XPhyto European CE-IVD Application for 25-Minute COVID-19 RT-PCR Test

written by Igor Makarov | February 16, 2021

February 16, 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 that all actions and procedures required for its European regulatory application for the rapid point-of-care SARS-CoV-2 (COVID-19) RT-PCR Test System ("Covid-ID Lab") have been completed. 3a expects ISO 13485 approval as a medical device manufacturer by late February and European regulatory approval as a commercial in vitro diagnostic device (CE-IVD) for Covid-ID Lab by early March.

Covid-ID Lab was designed to be a rapid, accurate and robust test system with reduced operating costs and increased convenience and portability. Initial manufacturing is planned for Germany with additional capacity in other jurisdictions 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. The Company will provide further information and updates in due course.

"We are very pleased with the team's swift development progress," said Hugh Rogers, CEO & Director of XPhyto. "Our goal was to create the fastest and most portable COVID-19 PCR test on the market. We are confident in our prospects for an expedited approval and look forward to commercial launch in short order."

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 commercial launch of its first biosensor product in the second half of 2021.

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.

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

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