Luminex Submits ARIES MRSA Assay for FDA Clearance

July 1, 2019

AUSTIN, Texas, July 1, 2019 /PRNewswire/ -- Luminex Corporation (NASDAQ: LMNX) announced that the company submitted the ARIES® MRSA Assay to the U.S. Food and Drug Administration (FDA) for clearance on Friday, June 28, 2019. The assay is a qualitative polymerase chain reaction (PCR)-based, *in vitro* diagnostic test for the direct detection of methicillin-resistant *Staphylococcus aureus* (MRSA) DNA from nasal swabs in patients at risk for nasal colonization.

"This submission demonstrates our continued dedication to expanding the menu of clinically relevant and high-value tests that support patient care throughout the world on our sample to answer platforms," said Homi Shamir, President and CEO of Luminex. "Our VERIGENE® II GI *Flex* and RSP *Flex* submissions, as well as the commercialization of our new SENSIPLEX™ instrument, remain on track with our previously communicated timelines."

According to the U.S. Centers for Disease Control and Prevention, in 2016, there was approximately one case of MRSA for every 30 people in the U.S. This works out to around 10 million cases of MRSA in the U.S. each year.[1,2] Rapid molecular tests for organisms such as MRSA have the potential to aid physicians in reigning in the spread of antimicrobial resistance and the associated negative outcomes for both patients and healthcare facilities by reducing the unnecessary use of antimicrobial therapies, thus allowing for more effective patient management.

The Luminex ARIES® System is a sample to answer, real-time system designed to increase laboratory efficiency, ensure result accuracy, and fit seamlessly into the modern laboratory. The system already offers six FDA and seven CE-IVD cleared assays, as well as the ability to run laboratory developed tests. "This assay will add another foundational test to the ARIES® System, increasing its value for customers and patients," said Shamir.

About Luminex Corporation

At Luminex, our mission is to empower labs to obtain reliable, timely, and actionable answers, ultimately advancing health. We offer a wide range of solutions applicable in diverse markets including clinical diagnostics, pharmaceutical drug discovery, biomedical research, genomic and proteomic research, biodefense research, and food safety. We accelerate reliable answers while simplifying complexity and deliver certainty with a seamless experience. To learn more about Luminex, please visit us at www.luminexcorp.com.

Cautionary Statement Regarding Forward-Looking Statements

Statements made in this release that express Luminex's or management's intentions, plans, beliefs, expectations or predictions of future events are forward-looking statements. Forward-looking statements in this release include statements regarding the expected timeline for the ARIES® MRSA Assay and the ARIES® System. The words "remain", "will", "could", "should" and similar expressions are intended to further identify such forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. It is important to note that the Company's actual results or performance could differ materially from those anticipated or projected in such forward-looking statements. Factors that could cause Luminex's actual results or performance to differ materially include risks and uncertainties relating to, among others, the timing and process for the FDA's clearance of the ARIES® MRSA Assay; market demand and acceptance of Luminex's products and technology, including ARIES®, MultiCode®, xMAP®, VERIGENE®, Guava®, Muse®, Amnis® and NxTAG® products; Luminex's ability to obtain and enforce intellectual property protections on Luminex's products and technologies; Luminex's ability to successfully launch new products in a timely manner; competition and competitive technologies utilized by Luminex's competitors; as well as the risks discussed under the heading "Risk Factors" in Luminex's Reports on Forms 10-K and 10-Q, as filed with the Securities and Exchange Commission. The forward-looking statements contained herein represent the judgment of Luminex as of the date of this press release, and Luminex expressly disclaims any intent, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements to reflect any change in Luminex's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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[1] Centers for Disease Control and Prevention. 2016. Healthcare-Associated Infections – Community Interface Surveillance Report, Emerging Infections Program Network, Methicillin-Resistant Staphylococcus aureus, 2016.
Available via the Internet: https://www.cdc.gov/hai/eip/pdf/2016-MRSA-Report-P.pdf

[2] Google search "U.S. Population 2016" Retrieved June, 2019.

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