Alere to Initiate Voluntary Withdrawal of the Alere INRatio® and INRatio®2 PT/INR Monitoring System

WALTHAM, Mass., July 11, 2016 – Following a collaborative process with the U.S. Food and Drug Administration (FDA), Alere Inc. (NYSE:ALR) will be initiating a voluntary withdrawal of the Alere INRatio® and INRatio®2 PT/INR Monitoring System. Alere is working with the FDA to determine the most appropriate timing for product discontinuation and will provide guidance on transitioning patients to an alternate solution to allow them to continue anti-coagulation monitoring in the least disruptive manner possible.

Alere's focus, as always, is on the safety of patients using the company's products by delivering high-quality products and services that patients and providers can rely on for consistently accurate and actionable information.

In December 2014, Alere initiated a voluntary correction to inform users of the Alere INRatio and INRatio2 PT/INR Monitoring System that patients with certain medical conditions should not be tested with the system. As part of its commitment to ensuring the safety of patients, Alere proactively reported these device concerns to the FDA and began conducting a thorough investigation into these events.

Over the course of the past two years, Alere invested in the research and development of software enhancements to address the potential, in certain cases, of the system to deliver a result that differs from that of another measurement method.

Although Alere is confident that the software enhancements it developed and submitted to the FDA at the end of 2015 effectively address this issue, the FDA notified the company that it believes the company's studies do not adequately demonstrate the effectiveness of the software modification and advised Alere to submit a proposed plan to voluntarily remove the INRatio device from the market.

In light of this input from the FDA and the company's business considerations, Alere has recently determined to voluntarily remove the INRatio system from the market. Alere is committed to ensuring an orderly transition for patients requiring anti-coagulation monitoring and will provide a timeline to discontinue the product line. Alere will provide further information on patient transition to patients and healthcare providers. We suggest that patients speak with their healthcare providers prior to making any changes to their current PT/INR monitoring practices.

For more information regarding this recall, go to www.inr-care.com.

About Alere

Alere believes that when diagnosing and monitoring health conditions, **Knowing now matters.™** Alere delivers on this vision by providing reliable and actionable information through rapid diagnostic tests, enhancing clinical and economic health 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 http://www.alere.com.

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