Luminex Receives FDA 510(k) Clearance for the ARIES® MRSA Assay

October 1, 2019

AUSTIN, Texas, Oct. 1, 2019 /PRNewswire/ -- Luminex Corporation (NASDAQ: LMNX) announced that the company has received U.S. Food and Drug Administration (FDA) 510(k) clearance for the ARIES® MRSA Assay. The assay is an integrated, real-time, polymerase chain reaction (PCR) based, qualitative, 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.

"MRSA causes more than 80,000 severe infections and kills more than 11,000 people in the U.S. each year.[1] The 510(k) clearance of our ARIES® MRSA Assay marks an exciting moment for our ARIES® product line and, most importantly, for patients throughout the United States," said Homi Shamir, President and CEO of Luminex. "In conjunction with our previously cleared ARIES® *C. difficile* Assay, this clearance empowers healthcare facilities to perform rapid, targeted testing for the two critical pathogens identified by The Centers for Medicare & Medicaid Services' Hospital-Acquired Condition Reduction Program (HACRP).[2] Together, these assays have the potential to significantly reduce healthcare acquired infections and greatly improve patient care and outcomes."

According to the U.S. Centers for Disease Control and Prevention, approximately one in 50 people in the U.S. is colonized with MRSA in their nose. This means there are approximately 6.6 million carriers of MRSA in the United States.[3,4] Rapid molecular tests, including the ARIES® MRSA Assay, can be a vital tool to aid physicians in reining 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, allowing for more effective patient management.

The Luminex ARIES® System is a sample to answer, real-time instrument designed to increase laboratory efficiency, ensure result accuracy, and fit seamlessly into the modern laboratory. The system features six FDA and seven CE-IVD cleared assays, as well as the ability to run laboratory-developed tests. "This assay adds another foundational test to our ARIES® platform, increasing its value for customers and patients," said Mr. 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 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 available market and customer acceptance for the ARIES® MRSA Assay and the ARIES® System. The words "potential", "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, market demand and acceptance of Luminex's products and technology; 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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2. https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Downloads/HAC-Reduction-Program-Fact-Sheet.pdf.

3. Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Division of Healthcare Quality Promotion (DHQP) https://www.cdc.gov/mrsa/healthcare/index.html Retrieved August, 2019.

4. https://www.census.gov/popclock/ Retrieved August, 2019.

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