XPhyto announces European Approval for 25 Minute COVID-19 PCR Test

written by Raj Shah | March 18, 2021
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- ***CE Mark received for in vitro diagnostic (IVD) test for the detection of SARS-CoV-2***
- ***Rapid results with ease of use – single 20-minute PCR cycle plus 5-minute detection process***
- ***High sensitivity – 104.73 c/PCR limit of detection with 95% confidence interval***
- ***High specificity – zero cross-reactivity on 19x respiratory infectious disease panel***
- ***High robustness – no impact on results from minor changes in process parameters***
- ***100% repeatability and laboratory precision observed***
- ***Sales launch in Europe planned for April 2021***

XPhyto Therapeutics Corp. (CSE:XPHY)(OTC:XPHYF)(FSE:4XT) ("XPhyto" or the "Company"), and its exclusive German diagnostics development partner, 3a-diagnostics GmbH ("3a"), are pleased to announce the European approval of its point-of-care SARS-CoV-2 (COVID-19) RT-PCR test system ("Covid-ID Lab"). Covid-ID Lab is now registered within the European Union as a commercial in vitro diagnostic (CE-IVD) test.

"Our test is one of the fastest PCR-based COVID-19 tests currently approved. With a sample collection to result time of 25 minutes, Covid-ID Lab combines the speed of a rapid screening test with the accuracy of a PCR diagnostic," said Hugh Rogers, CEO and Director of XPhyto. "Covid-ID Lab is designed for point-

of-care testing, particularly in satellite and small-scale labs, such as transportation hubs, borders, care facilities, schools, pharmacies, and hospitality settings.”

Covid-ID Lab is a multiplex viral RNA probe kit based on the reverse transcriptase-polymerase chain reaction (RT-PCR) method. For assay performance, Covid-ID Lab requires only a single 20-minute PCR thermal cycle without prior RNA extraction as part of the sample preparation. Many widely available standard PCR instruments are suitable to run the test. Results are collected after the PCR cycle via easy-to-read optical indicator strips on a simple fluidics platform. The elimination of RNA extraction for sample preparation reduces the risk of cross-contamination and minimizes the need for lab materials and trained personnel. The rapid results, minimal laboratory equipment, and ease of use are expected to translate into reduced operating costs, greater convenience and portability.

During validation of the assay, the limit of detection for SARS-CoV-2 RNA was determined to be 104.73 c/PCR within a 95% confidence interval. Specificity of 100% against 19 other pathogens of serious respiratory infections was demonstrated on a respiratory verification panel. Precision was determined through evaluation of variance of the analysis results due to random deviations, a repeatability/intra-assay precision evaluation (same lab, user, equipment, etc.), and a laboratory precision evaluation (different lab, user, equipment, etc.). Robustness was measured by evaluation of the impact of minor changes on process parameters (transport medium, PCR cycler model, ramp rate, template volume, hybridization mixing ratio, etc.). The validation studies were carried out accordingly to ICH Q2 (R1) Validation of Analytical Procedures: Text and Methodology and VQ-015 Validation of Methods, European Medicines Agency. The quality management system was in accordance with EN ISO 13485: 2016 and EN ISO 9001: 2015.

XPhyto is currently in discussions with various potential distribution and wholesale partners as well as potential licensees. The sales launch in Europe is targeted for April 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.

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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