



Alere Awarded U.S. Government Contract to Advance Development of Point-of-Care Molecular Diagnostic for Pandemic Influenza

The U.S. Department of Health and Human Services will fund up to \$12.9 million for the development of Alere's next-generation POC molecular influenza test

WALTHAM, Mass., Oct. 1, 2014 – Alere Inc. (NYSE: ALR), a leading global provider of point-of-care rapid diagnostics, today announced that it has entered into a contract with the U.S. Department of Health and Human Services' Biomedical Advanced Research and Development Authority (BARDA) to develop diagnostic countermeasures for pandemic influenza.

Under the terms of the 3.5 year contract, BARDA will provide up to \$12.9 million to support the development of a rapid, molecular, low-cost influenza diagnostic device with PCR-like performance at the point-of-care. The project is designed to help support future preparedness and medical response to an influenza pandemic. Funding from BARDA is subject to successful completion of various interim feasibility and development milestones as defined in the agreement. In connection with Alere's development of a rapid, molecular, low-cost influenza diagnostic device, Alere will be responsible for conducting clinical trials to support FDA 510(K) clearance and obtaining CLIA waiver as well as manufacturing and commercializing the resulting molecular influenza test.

Alere will use the funding to develop the next generation of its current Alere™ i Influenza A & B test, which improves rapid flu testing by providing highly accurate, molecular results in under 15 minutes. Alere i Influenza A & B was launched in January 2014 in Europe and received clearance from the U.S. Food and Drug Administration (FDA) in June 2014.

The next-generation product platform will be intended for even more widespread use outside of the traditional healthcare system, while not compromising the level of clinical performance.

"Being awarded the BARDA contract is further validation of the significant benefits provided by the Alere i molecular technology," said Avi Pelossof, Alere Global President, Infectious Disease. "We look forward to working with BARDA on the development of a next-generation Alere i Influenza test that will deliver the same high performance at a lower cost, making it even more accessible for use in any environment."

Advanced development of Alere's next-generation molecular influenza test is part of BARDA's comprehensive approach to developing medical countermeasures for pandemic flu

preparedness. The program includes developing vaccines, therapeutics, diagnostics and non-pharmaceutical countermeasures for influenza preparedness and building and sustaining facilities for their domestic manufacturing.

According to the U.S. National Strategy for Pandemic Influenza, the influenza virus causes 36,000 deaths and more than 200,000 hospitalizations each year. In addition to this human toll, influenza is annually responsible for a total cost of over \$10 billion in the U.S. These numbers have the potential to grow exponentially if a worldwide outbreak, or pandemic, of a new influenza virus occurs.¹ According to the World Health Organization, three pandemics occurred in the 20th century. The most severe occurrence (1918-1919) caused the deaths of between 20-40 million people worldwide.²

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About Alere

Alere's global leading rapid diagnostics products and services, as well as its new product development efforts, focus on infectious disease, cardiometabolic disease and toxicology. Alere is headquartered in Waltham, Massachusetts. For more information regarding Alere, please visit www.alere.com.

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¹ U.S. National Strategy for Pandemic Influenza, <http://www.flu.gov/planning-preparedness/federal/pandemic-influenza.pdf>, p. 1.

² World Health Organization, Pandemic Influenza Risk Management – WHO Interim Guidance, http://www.who.int/influenza/preparedness/pandemic/GIP_PandemicInfluenzaRiskManagementInterimGuidance_Jun2013.pdf?ua=1, Table 3, p. 19.