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Spirosure launches Fenom PRO™ at European Respiratory Society (ERS) International Congress 2017

Point-of-care portable breath analyzer measures patients' nitric oxide in exhaled breath, a biomarker foreshadowing airway obstruction

PLEASANTON, Calif., Sept. 8, 2017 — **Spirosure** Inc. announced today that its CE-marked **Fenom PRO Point-of-Care Breathalyzer** is being launched at the world's largest meeting for respiratory physicians, scientists and allied health professionals: the European Respiratory Society (ERS) International Congress 2017 in Milan, Italy. Fenom PRO is CE-marked for use in Europe by allergists, immunologists and pulmonologists. Spirosure will exhibit Fenom PRO at booth #D5.

Spirosure's patent-protected **Fractional exhaled Nitric Oxide (FeNO)** breath analyzer combines advanced materials with proprietary algorithms to provide high sensitivity in its ability to detect very small particle concentrations (parts per billion or "ppb" measurement). At the point of care, the patient exhales at a slow rate for 10 seconds to generate results in less than 30 seconds.

"We believe that **Fenom PRO** is a game-changing connected medical device used by healthcare professional as a tool that assists in the diagnosis and monitoring of asthma, and it comprises sensors in addition to a digital ecosystem - designed for enhancing clinical decision support," said **J. Dean Zikria**, CEO of Spirosure.

Fenom PRO will have a companion app and website, called Fenom CONNECT™. The Fenom CONNECT app will help patients follow their 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 will allow for even greater insight into patients' issues, thus giving more information to the physician for improved clinical decision support, according to Zikria.

"We believe that FeNO monitoring of asthma patients at the point of care offers great potential to advance asthma therapy, monitor adherence of controller maintenance medication use, *and* may reduce the risk of asthma emergency visits and hospitalizations," explained Dr. Randall Brown, director of asthma programs at the Center for Managing Chronic Disease at the 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 only some insight 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.

This product launch will be Spirosure's first, but development continues to enhance Fenom CONNECT as well as work on a handheld FeNO device that can be used by asthma patients at home. Please note that the handheld FeNO device project, called Fenom HOME, does not have a CE Mark or FDA approval 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 provides exhaled nitric oxide information to a physician at point-of-care. Fenom PRO™ is a breath monitor that is limited for use by Federal Law (USA) to healthcare professionals in clinical trials to help manage asthma patients and is not available for sale in the United States at this time.

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