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Spirosure Receives FDA Clearance to Sell Its Point-of-Care Asthma Monitor, Fenom Pro™

PLEASANTON, Calif., Feb. 25, 2019 — Spirosure Inc. announced today that it has received FDA clearance of its patent-protected **Fenom Pro Asthma Monitor** for use by allergists, immunologists and pulmonologists to help patients manage asthma by measuring the fraction of exhaled nitric oxide (FeNO) in their patients' breath. FeNO is an established biomarker for airway inflammation in human exhaled breath. Measurement of FeNO by Fenom Pro is a method to measure the decrease in FeNO concentration in asthma patients that often occurs after treatment with anti-inflammatory pharmacological therapy as an indication of therapeutic effect in patients with elevated FeNO levels.

Spirosure's Fractional exhaled Nitric Oxide (FeNO)-based Fenom Pro Asthma Monitor uses state-of-the-art technology with proprietary algorithms to detect exhaled nitric oxide (NO) molecules in concentrations of parts per billion (or "ppb") in human breath. The noninvasive measurement occurs at the point of care where 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 measurement with Fenom Pro is designed to be used as part of regular assessment of patients by healthcare professionals and for monitoring of patients with asthma. Fenom Pro is suitable for children, approximately 7 to 17 years of age, and adults 18 years and older.

"Fenom Pro is a game-changing device for asthma management," said Dr. Solomon Ssenyange, Chairman and CEO of Spirosure. "FeNO-monitoring of asthma patients at point of care not only offers significant potential to advance asthma therapy and monitor adherence to asthma-maintenance medication use, but also may reduce the risk of asthma emergency department visits and hospitalizations."

Today's standard of care (SOC) 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 asthma sufferers go untreated: approximately 50% of children and 33% of adults. Fenom Pro looks to help change these statistics.

A recent study ("Cost-Effectiveness Analysis of Monitoring Fractional Exhaled Nitric Oxide [FeNO] in the Management of Asthma") published in the July 2018 issue of *Managed Care* concluded "that the use of FeNO monitoring to guide asthma management is a cost-effective strategy compared with current SOC alone because the addition of FeNO monitoring increases QALYs (quality-adjusted life years) and reduces health care costs."

(more)

Fenom Pro, which is also cleared for sale in Europe, is Spirosure's initial product. A handheld consumer-centric FeNO device that includes a connected smartphone app designed to be used by asthma patients at home is under development. Spirosure met with the FDA in January 2019 in a Pre-submission meeting ahead of its planned 510(k) submission to market Fenom Home in the U.S.

Dr. Solomon Ssenyange added: "Successful completion of this pre-submission meeting represents a further key milestone of advancing Fenom Home toward the market. We are excited at the potential benefits offered for this first-of-its-kind home FeNO monitor and accompanying smartphone app for asthma patients once approved, and we look forward to submitting this groundbreaking FeNO-measuring product for regulatory clearance within a year."

About SPIROSURE

Spirosure Inc., founded in 2011 as Spirometrix by Dr. Solomon Ssenyange and Ryan Leard, is an innovative company that focuses on the development and commercialization of novel breath analysis devices for application in diagnosis and management of asthma as well as respiratory diseases. 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.

Fenom Home is not FDA-cleared or CE-marked and is not available in the United States or elsewhere at this time.

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