Alere Achieves FDA Clearance for Alere™ Reader Platform and Alere BinaxNOW® Influenza A & B Card 2

WALTHAM, Mass., April 11, 2017 – Alere Inc. (NYSE: ALR), a global leader in rapid diagnostics, today announced that its Alere™ Reader, a diagnostic analyzer that can be used in both point-of-care and laboratory settings, has received 510(k) marketing clearance from the US Food and Drug Administration (FDA). The Alere Reader will be initially available for use with the BinaxNOW® Influenza A & B Card 2, with other lateral flow applications and assays to follow. This reformulated test card is the first rapid antigen influenza test to achieve 510(k) clearance as a Class II assay under the new FDA reclassification requirements.

This announcement represents the introduction into the US market of the Alere Reader, a diagnostic platform with objective result interpretation and connectivity capabilities that can be used to evaluate a wide variety of lateral flow immunoassay formats. This follows a successful release of the Alere Reader into Europe and select Asian markets since In-Vitro Diagnostic (IVD) CE marking in August 2016.

With the intent to expand the settings in which this platform can be deployed, Alere expects to promptly submit an application for CLIA (Clinical Laboratory Improvement Amendments) waiver of the Alere BinaxNOW Influenza A & B Card 2 test for use on the Alere Reader.

“The Alere BinaxNOW Influenza A & B Card 2 test with the Alere Reader, improves what is already a leading rapid testing solution for influenza diagnosis in two key ways: by eliminating operator subjectivity and by connecting test results with information management systems,” said Avi Pelossof, Alere Global President of Infectious Disease. “The Alere Reader platform, paired with Alere’s market-leading lateral flow portfolio, will ensure that over time this novel technology will be accessible for use with a wide variety of diseases and conditions across numerous clinical settings.”

The Alere Reader helps support key goals of healthcare and regulatory stakeholders by ensuring the accuracy and reproducibility of test results. By utilizing the Alere Reader at the point-of-care, providers can obtain highly accurate results within an actionable timeframe and then administer the appropriate treatment quickly. In addition to the Alere Reader, Alere’s extensive flu portfolio includes: Alere™ i Influenza A & B, the first-ever CLIA-waived molecular flu test, and the Alere™ Influenza A & B dipstick test.

With the Alere Reader, physicians, lab technicians and other healthcare personnel insert test cards into the platform, which detects, identifies and analyzes the completed lateral flow assay. Results are displayed on an intuitive touch screen, can immediately be linked to patient electronic medical records and back-end information systems, or can be printed.
Further, the Alere Reader provides the user additional confidence in the results with an automated function that ensures quality controls have been tested.

Cautionary Statement Regarding Forward-Looking Statements
This communication contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including statements regarding: the expected benefits and performance characteristics of the Alere™ Reader; the Alere Reader will be initially available for use with the BinaxNOW® Influenza A & B Card 2, with other lateral flow applications and assays to follow; Alere expects to promptly submit an application for CLIA (Clinical Laboratory Improvement Amendments) waiver of the Alere BinaxNOW Influenza A & B Card 2 test for use on the Alere Reader; and the Alere Reader platform, paired with Alere’s market-leading lateral flow portfolio, will ensure that over time this novel technology will be accessible for use with a wide variety of diseases and conditions across numerous clinical settings. Readers can also identify these statements by forward-looking words such as “may,” “could,” “should,” “would,” “intend,” “will,” “expect,” “anticipate,” “believe,” “estimate,” “continue,” “goal” or similar words. A number of important factors could cause actual results of Alere and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, (i) the anticipated benefits and performance characteristics of the Alere Reader may not be realized, (ii) the expected uses of the Alere Reader and the potential future applications of the Alere Reader may not be realized, (iii) the Company may not be able to promptly submit, or submit at all, an application for CLIA waiver of the Alere BinaxNOW Influenza A & B Card 2 test for use on the Alere Reader and such application may not be granted by the applicable regulatory authorities in a timely manner or at all; (iv) the Company may not be able to commercialize or obtain the necessary regulatory approvals or for other reasons may not make the Alere Reader technology accessible for use with a wide variety of diseases and conditions across numerous clinical settings and (v) the risk factors detailed in Part I, Item 1A, “Risk Factors,” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (as filed with the SEC on August 8, 2016) and other risk factors identified herein or from time to time in our periodic filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this communication. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

About Alere
Alere believes that when diagnosing and monitoring health conditions, Knowing now matters™. Alere delivers reliable and actionable information through rapid diagnostic tests, resulting in better clinical and economic healthcare outcomes globally. Headquartered in Waltham, Mass., Alere focuses on rapid diagnostics for infectious disease, cardiometabolic disease and toxicology. For more information on Alere, please visit www.alere.com.

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