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Spirosure makes FDA 510(k) submission for clearance to sell Fenom PRO™ Point-of-Care Breathalyzer in the U.S.

CE mark already in place for portable analyzer that helps patients manage their asthma by measuring nitric oxide (NO) in their exhaled breath, a biomarker foreshadowing airway obstruction

PLEASANTON, Calif., Dec. 11, 2017 — Spirosure Inc. announced today that it has made an FDA 510(k) submission seeking U.S. clearance for its **Fenom PRO Point-of-Care Breathalyzer**, which was launched in September at the world's largest meeting for respiratory physicians, scientists and allied health professionals: the European Respiratory Society (ERS) International Congress 2017. Fenom PRO is CE-marked for use in Europe by allergists, immunologists and pulmonologists.

Spirosure's patent-protected, **Fractional exhaled Nitric Oxide (FeNO)**-based Fenom PRO™ breath analyzer is designed to **help patients manage their asthma**. This portable, non-invasive device uses state-of-the-art technology with proprietary algorithms to detect nanoscopic-sized nitric oxide (NO) molecules in concentrations of parts per billion (or "ppb") in human breath. At point of care, the patient exhales at a slow rate for 10 seconds to generate results in less than 30 seconds. FeNO is increased in some airway inflammatory processes, such as asthma, and decreases in response to anti-inflammatory treatment. FeNO measurements with Fenom PRO may be used as part of regular assessment and for monitoring of patients with these conditions. Fenom PRO is suitable for children, approximately 5-17 years, and adults 18 years and older.

"**Fenom PRO** is a game-changing, *connected* medical device now being used by healthcare professionals in Europe as a tool that assists them in diagnosing and monitoring their patients' asthma. It is comprised of sensors along with a digital ecosystem designed for supporting their clinical decisions," said **Dr. Solomon Ssenyange**, Chairman and CEO of Spirosure.

Fenom PRO is designed to include use of a companion app and website, called Fenom CONNECT™. The Fenom CONNECT app will help patients follow their physician-developed asthma action plan and give them air quality and pollen information to help make informed decisions. The Fenom CONNECT website will allow physicians to quickly configure their patients' asthma action plans and assess how their patients have been doing. Fenom CONNECT is designed to allow for even greater insight into patients' issues, thus giving more information to the physician for improved clinical decision support.

(more)

"FeNO-monitoring of asthma patients at point of care not only offers great potential to improve asthma therapy but also monitor adherence of controller maintenance medication use, *and* may reduce the risk of asthma emergency visits and hospitalizations," explained **Randall W. Brown, M.D.**, pulmonologist and director of asthma and COPD Programs, Center for Managing Chronic Disease, University of Michigan; and a Scientific Advisor to Spirosure. "Also, it's important to note that the European Respiratory Society is one of several medical professional organizations that has advanced protocols advocating FeNO testing for the assessment, management, and long-term monitoring of asthma."

Today's standard of care for diagnosing and monitoring asthma is characterized by products, technologies and procedures that have not changed significantly in decades — such as *spirometers*. These technologies offer limited support for clinicians to make better clinical decisions for their patients in terms of initial diagnosis and continuous monitoring of asthmatic conditions. In terms of diagnosis of asthma, large numbers of asthmatics go untreated: 50% of children, and 33% of adults. Regarding monitoring, there are no solid-state devices to measure airway inflammation.

Fenom PRO™, which is currently available in Europe, is Spirosure's initial product with additional deployment of its companion Fenom CONNECT also underway. A handheld consumer-centric FeNO device that is designed to be used by asthma patients at home is under development for European launch later in 2018. Please note that the handheld FeNO device project, called Fenom HOME, does not have a CE mark or FDA clearance at this time.

About the Fenom PRO™ Point-of-Care Breath Analyzer

The Spirosure Fenom PRO™ Point-of-Care Breath Analyzer is a portable, battery-operated device that comprises a solid-state senor which uses an electrochemical reaction to yield a millivolt output, which is then translated by an algorithm into nitric oxide (NO) levels – at the "parts per billion" (ppb) level. At the physician's office or in the hospital, the patient breathes into the Fenom PRO™ device for about 10 seconds. The device then measures the NO content in the lungs, yielding a result in less than 30 seconds. The Fenom PRO™ device connects automatically to a cloud-based decision repository and support system that offers 'big data' insights about the 250^{+} million people worldwide who suffer from asthma. The Fenom PRO is CE-marked for commercialization in Europe. The device is not currently available in the United States.

About SPIROSURE

Spirosure Inc., founded in 2011 as Spirometrix by Dr. Solomon Ssenyange and Ryan Leard as a personal mission to aid asthma patients in the management of their ailment, focuses on the development and commercialization of novel breath analysis devices for application in **diagnosis and management of asthma**. In recent years, non-invasive measurement and monitoring of the **fraction** of **exhaled nitric oxide (FeNO)** in exhaled breath has become established as ***the*** biomarker of asthma. The sensor-based technology was licensed from Professor Prabir Dutta's innovative laboratories at The Ohio State University as the company was founded.

CAUTION: The Fenom PRO™ Point-of-Care Breath Analyzer is an investigational device in the United States that is intended to provide exhaled nitric oxide information to a physician at point of care. Fenom PRO™ is not currently available for sale in the United States at this time.

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