XPhyto Partner Receives ISO Certification for 25-Minute COVID-19 RT-PCR Test

written by Raj Shah | March 10, 2021

March 10, 2021 (Source) – XPhyto Therapeutics Corp. (CSE:XPHY / OTCQB:XPHYF / FSE:4XT) ("XPhyto" or the "Company"), and its exclusive German diagnostics development partner, 3a-diagnostics GmbH ("3a"), are pleased to announce successful EN ISO 13485 certification for the rapid point-of-care, SARS-CoV-2 RT-PCR Test System ("Covid-ID Lab"). This standardization and quality assurance certification provides authorization for distribution of Covid-ID Lab upon receipt of CE mark (CE-IVD) approval. The Company expects CE-IVD approval as an in vitro diagnostic product in March 2021.

EN ISO 13485 is the internationally recognized European standard for quality control and management systems in the design and manufacture of medical devices. It is accepted as the basis for CE certification of medical devices under relevant European directives and regulations.

"We are pleased to remain on schedule with the launch of Covid-ID Lab and will continue to move forward as efficiently as ever," said Hugh Rogers, CEO and director of XPhyto. "At the same time, our experienced launch team is working hard to bring Covid-ID Lab to market and to establish German and international licensing and distribution partnerships."

Covid-ID Lab was designed to be a rapid, accurate and robust COVID-19 test system with reduced operating costs and increased convenience and portability. As previously announced on February 24, 2021, the company placed its first production order from 3a

for 9,600 individual tests. Delivery of this first order is expected by mid-March 2021 and is primarily intended to provide potential German and international distributors and licensees and their respective government regulators with test samples for review and evaluation. Initial commercial manufacturing is planned for Germany, with additional capacity in other jurisdictions expected to follow. The sales launch in Europe is targeted for April 2021. XPhyto is currently in discussions with potential distribution and wholesale partners in Europe and the Middle East.

XPhyto and 3a are also developing a portfolio of oral biosensor screening tests for detection of bacterial and viral infectious diseases, including influenza A, group A strep, stomatitis, periimplantitis, and periodontitis. Additional pandemic-focused biosensors are in development, specifically for H1N1 (swine flu), and H5N1 (avian flu). The Company is planning the commercial launch of its first biosensor product in the second half of 2021.

The Company will provide further information and updates in due course.

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the COVID-19 pandemic. Further, its COVID-19 related test products are not yet approved and are still subject to risks associated with the regulatory approval process.

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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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.