin, mescaline, LSD, MDMA, DMT, in Canada.

XPhyto believes that the development of standardized drug formulations with precise, predictable and efficient API delivery for clinical study and therapeutic use, is critical to advancing the field of psychedelic medicine.

The Company will provide further information and updates for each of the business initiatives set out above in due course.

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.:
Hugh Rogers, CEO and Director

Investor Inquiries:
Mr. Knox Henderson
T: 604-551-2360
E: info@xphyto.com

Media Inquiries:
MC Services AG
Julia Hofmann, Andreas Jungfer
T: +49 89 210 228 0
E: xphyto@mc-services.eu

Forward-Looking Statements

This news release includes statements containing forward-looking information within the meaning of applicable Canadian securities law (“forward-looking statements”). Forward-looking statements are frequently characterized by words such as “develop”, “plan”, “continue”, “expect”, “project”, “intend”, “believe”, “anticipate”, “estimate”, “potential”, “propose” and other similar words, or statements that certain events or conditions “may” or “will” occur, and in this release include the statement regarding the Company’s goal of building a successful diagnostic, drug delivery, and medical cannabis company. Forward-looking statements are only predictions based on the opinions and estimates of management at the date the statements

are made and are subject to a variety of risks and uncertainties and other factors that could cause actual events or results to differ materially from those projected in the forward-looking statements, including: that the Company may not succeed in developing a commercial product; that the sale of products may not be a viable business; that the Company may be unable to scale its business; product liability risks; product regulatory risk; general economic conditions; adverse industry events; future legislative and regulatory developments; inability to access sufficient capital from internal and external sources, and/or inability to access sufficient capital on favourable terms; currency risks; competition; international risks; and other risks beyond the Company's control. The Company is under no obligation, and expressly disclaims any intention or obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as expressly required by applicable law.

Neither the CSE nor its Market Regulator (as that term is defined in the policies of the CSE) accepts responsibility for the adequacy or accuracy of this news release.