OraSure Technologies Addresses FDA Warning Letter Received by Its Subsidiary DNA Genotek

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BETHLEHEM, Pa., Jan. 7, 2014 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. (Nasdaq:OSUR) announced that its molecular collection systems subsidiary, DNA Genotek, received a warning letter from the U.S. Food and Drug Administration (FDA) which the FDA posted today on its website. The warning letter primarily focuses on DNA Genotek's response to two observations issued by the FDA on Form 483 as a result of a routine inspection of DNA Genotek's Ottawa, Canada facilities in September 2013.

DNA Genotek is actively engaged and working with the FDA to address the agency's observations and will continue to sell and market all of its products while responding to the warning letter. No material impact to product sales or OraSure's consolidated financial performance is expected as a result of the issues raised by the warning letter.

The warning letter requests additional documentation related to finished product acceptance testing activities for DNA Genotek's ORAcollect OC-100 collection device, a swab-like product with a small customer base that accounted for approximately one-half of one percent of OraSure's consolidated revenues in 2013. The letter notes that DNA Genotek does not currently have in place an approved premarket approval application or 510(k) clearance for its ORAcollect OC-100 device.

In addition, the warning letter indicates the need for additional documentation regarding design and development activities for DNA Genotek's products and focuses in particular on the design planning and design history file for its 510(k) cleared OrageneDx collection device, a product primarily used in commercial applications. A product similar to OrageneDx, sold under the name OrageneDiscover, is used primarily for research applications and was not specifically addressed by the warning letter.

A copy of the warning letter can be found on the FDA's website at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm379997.htm.

"We take this letter from the FDA very seriously and we are working closely with the agency to ensure we fully address their concerns and observations," said Douglas A. Michels, President and CEO of OraSure Technologies. "We are committed to providing the highest quality products to our customers and to continuously enhancing our systems and processes."

About OraSure Technologies

OraSure Technologies is a leader in the development, manufacture and distribution of oral fluid diagnostic and collection devices and other technologies designed to detect or diagnose critical medical conditions. Its innovative products include rapid tests for the detection of antibodies to HIV and HCV at the point of care and testing solutions for detecting various drugs of abuse. In July 2012, the Company received approval from the U.S. Food and Drug Administration for the Company's OraQuick® In-Home HIV Test for sale directly to consumers in the over-the-counter (OTC) market - making it the first and only rapid OTC HIV test approved in the U.S. In addition, the Company is a leading provider of oral fluid sample collection, stabilization and preparation products for molecular diagnostic applications. OraSure's portfolio of products is sold globally to various clinical laboratories, hospitals, clinics, community-based organizations and other public health organizations, research and academic institutions, distributors, government agencies, physicians' offices, and commercial and industrial entities. The Company's products enable healthcare providers to deliver critical information to patients, empowering them to make decisions to improve and protect their health.

For more information on OraSure Technologies, please visit www.orasure.com.

Important Information

This press release contains certain forward-looking statements, including with respect to product sales and availability and financial performance. Forward-looking statements are not guarantees of future performance or results. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: ability to market and sell products, whether through an internal, direct sales force or third parties; ability to manufacture products in accordance with applicable specifications, performance standards and quality requirements; ability to obtain, and timing and cost of obtaining, necessary regulatory approvals for new products or new indications or applications for existing products; ability to comply with applicable regulatory requirements; ability to effectively resolve 483 observations, warning letters and other findings or communications from the FDA and other regulators; changes in relationships, including disputes or disagreements, with strategic partners or other parties and reliance on strategic partners for the performance of critical activities under collaborative arrangements; failure of distributors or other customers to meet purchase forecasts or minimum purchase requirements for the Company's products; impact of replacing distributors; inventory levels at distributors and other customers; ability to integrate and realize the full benefits of the Company's acquisition of DNA Genotek; ability of DNA Genotek to achieve its financial and strategic objectives; ability to identify, complete, integrate and realize the full benefits of future acquisitions; impact of competitors, competing products and technology changes; impact of the economic downturn, high unemployment and poor credit conditions; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; ability to develop, commercialize and market new products, including the OraQuick® In-Home HIV test; market acceptance of oral fluid testing or other products; changes in market acceptance of products based on product performance, extended shelf life or other factors; ability to fund research and development and other products and operations; ability to obtain and maintain new or existing product distribution channels; reliance on sole supply sources for critical products and components; availability of related products produced by third parties or products required for use of our products; history of losses and ability to achieve sustained profitability; ability to utilize net operating loss carry forwards or other deferred tax assets; volatility of our stock price; uncertainty relating to patent protection and potential patent infringement claims; uncertainty and costs of litigation relating to patents and other intellectual property; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; ability to sell products internationally, including the

impact of changes in international funding sources and testing algorithms; adverse movements in foreign currency exchange rates; loss or impairment of sources of capital; ability to retain qualified personnel; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; customer consolidations and inventory practices; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general political, business and economic conditions. These and other factors are discussed more fully in the Company's Securities and Exchange Commission filings, including its registration statements, Annual Report on Form 10-K for the year ended December 31, 2012, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. The forward-looking statements are made as of the date of this press release and OraSure Technologies undertakes no duty to update these statements.

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