

MedMira receives the CE mark for its Reveal® TP (Syphilis) and starts clinical trials in Canada

Halifax, Nova Scotia, 9 March, 2022 – Today, MedMira Inc. (MedMira) (TSXV: MIR) launches its Reveal® TP (Syphilis) product in Europe and gets clinical trial underway in Canada. The Company received the CE mark today and is now available in Europe and any countries accepting the CE mark. Furthermore, the Company continues their work on the Investigational Testing Application (ITA) for the planned clinical trial in Canada to start in the spring with the support and partnership of REACH Nexus (www.reachnexus.ca) at the MAP Centre for Urban Health Solutions (www.maphealth.ca), housed at St. Michael's Hospital of Unity Health Toronto.

Syphilis is a sexually transmitted blood-borne infections (STBBIs) caused by the bacterium *Treponema pallidum*. When left untreated syphilis moves to the tertiary stage causing the re-occurrence of lesions and more severe symptoms of syphilis such as serious multi-organ infections, vascular, and neurological damage. Congenital syphilis occurs when a syphilis-infected mother passes the infection onto her baby during pregnancy which can lead to stillbirth or death shortly after birth, miscarriage, prematurity, deformed bones, brain and nerve problems of the baby.

Based on the increasing prevalence of syphilis, its increased toll on public health, and the renewed focus on the diagnosis and treatment of syphilis, market analysts have placed syphilis diagnostics with the projected compounded annual growth rate (CAGR) of about 3%, the highest amongst infectious diseases market, and the market size for syphilis rapid test kits at 606.4 million USD in 2022. Additionally, a recent study by researchers at Columbia University reported the use of 1.2 million syphilis diagnostic tests in just 81 state and local Public Health Labs (PHLs) in the US during 2016, thus showing the high market demand.

“While MedMira’s team has placed a major focus in our REVEALCOVID-19® and VYRA® product lines, we continued working on the infectious diseases products with emphasis on the three major markets: HIV, HCV and TP. Despite the world’s attention to the COVID-19 situation, other diseases do not take a break and we are firmly committed to helping people know...®. Therefore, we are pleased to receive the CE mark for the Point-of Care settings to provide greater access to the end-users,” says Hermes Chan, CEO of MedMira. “Furthermore, we see a tremendous need for fast and reliable testing procedures in Canada in order to assist the health care system with a high quality and cost-efficient solution. We are excited to have the opportunity to work with Dr. Sean Rourke and his team at REACH Nexus to initiate the regulatory process, and confident that Reveal® TP will soon be made available in Canada.”

The World Health Organization (WHO), in 2021, noted the unacceptably high prevalence of syphilis and highlighted the need to efficiently advance the goal of eliminating syphilis as a public health threat by 2030. Recent data from both the European Union and Canada further support the need for effective strategies to combat the increasing rates of syphilis. Canada reported an incidence rate of 24.7 per 100,000 in 2020, up from 5.1 per 100,000 in 2011. While in 2018 alone, the European CDC (ecdc) reported about 34,000 new confirmed cases of syphilis. Since treatment options that can prevent the progression of syphilis are available, rapid diagnosis and treatment of infected individuals along with the rapid identification and treatment of sexual contacts should be a high priority.

“We need more rapid point-of-care (POC) testing options approved in Canada to reach the undiagnosed with HIV, syphilis and other blood-borne infections and sexually transmitted infections (STBBIs)” said Dr. Sean B. Rourke, director of REACH Nexus and scientist at MAP Centre for Urban Health Solutions at St. Michael's Hospital of Unity Health Toronto. “We are very excited about the partnership and implementation science work we are doing with MedMira that will have real-life impacts for Canadians and people around the world. The approach we are taking to addressing the rising number of STBBIs are “game-changers” for Canada. Not everyone has access to the testing they need for STBBIs because of health inequities, stigma and various forms of discrimination. We need to democratize rapid testing – get more POC and self-testing (for use at home) approved by Health Canada – so that all Canadians have access to the testing they need to make decisions about their health and wellbeing, when and where it’s best for them.”

With funding from the Canadian Institutes of Health Research (CIHR), Dr. Rourke and his team at REACH Nexus is leading efforts to address these epidemics by working collaboratively with Canadian *in vitro diagnostic* developers, health care providers, community stakeholders and people with lived experience, researchers,



health ministries and public health to bring new POC tests to market here in Canada – while also addressing the burden of these epidemics to Canadians at the same time. Using this novel implementation science approach, the work is progressing well in northern Alberta under the leadership of Dr. Ameeta Singh at the University of Alberta to “test and treat” for HIV and syphilis while evaluating the performance of the Multiplo®, HIV and syphilis POC test made by MedMira. And later this spring, work will get underway in Saskatchewan to conduct another “test and treat” implementation science study to address the syphilis outbreaks there using the Reveal® TP (Syphilis) Product while also collecting performance data MedMira will use for their licensing application to Health Canada.

MedMira along with their partners from REACH Nexus have identified clinical /community sites in the Western part of Canada as an ideal location for this next “test and treat” clinical trial and implementation science study, subject to Health Canada’s authorization.

About REACH Nexus at MAP Centre for Urban Health Solutions

REACH Nexus is an ambitious national research group working on how to address HIV, Hepatitis C, and other sexually transmitted and blood-borne infections (STBBIs) in Canada. Their focus is on reaching the undiagnosed, implementing and scaling up new testing options, strengthening connections to care, improving access to options for prevention (PrEP and PEP) and ending stigma. We work in collaboration and partnership with people living with HIV; community-based organizations; front-line service providers; healthcare providers and decision makers; public health agencies; researchers; business leaders; industry partners, and federal, provincial and regional policymakers. Follow us on Twitter, Instagram and Facebook.

About MedMira

MedMira is a leading developer and manufacturer of Rapid Vertical Flow® diagnostics. The Company’s tests provide hospitals, labs, clinics and individuals with instant disease diagnosis, such as HIV, Syphilis, Hepatitis, and SARS-CoV-2, in just three easy steps. The Company’s tests are sold globally under the REVEAL®, REVEALCOVID-19®, Multiplo® and Miriad® brands. Based on its patented Rapid Vertical Flow® Technology, MedMira’s rapid HIV test is the only one in the world to achieve regulatory approvals in Canada, the United States, China and the European Union. MedMira’s corporate offices and manufacturing facilities are located in Halifax, Nova Scotia, Canada. For more information visit [medmira.com](https://www.medmira.com). Follow us on [Twitter](#) and [LinkedIn](#).

This news release contains forward-looking statements, which involve risk and uncertainties and reflect the Company’s current expectation regarding future events, including statements regarding possible regulatory approval, product launch, future growth, and new business opportunities. Actual events could materially differ from those projected herein and depend on a number of factors including, but not limited to, changing market conditions, successful and timely completion of clinical studies, uncertainties related to the regulatory approval process, establishment of corporate alliances and other risks detailed from time to time in the company quarterly filings.

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