Alere receives FDA Approval for Alere Determine™ HIV-1/2 Ag/Ab Combo

WALTHAM, Mass., August 9, 2013 – Alere Inc. (NYSE: ALR), a global leader in enabling individuals to take charge of their health at home through the merger of rapid diagnostics and health information, announced today that it has received U.S. Food and Drug Administration (FDA) approval of its pre-market application (PMA) to market Alere Determine™ HIV 1/2 Ag/Ab Combo in the United States for the detection of HIV-1 p24 antigen and antibodies to HIV-1/HIV-2. The FDA approval allows Alere to market Alere Determine™ HIV 1/2 Ag/Ab Combo as a CLIA (Clinical Laboratory Improvement Amendments) moderately complex medical device.

Alere Determine™ HIV-1/2 Ag/Ab Combo is the first and only FDA-approved rapid point-of-care test that detects both HIV-1/2 antibodies and the HIV-1 p24 antigen, which can appear days after infection and prior to[1,2] HIV-1/2 antibodies.

According to the Centers of Disease Control and Prevention (CDC), there are 1.4 million Americans living with HIV, and approximately 207,000 (18%) whose infections have not been diagnosed.[3] In 2010, the CDC estimated that there were 47,500 newly infected people with the virus in the United States, indicating that HIV remains a serious health problem.[4] HIV testing is essential for healthcare and social services to improve the quality of life and survival for persons who have HIV. Individuals who are acutely infected with HIV, which is defined as the interval between the appearance of HIV RNA in plasma and the detection of HIV-1 specific antibodies, contribute disproportionately to HIV transmission.[5] With the use of the Alere Determine™ HIV 1/2 Ag/Ab Combo, HIV can be detected earlier than second and third generation antibody-only tests.

Avi Pelossof, Alere Global President of Infectious Disease, said, “We are pleased that the FDA has issued the approval for Alere Determine™ HIV 1/2 Ag/Ab Combo. Our next step is to complete the CLIA waiver trials with the intention to submit the data in late 2013 or early 2014.”

Pelossof added, “The Alere Determine™ Combo can help to identify additional cases that would not be detected using second and third generation antibody-only tests.[6] We anticipate Alere Determine™ Combo to play a critical role in the U.S. to help identify individuals with HIV and to help break the infection cycle.”

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About Alere Inc.

By developing new capabilities in near-patient diagnosis, monitoring and health management, Alere enables individuals to take charge of improving their health and quality of life at home. Alere's global leading products and services, as well as its new product development efforts, focus on cardiology, infectious disease, toxicology and diabetes. Alere is headquartered in Waltham, Massachusetts. For additional information on Alere, please visit www.alere.com

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[5] Pilcher CD, Tien HC, Eron JJ, et al. Brief but efficient: acute HIV infection and the sexual transmission of HIV. J Infect Dis 2004;189:1785–92.

[6] Masciotra, S. Performance of the Alere Determine HIV-1/2 Combo Rapid Test with Specimens from U.S. HIV-1 Seroconvertes and HIV-2 Positive Specimens from Ivory Coast.2012 HIV Diagnostics Conference; Atlanta, GA.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the federal securities laws, including statements regarding the timing of the completion of CLIA waiver trials and data submissions and the anticipated future effectiveness and importance of the product in improving healthcare. These statements reflect our current views with respect to future events and are based on management's current assumptions and information currently available. Actual results may differ materially due to numerous factors including, without limitation, our ability to successfully manufacture and distribute the product; market acceptance of the product; changes in law or regulation and our ability to comply with regulatory requirements related to the product, as well as the other risks described in the "Risk Factors" section of our Annual Report on Form 10-K filed with the SEC on March 1, 2013, as amended. We undertake no obligation to update any forward-looking statements contained herein.

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