



NANOMIX RECEIVES CE MARK FOR DIAGNOSTIC PANEL THAT AIDS IN RAPID IDENTIFICATION OF SERIOUS, LIFE-THREATENING INFECTIONS

-- S1 Assay Panel Designed for Use with the Nanomix eLab Analyzer --

EMERYVILLE, Calif. — December 4, 2019 — Nanomix announced today that the company has received CE Mark for its S1 Assay for the rapid, simultaneous detection and quantification of lactate (LAC), procalcitonin (PCT), and C-reactive protein (CRP) from human plasma specimens. Nanomix, a leader in the development of mobile, affordable, point-of-care diagnostics for use in settings where time to diagnosis is critical, developed the S1 Assay to aid in the rapid detection of serious infections, including sepsis and bacteremia.

Many serious infections are difficult to detect based on clinical symptoms alone, and the associated mortality is high. The risk of death from sepsis, for example, rises 8 percent with each hour that treatment is delayed.^{1,2} The Nanomix S1 Assay is intended to provide critical diagnostic information rapidly to physicians, allowing them to accelerate and improve the clinical decision-making process. Simple, accurate and cost-effective, the S1 Assay combines three tests in a unique point-of-care format that delivers results in the initial patient evaluation.

The S1 Assay is designed for use with the Nanomix eLab analyzer, a handheld system utilizing a microfluidic-based, single-use consumable with an electrochemical sensor for the automated, simultaneous detection of multiple analytes. The Nanomix eLab analyzer is an easy-to-use, mobile test system that provides laboratory-quality diagnostic results in minutes. It utilizes a touchscreen graphical interface, includes a built-in barcode scanner, features both Bluetooth and USB connectivity, and is designed for use within or outside traditional laboratory settings. The S1 Assay panel runs on the eLab analyzer in approximately 11 minutes. Nanomix is currently evaluating a whole blood version of the test.

“This novel assay increases the relevant information available to clinicians in the evaluation of serious infections, when urgent decision-making is required,” said David Ludvigson, president and CEO of Nanomix. “The Nanomix S1 Assay is the first multiplex product to address the diagnosis of life-threatening infections at the initial point of care.”

The S1 Assay panel provides quantitative results for LAC, PCT, and CRP from human plasma. LAC is commonly used in the initial evaluation of sepsis, but its results are neither specific nor sensitive enough to be used alone. The S1 Assay adds PCT and CRP, tests that indicate a patient’s inflammation and bacterial infection. These tests are typically performed in a central laboratory with turnaround times of several hours. As a

result, information about the levels of these targets has not been available during initial patient evaluations. The S1 Assay, by contrast, delivers all three results within 11 minutes, making information available in the critical decision-making window for diagnosis and initial treatment of serious infections.

Nanomix anticipates that the S1 Assay panel and eLab instrument will be available in CE-regulated markets in 2020 through distribution. The company also plans to submit the product to the US Food and Drug Administration in 2020.

About Nanomix

Nanomix is the leader in the development of mobile point-of-care diagnostics, with a platform and assays that provide rapid, accurate, quantitative information for use in settings where time is critical to clinical decision-making and improved patient care. The company designed its products to broadly impact health care delivery by bringing diagnostics to the point of initial patient interaction, whether in the hospital or in pre-hospital, remote, or alternative settings, thus enabling faster clinical decision-making and the potential to treat in place. The company's first assay addresses the critical need for faster sepsis diagnosis. Nanomix is developing a pipeline of other high-value tests where the rapid availability of quality diagnostic information can improve patient outcomes. More information is available at <http://www.nano.com>.

¹ Lindvig, et. al., *Eur J Emerg Med*. 2016.

² Kumar, Roberts, Wood, et. al., *Crit Care Med*. 2006.